Addendum 1

to the Draft Assessment Report

of 08 November 2002

(relating to Volume 1 + 3)

Boscalid

30 January 2006

Rapporteur Member State: Germany

Contents

To Volume 1:

2.3 Impact on human and animal health

2.3.1 Effects having relevance to human and animal health arising from exposure to the active substance or to impurities contained in the active substance or to their transformation products

2.3.1.6 Reproductive toxicity

The reproductive toxicity of boscalid was investigated in a two-generation reproduction study in rats as well as in developmental toxicity studies in rats and rabbits. Since actual food consumption data were available these have been used throughout to calculate the exposure levels for the two-generation study. The dose information in mg/kg bw/d which was given based on a conversion factor of 15 in Volume 1 of the DAR has been replaced by the values based on actual consumption in this Addendum.

Boscalid had no adverse effects on reproductive performance or fertility of the F0 or F1 parental animals of all substance-treated groups up to a dose of 10000 ppm (1165 mg/kg bw/d). Signs of general toxicity/systemic effects occurred in both parental generations at 1000 and 10000 ppm. The effects at 10000 ppm were characterised by decreased food consumption and reduced body weights during parts of the administration period. Pathology showed statistically significantly increased liver weights, centrilobular hypertrophy of liver cells and centrilobular liver cell degeneration in single or all male and/or female animals. Systemic effects at 1000 ppm were confined to an increased incidence of centrilobular hepatocellular hypertrophy, which occurred in few F0 and F1 parental animals. No substance-related effects were noted at 100 ppm. Substance-induced signs of developmental toxicity were observed in progeny of the F0 and F1 parents at 1000 and 10000 ppm. At 10000 ppm a slightly increased pup mortality of the F2 litters was noted between days 0 and 4 post partum only. Pup body weight development was impaired in both F1 and F2 litters. At 1000 ppm, slightly decreased body weight gains were recorded for the male F2 pups only. 100 ppm did not induce any indication of developmental toxicity. The NOAEL for parental toxicity of the test substance was established at 100 ppm (11 mg/kg bw/d) for the F0 and F1 parental males and females. The NOAEL for developmental toxicity was 1000 ppm (113 mg/kg bw/d) for the male and female F1 and female F2 progeny and 100 ppm (11 mg/kg bw/d) for the male F2 progeny.

In the developmental toxicity study in rats, incomplete ossification of the thoracic centrum was observed at the highest dose tested (1000 mg/kg bw/d) in the absence of overt maternal toxicity. At this limit dose level there were also no signs of maternal toxicity. However, results from the 90-day oral feed study in rats indicate that liver toxicity would have been detected in dams at 1000 mg/kg bw/d. The NOAEL for developmental toxicity in rats was established at 300 mg/kg bw/d.

In the rabbit developmental toxicity study, incomplete ossification of the thoracic centrum was also observed at significantly increased incidences at the highest dose level (1000 mg/kg bw/d). At this dose level there was overt maternal toxicity (clinical signs of toxicity, reduced body weight and body weight gain). At 300 mg/kg bw/d clinical signs (abortion and discoloured/reduced faeces) were observed in a single animal only. Thus, the NOAELs for maternal and for developmental toxicity were 100 mg/kg bw/d and 300 mg/kg bw/d, respectively.

Results of all reproduction toxicity studies are summarised in Table 2.3-3.

Table 2.3-3: Summary of reproductive toxicity studies with boscalid

Study dose levels purity	**Target**	**NOAEL mg/kg bw/d**	**LOAEL mg/kg bw/d**	**Effects**
Rat 2-generation study 0–100–1000–10000 ppm purity: 94.4 %	Parental tox.	11 (100 ppm)	113 (1000 ppm)	≥ 1000 ppm: ↑ hepatocell. hypertrophy 10000 ppm: ↓ bw gain & feed intake ↑ liver wt & hepatocyte degeneration
	Fertility	1165 (10000 ppm)	–	No effects observed
	Offspring tox.	11 (100 ppm)	113 (1000 ppm)	≥ 1000 ppm: ↓ bw gain 10000 ppm: ↑ Male F2 pup mortality during days 0–4 p.p.
Rat teratogenicity 0–100–300–1000 mg/kg bw/d purity: 94.4 %	Maternal tox.	1000	–	No effects observed
	Developmental tox.	300	1000	1000 mg/kg bw/d: ↑ Incomplete ossification of the thoracic centrum
Rabbit teratogenicity 0–100–300–1000 mg/kg bw/d purity: 94.4 %	Maternal tox.	100	300	300 mg/kg bw/d: 1 doe with abortion and reduced / discoloured faeces 1000 mg/kg bw/d: 4 does with abortion ↓ feed intake, bw & bw gain
	Developmental tox.	300	1000	1000 mg/kg bw/d: ↑ Incomplete ossification of the thoracic centrum

2.3.1.8 Further toxicological studies

Concerns regarding a possible immunotoxic effect of boscalid based on reduced spleen weights of parents and offspring in the 2-generation study in rats have been addressed by the applicant with an additional immunotoxicity study. Boscalid did not have an effect on cellular or humoral immune functions in male rats as evidenced by analysis of subsets of thymic and splenic lymphocytes and of sheep red blood cell-specific IgM antibody formation.

2.3.3 AOEL

The calculation of a systemic AOEL using the NO(A)EL from the 1-year toxicity study in the dog corrected with the oral bioavailability in the rat has been criticized as not being a scientifically sound procedure and it has been suggested that the NO(A)EL from the 90-day rat study is used instead.

The studies in the dog were chosen to derive the point of departure on the scientific grounds that they supported a much more precise estimate of the NOAEL and LOAEL than any of the rat studies. ADME data from rats indicated that gastrointestinal absorption can be saturated in mammals. In rats this appeared to be the case at a dose of 50 mg/kg bw where oral bioavailability was only about 45 % and became even more prominent at a dose of 500 mg/kg bw where gastrointestinal absorption decreased to about 12 % of administered dose. No information about the shape of the bioavailability curve was available in the dose range below 50 mg/kg bw so that there is no scientific basis to assume that a gastrointestinal absorption value of 44 % is more valid for rats at a dose of 34 mg/kg bw/d than it is for dogs at a dose of 22 mg/kg bw/d. Because of these uncertainties, the lack of ADME data in dogs, and in order to achieve adequate protection for operators the RMS considered it prudent to assume that gastrointestinal absorption at the NOAEL could have been saturated to some extent in dogs as well as in rats.

2.3.4 Acute Reference Dose (ARfD)

The question has been raised whether an ARfD should be set for boscalid on the basis that a reduction in the ossification of vertebral structures (thoracic centra and to a lesser extent sacral arches) was noted at a dose of 1000 mg/kg bw/d in rat and rabbit developmental toxicity studies. This finding is considered to be of minor toxicological relevance as such variations, although often indicative of generalised embryofoetal toxicity, represent only a difference of a few hours in relative development of foetuses at the time of sacrifice. Moreover, in the absence of malformations of the underlying cartilaginous structures, no true adversity would be associated with this type of change. Retardations of skeletal ossification could fulfill the criteria for the derivation of an ARfD when they are elicited by a single dose of a toxicant. In the case of boscalid there are insufficient data to decide whether the developmental retardation was induced on a single occasion during the embryofoetal period or whether it was a consequence of repeated exposure of the dam and the conceptus. The sensitive period for skeletal ossification changes is much broader than for malformations for which a limited time window of sensitivity can be assumed. In humans this process continues for several months and is thus less likely to be notably affected by a single dose above the ADI than it would be the case in the common animal models.

Based on the low acute toxicity of boscalid and the lack of concern regarding developmental toxicity in humans allocation of an ARfD is not considered necessary.

Acute dietary risk assessment

Since there is from the toxicological point of view no need to set an ARfD there is no need to conduct an acute dietary risk assessment.

An acute dietary risk for consumers is highly unlikely.

2.4 Residues

2.4.1 Definition of residues relevant to MRLsPlants

Plants

The metabolism of boscalid was investigated in grapes, lettuce and beans. Unchanged parent compound formed the major part of the residue in these studies. The cleavage products

M510F62 (chlorophenylaminobenzene) and M510F47 (chloronicotinic acid) and in addition hydroxy-parent and sugar conjugates were identified in beans. All metabolites were of minor importance. Therefore parent only is included in the residue definition.

Residue definition plant**: Boscalid**

Animals

Metabolism studies performed on goats and hens show that residues in products of animal origin derive from the parent compound as well as from the hydroxylated metabolite M510F01 including its conjugates. Further metabolites result from a substitution of the chlorine of the 2-chloropyridine moiety by the thiol group of glutathione to create metabolites as the cysteine conjugate. Boscalid derived residues were also bound in liver based on this substitution (most likely SH-groups from cysteine containing protein). The amide bond of boscalid was very stable under metabolic conditions in goats and hens.
The results of the goat and hen metabolism studies selects the following compounds that are listed differentiated in residues for monitoring purposes and residues for risk assessment:

Residue definition for monitoring:	**Boscalid, M510F01 (including its conjugates) calculated as boscalid**
Residue definition for risk assessment:	**Nicobifen, M510F01 (including its conjugates) conjugates) calculated as boscalid** **M510F53 (for bound residues in liver and minor metabolites in milk)**

2.4.2 Residues relevant for consumer safety

Chronic dietary intake levels were estimated using the proposed MRL values derived from supervised residue trials in the EU-monograph as well as from German national registration process and from the livestock feeding studies in cows and hens. The results obtained on the basis of the German (VELS) and WHO European regional diet were compared with the ADI value of 0.04 mg/kg. A chronic dietary consumer risk is unlikely.

TMDI (WHO European diet 1998):	0.022 mg/kg bw/day – 54 % of the ADI
TMDI (German diet, child 16.15 kg):	0.025 mg/kg bw/day – 63 % of the ADI

Since it is not necessary to set an ARfD an acute risk for consumers can be excluded.

2.8.3.3 Appendix III.3: Chapter 3 (impact on human and animal health)

Absorption, distribution, excretion and metabolism in mammals (Annex IIA, point 5.1)

Rate and extent of absorption	Approx. 44 % (based on bile excretion within 48 h and urinary exretion within 6 h, low dose)
Distribution	Widely distributed. Highest residues in liver and adipose tissue (8-h, low dose) In high-dose females, highest residues were observed in thyroid and kidney
Potential for accumulation	No evidence
Rate and extent of excretion	Complete excretion of low dose within 48 h (approx. 20 % via urine and 80 % via faeces)
Metabolism in animals	Extensive (< 1 % of absorbed dose excreted as parent via urine or bile), 38 metabolites identified in rat matrices. Major pathway was hydroxylation at the diphenyl moiety and subsequent O-glucuronidation
Toxicologically significant compounds (animals, plants and environment)	Parent and metabolites

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral	> 5000 mg/kg bw
Rat LD_{50} dermal	> 2000 mg/kg bw
Rat LC_{50} inhalation	> 6.7 mg/l air (nose-only dust exposure)
Skin irritation	Non-irritant
Eye irritation	Non-irritant
Skin sensitization (test method used and result)	Not a skin sensitiser (M&K test)

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Liver, thyroid
Lowest relevant oral NOAEL / NOEL	Dog 1-yr: 800 ppm (22 mg/kg bw/d)
Lowest relevant dermal NOAEL / NOEL	Rat 28-day: 1000 mg/kg bw/d
Lowest relevant inhalation NOAEL / NOEL	No studies submitted, not required.

Genotoxicity (Annex IIA, point 5.4)

	No genotoxic potential

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target / critical effect	Liver, thyroid
Lowest relevant NOAEL / NOEL	Rat 2-yr: 100 ppm (4.4 mg/kg bw/d)
Carcinogenicity	Slight increase of thyroid follicular cell adenomas; not relevant to man. No classification and labelling necessary.

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect	Slightly reduced viability and decreased pup wt during lactation in the presence of parental adverse effects
Lowest relevant reproductive NOAEL / NOEL	100 ppm (11 mg/kg bw/d)
Developmental target / critical effect	Delayed ossification in rabbits and rats in the presence of maternal toxicity at the limit dose
Lowest relevant developmental NOAEL / NOEL	Rat & rabbit: 300 mg/kg bw/d

Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 5.7)

	No evidence from oral acute and 90-d neurotoxicity studies. No evidence from developmental neurotoxicity study

Other toxicological studies (Annex IIA, point 5.8)

Toxic effects of metabolites	Para-chlorobenzoic acid (degradation product in aquatic environment): literature survey data indicates that para-chlorobenzoic acid exhibits higher acute oral toxicity than boscalid. No concern from limited in-vitro genotoxicity data
Mechanistic studies	Boscalid is an inducer of cytochrome P450; T3 and T4 levels are decreased and TSH is increased. The increased metabolism of T4 via hepatic enzyme conjugation appeared to be responsible for the increased TSH.
Immunotoxicity	No toxic potential on cellular and humoral immune functions

Medical data (Annex IIA, point 5.9)

	No data (new compound)

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI	0.04 mg/kg bw	Rat 2-yr oral feed	100
AOEL systemic	0.1 mg/kg bw/d	Dog 1-yr oral feed; corrected for 44 % oral absorption	100 x [44 %]
ARfD (acute reference dose)	Not allocated	Not necessary, based on low acute toxicity and lack of developmental toxicity concerns	

Dermal absorption (Annex IIIA, point 7.3)

	Rat in vivo: 7 %; rat/human in-vitro dermal penetration ratio: 1 => 7 % human dermal absorption proposed for use in

	exposure calculations

Acceptable exposure scenarios (including method of calculation)

Operator	Intended uses acceptable (operator exposure < systemic AOEL; German model: without PPE and UK-POEM: with PPE)
Workers	Intended uses acceptable
Bystanders	Intended uses acceptable

3.1 Background to the proposed decision

Residue data

The metabolism of boscalid in plants was investigated in grapes, lettuce and beans. The metabolic pattern is similar in all three crop groups. Therefore the metabolism in plants is considered to be proofed.
The residue definition for plants is proposed as parent compound only

The metabolism and distribution of radioactive labelled boscalid was investigated in lactating goats and laying hens.
For monitoring purposes the residue definition for food of animal origin is proposed as boscalid and metabolite M510F01 (including its conjugates) calculated as boscalid.
For risk assessment bound residues in liver and minor metabolites in milk (M510F53) should be considered too.

The residue situation for the intended uses of boscalid in grapes, beans, peas and rape seed is covered by a sufficient number of residue trials. On basis of these data, of additional data submitted in the German national registration process and of possible residues in succeeding crops the possible intake of residues by consumers was calculated. In a chronic risk assessment no unacceptable risk for consumers could be identified. An acute risk is not to be expected since there was no necessity to set an Acute Reference Dose (ARfD).

Due to its persistent nature in soil and its ability to be transported systemically in plants the parent compound boscalid may occur in crops grown in rotation. A confined rotational crop study as well as field trials indicate that residue levels above 0.05 mg boscalid/kg are possible in crops grown in rotation. Therefore a MRL of 0.5 mg/kg is proposed for those crops not covered by residue or rotational crop studies.

3.2 Proposed decision concerning inclusion in Annex I

The inclusion of the active substance boscalid in Annex I of Directive 91/414/EEC is recommended.

To Volume 3:

B.1.2 Identity of the plant protection product (Annex IIA 3.1; Annex IIIA 1) (Dossier Documents J, K-II, L-II, K-III and L-III) (to be included for each preparation for which an Annex III dossier was submitted)

B.1.2.1 Current, former and proposed trade names and develpment code numbers (Annex IIIA 1.3)

Trade Name:	"BAS 510 01 F" (preliminary designator) (country specific altematives are under consideration)	
Code Number:	Plant Protection Product:	BAS 510 01 F
	Active Substance:	BAS 510 F
	proposed common name:	boscalid (formerly known as nicobifen)
	BASF intemal No.	Reg. No. 300355

B.1.2.2 Applicant (Annex IIIA 1.1)

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Agricultural Center
Product Registration Management
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B.3.5 Further information on the plant protection product (Annex IIIA 4)

B.3.5.1 Packaging (type, materials, size, etc.), compatibility of the preparation with proposed packaging materials (Annex IIIa 4.1)

B.3.5.1.1 Description of packaging (Annex IIIA 4.1.1)

A second type of packaging was added to the already existing square block bottom paper bag. BAS 510 01 F is also to be marketed in high-density polyethylene containers. They are sealed by foil seals, protected by screw caps of polyethylene or polypropylene.

0.25 litre bottle: material: HDPE
shape/size: cylindrical / approx. 62.5 mm diameter x 126 mm
opening: 42 mm inner diameter
closure: polypropylene screw cap
seal: H F-seal

1 litre bottle: material: HDPE
shape/size: cylindrical / approx. 91 mm diameter x 234 mm
opening: 42 mm inner diameter
closure: polypropylene screw cap
seal: H F-seal

2.2 litre bottle: material: HDPE
shape/size: rectangular / approx. 140 mm x 96 mm x 220 mm
opening: 54 mm inner diameter
closure: polypropylene screw cap
seal: H F-seal

5 litre container: material: HDPE
shape/size: rectangular / approx. 190 mm x 140 mm x 318 mm
opening: 54 mm inner diameter
closure: polyethylene screw cap
seal: H F-seal

10 litre container: material: HDPE
shape/size: rectangular / approx. 230 mm x 165 mm x 375 mm
opening: 54 mm inner diameter
closure: polyethylene screw cap
seal: H F-seal

B.3.5.1.2 Suitability of packaging (Annex IIIA 4.1.2)

Reference number: PHY2005-1126
Report: Schreiner (2004)
EU Performance Tests
BASF AG,
Ludwigshafen, Germany
unpublished

Guidelines: None
GLP: No

The packaging is suitable according to ADR Method 3552 (drop test) for transporting solids.

B.3.5.1.3 Resistance of Packaging material to its contents (Annex IIIA 4.1.3)

During the handling or storage of BAS 510 01 F, corrosiveness of the formulation towards containers or the packaging material (Lupolen) was not observed. Thus, it is anticipated that the square block bottom paper bag, laminated with polyethylene on the inner side, and the high-density polyethylene containers won't be impaired by any corrosion.

B.3.6 References relied on

Annex point/ reference number	Author(s)	Year	Title source (where different from company) report no. GLP or GEP status (where relevant), published or not BBA registration number	Data protection claimed Y/N	Owner
AIIIA-4.1.2	Schreiner	2004	EU Performance Tests BASF DocID 2004/1016332 not GLP, unpublished PHY2005-1126	Y	BAS

B.6 Toxicological and Metabolism Studies

B.6.3 Short-term toxicity (Annex IIA 5.3)

B.6.3.2 Dermal studies

B.6.3.2.1 Rat, 28 Days

Report: Mellert W. et al., 2000 (TOX2001-718)
BAS 510 F - Repeated dose dermal toxicity study in Wistar rats - Administration for 4 weeks
BASF AG, Ludwigshafen/Rhein, Germany
BASF RegDoc# 2000/1013240, unpublished

Supplementary comment:
Stauber F., 2005
BASF Doc# 2005/1015024, unpublished

In addition to the findings described in the DAR, a slight increase in the number of female animals with gastric erosion or ulcers was noted in this dermal study at the dose of 1000 mg/kg bw/d (4/10 vs. 1/10 in the control group). No similar observations were made in high dose males. The applicant has submitted a response regarding a possible relationship of this finding to dermal treatment with boscalid.

No mechanistic explanation for these gastric lesions could be discovered. Since no comparable, dose-related findings were made in the 90-day oral study (Mellert W. et al., 2000 BASF RegDoc# 2000/101219) with daily doses up to 1225 mg/kg bw in females, the lesions are obviously not elicited by a direct contact of the gastric epithelia with the test substance. Indirect mechanisms related to stress phenomena could be envisaged. However, no indications for a specifically higher stress in female rats treated dermally with a dose of 1000 mg/kg bw were noted. Therefore, a chance occurrence is considered the most likely explanation. In accordance with the original evaluation in the DAR the dose of 1000 mg/kg bw/d is considered to be the NOAEL in this study.

B.6.8 Further toxicological studies (Annex IIA 5.8)

B.6.8.2 Supplementary studies with the active substance

Report: Kosaka T. 2003 (TOX2005-2345)
BAS 510 F: 4-week oral feeding immunotoxicity study in rats
The Institute of Environmental Toxicology (IET); Uchimoriya-machi 4321, Mitsukaido-shi, Ibaraki 303-0043; Japan
Study Code IET 03-0018
BASF RegDoc# 2003/1025755, unpublished
(Experimental work from April 2003 - June 2003)

GLP: Yes
(laboratory certified by Agricultural Production Bureau, Ministry of Agriculture, Forestry and Fisheries, Japan (MAFF))

Guideline: EPA immunotoxicity test guideline OPPTS 870.7800, 1998

Deviations: None

Acceptability: The study is considered to be acceptable.

Material and Methods:

Test material: Boscalid; batch No. N37, purity: 94.4 %.
Test animals: Male Wistar rats (Crj:Wistar; Charles River Japan)

Boscalid was administered to groups of 16 male Wistar rats at dietary concentrations of 0, 100, 1000 and 10000 ppm for 4 weeks, corresponding to a substance intake of 0, 7.8, 76.3 and 769 mg/kg bw/d. The test substance concentrations were chosen in accordance with those of the 2-generation study in rats (refer to B.6.6.1 of the DAR). As positive control, cyclophosphamide was administered by gavage to 16 male Wistar rats per group at doses of 0 (0.5 % methyl cellulose solution as vehicle control) and 3 mg/kg bw/d. The animals were about six weeks old at initiation of test substance administration. Animals were observed for clinical signs, moribundity and death on a daily basis. Food consumption and body weight (twice a week) were recorded. Out of each group 8 animals were selected for organ weight determination (thymus, spleen) and flow cytometry analysis of lymphocytes. The remaining 8 animals were injected with sheep red blood cells as an antigen 6 days before the termination of the study and anti-SRBC immunoglobulin M (IgM) was measured after the test substance administration period.

Findings:

The stability and the homogeneity of test substance and positive control substance were verified by analysis of the diet and the dosing solution, respectively, and were found to be within acceptable limits.

One animal of the 10000 ppm group was killed during week 3 of the study due to deteriorating health unrelated to the test substance. No clinical signs were observed in the remaining animals. In the treatment groups as well as in the positive control group food consumption and body weights were comparable to those of the controls throughout the treatment period. There were no significant changes in the organ weight (absolute and relative) of spleen and thymus, number of cells in thymus and spleen, and cell numbers of lymphocyte subsets. A significant increase in the Pan T-cell subset of the 100 ppm group was noted as isolated finding; however, in the absence of similar results in the 1000 and 10000 ppm groups this finding was not considered to be test substance-related. In the cyclophosphamide group statistically significant decreases were found in organ weights, cellularity and splenic and thymic lymphocyte subsets.

In the groups treated with boscalid no significant differences in serum anti-SRBC IgM antibody titers were observed with respect to the control group whereas in the cyclophosphamide group, the anti-SRBC IgM antibody titer was significantly lower than that of the corresponding control.

Conclusion:

Following the administration of 100, 1000 and 10000 ppm of boscalid in the diet for a period of 28 days in male Wistar rats, there were no immuno-toxicological effects on lymphocyte subsets of thymic and splenic cells as well as SRBC-specific IgM antibody titers that could be related to the test substance. The immune-suppressive effects of cyclophosphamide were indicative of the reliability of the method and procedures used.

B. 6.10.1 Summary

Further toxicological studies
In an immunotoxicity study with male rats, boscalid did not have an effect on cellular or humoral immune functions in male rats as evidenced by analysis of subsets of thymic and splenic lymphocytes and of SRBC-specific IgM antibody titers.

B. 6.15 References relied on

Annex point(s)	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Report No.** **GLP or GEP status (where relevant), published or not** **BBA registration number**	**Data protection claimed Y/N**	**Owner**
AII A 5.8.2/3	Kosaka T.	2003	BAS 510 F: 4-week oral feeding immunotoxicity study in rats 2003/1025755 GLP, unpublished TOX2005-2345	Y	BASF

B.7 Residue data

B.7.3 Definition of the residue (Annex IIA 6.7; Annex IIIA 8.6)

<u>Products of animal origin</u>
It is questioned whether to include the metabolites BAS510F53 or BA510F52 in the residue definition for risk assessment.
The difficulty of this question is that both metabolites are not present in animal matrices. They are the result of a chemical treatment which is necessary to liberate bound residues. Depending on the conditions of cleavage one or the other metabolite will be present.

Bound residues were cleaved under microwave treatment with formic acid to form BAS510F52 <u>or</u> with acetic acid to form BAS510F53. Since the cleavage with acetic acid is also described for milk, it was decided to take BAS510F53 as compound representing the bound residues in liver.

B.7.6 Residues resulting from supervised trials (Annex IIA 6.3; Annex IIIA 8.2)

Reports: Beck, J.; Greener, N. Mackenroth, C., 2003 (RIP2004-901)
Study on the residue behaviour of Boscalid (BAS F510 F) in grapes (wine) after application of BAS 510 01F under field conditions in Germany, France, Italy and Spain, 2002
BASF AG, Ludwigshafen/Rhein, Germany
BASF RegDoc# 2003/1001357, unpublished
GLP: Yes

Moreno, S., 2003 (RIP2004-902)
Study on the residue behaviour of Boscalid (BAS 510 F) in grapes (wine) after application of BAS 510 01F under field conditions in Spain, 2002
BASF AG, Ludwigshafen/Rhein, Germany
BASF RegDoc# 2003/1001279, unpublished
GLP: Yes

Amendment with minor corrections:
Moreno, S., 2003 (RIP2004-903)
Report Amendment No. 1! Study on the residue behaviour of Boscalid (BAS 510 F) in grapes (wine) after application of BAS 510 01 F under field conditions in Spain, 2002
BASF AG, Ludwigshafen/Rhein, Germany
BASF RegDoc# 2003/1009789, unpublished
GLP: Yes

Schulz, H.; 2004 (RIP2005-2259)
Study on the residue behaviour of Boscalid (BAS 510 F) in vines after application of BAS 510 01 F under field conditions in France (N&S), Spain, Italy and Germany, 2003
BASF AG, Ludwigshafen/Rhein, Germany
BASF RegDoc# 2004/1015915, unpublished

GLP: Yes

The intended use for Boscalid in grapes was changed. Instead of 3 x 0.7 kg a.i./ha the critical GAP is now 1 x 0.6 kg a.i./ha. Since this new GAP was not covered by adequate residues trials, new trials were conducted in 2002/2003.

Material and methods:
During the growing seasons 2002 and 2003, a total of 17 field trials were conducted in different representative wine growing areas in Germany, Spain, France and Italy (8 in Northern EU, 9 in the South) to determine the residue levels of boscalid. The WG formulation BAS 510 01 F (trade name in Germany: “Cantus”) was tested. It was applied once at growth stages of 79 to 89 (BBCH code) about 28 days before expected harvest. Different varieties of both white and red wine were used. The application rate was 1.2 kg/ha (= 600 g a.i./ha). The product was applied with a spray volume of 800 l/ha.
In all trials, grape samples were taken directly after the last application (0 DALA) as well as about 3, 4 and 5 weeks thereafter.
The samples were analyzed with BASF method no. 445/0 which quantifies the parent compound boscalid (BAS 510) with a limit of quantitation of 0.05 mg/kg. The overall average results of procedural recovery experiments obtained with each analytical series were at about 82%. Fortification levels were between 0.05 mg/kg and 5.0 mg/kg.

Findings:
In the trials treated with BAS 510 01 F, the residues of boscalid (BAS 510 F) found directly after the last application ranged between 0.18 and 1.96 mg/kg. After about four weeks at the proposed PHI, the residues were between 0.13 and 1.35 mg/kg. After about 5 weeks residues between 0.09 and 1.47 mg/kg were left.
The trial details and results are list in the following tables.

Table B.7.6- 1 Residue trials grapes – Northern Europe

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Boscalid
Crop / crop group : Grapes

Federal Institute for Risk Assessment, Thielallee 88 - 92
D-14195 Berlin
Federal Republic of Germany

Content of as (g/kg or g/L) : 500 g/kg
Formulation (e.g. WP) : WG
Commercial product (name) : Cantus (submitted to WN1 **005116-00**)
Applicant : BASF Aktiengesellschaft

Indoors / outdoors : Outdoors (Northern Europe)
Other as in formulation (common name and content) : --
Residues calculated as : Boscalid

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity / Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg as / ha	Water l / ha	kg as / hL						
	(a)	(b)				(c)		(a)		(d)	(e)
2003/1001357 DU2/13/02 DE-74193 Stetten a.H. 13.05.2004	Spät-burgunder	1) 20.10.98 2) 14.-28.06.02 3) 02.10.02	0.6	800	0.075	03.09.02	BBCH 83	grapes	0.38 0.33 0.35 0.41	0 21 28 35	RIP2004-901
2003/1001357 DU4/14/02 DE-67157 Wachenheim 13.05.2004	Riesling	1) 12.10.90 2) 01.-14.06.02 3) 25.09.02	0.6	800	0.075	19.08.02	BBCH 79	grapes	0.85 0.71 0.48 0.45	0 22 28 35	RIP2004-901
2003/1001357 FAN/15/02 FR-67560 Rosheim, Alsace FR-North	Chardonnay	1) 01.04.95 2) 10.-25.06.02 3) 17.-18.09.02	0.6	800	0.075	14.08.02	BBCH 79	grapes	1.26 1.12 0.79 0.91	0 21 29 35	RIP2004-901

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity / Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg as / ha	Water l / ha	kg as / hL						
	(a)	(b)				(c)		(a)		(d)	(e)
13.05.2004											
2003/1001357 FBM/12/02 FR-49190 Saint Aubin de Luigné FR-North 13.05.2004	Grolleau	1) 12.03.63 2) 18.-26.06.02 3) 30.09.02	0.6	800	0.075	03.09.02	BBCH 83	grapes	0.26 0.24 0.13 0.26	0 23 28 35	RIP2004-901
2004/1015915 DU2/06/03 DE-69168 Wiesloch 05.01.2006	Riesling	1) 01.10.85 2) 06.06.-20.06.03 3) 10.10.03	0.6	800	0.075	01.09.03	BBCH 85	grapes	0.19 0.24 0.23 0.20	0 21 28 35	RIP2005-2259
2004/1015915 DU4/06/03 DE-76831 Eschbach 05.01.2006	Spätburgunder	1) 10.05.93 2) 10.05.-20.05.03 3) 25.09.03	0.6	800	0.075	01.09.03	BBCH 83	grapes	0.79 1.03 0.43 0.51	0 21 28 35	RIP2005-2259
2004/1015915 FAN/03/03 FR- 67560 Rosheim FR-North 05.01.2006	Chardonnay	1) 01.04.95 2) 03.06.-15.06.03 3) 10.09.-18.09.03	0.6	800	0.075	13.08.03	BBCH 83	grapes	0.65 0.50 0.78 0.61	0 21 28 35	RIP2005-2259

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity / Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg as / ha	Water l / ha	kg as / hL						
	(a)	(b)				(c)		(a)		(d)	(e)
2004/1015915 FBM/02/03 FR- 49540 Martigné-Briand FR-North 05.01.2006	Chenin	1) 05.03.93 2) 17.06.- 23.06.03 3) 22.09.03	0.6	800	0.075	27.08.03	BBCH 83	grapes	0.80	0	RIP2005-2259
									0.36	21	
									0.39	28	
									0.35	35	

Remarks:
(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Note: All entries to be filled in as appropriate

Table B.7.6-2 Residue trials grapes – Southern Europe

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Boscalid
Crop / crop group : Grapes

Federal Institute for Risk Assessment, Thielallee 88 - 92
D-14195 Berlin
Federal Republic of Germany

Content of as (g/kg or g/l) : 500 g/kg
Formulation (e.g. WP) : WG
Commercial product (name) : Cantus (submitted to WN1 **005116-00**)
Applicant : BASF Aktiengesellschaft

Indoors / outdoors : Outdoors (Southern Europe)
Other as in formulation
(common name and content) : --
Residues calculated as : Boscalid

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity / Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg as / ha	Water l / ha	kg as / hL						
	(a)	(b)				(c)		(a)		(d)	(e)
2003/1001357 ALO/25/02 ES-41710 Utera Seville 13.05.2004	Cardenal	1) 15.02.87 2) 25.04-10.05.02 3) 15.-25.07.02	0.6	800	0.075	10.06.02	BBCH 79	grapes	0.53 0.19 0.23 0.12	0 21 28 35	RIP2004-901
2003/1001357 AYE/18/02 ES-11471 Jerez de la Frontera, Cadiz 13.05.2004	Palomino	1) 22.01.86 2) 25.04.-12.05.02 3) 10.08.-10.09.02	0.6	800	0.075	22.07.02	BBCH 81	grapes	0.23 0.24 0.20 0.21	0 21 28 35	RIP2004-901

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity / Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg as / ha	Water l / ha	kg as / hL						
	(a)	(b)				(c)		(a)		(d)	(e)
2003/1001357 ITA/22/02 IT-15058 Viguzzolo Piemonte 13.05.2004	Barbera	1) -- 2) 01-15.06.02 3) 10.-18.09.02	0.6	800	0.075	12.08.02	BBCH 83	grapes	1.96 1.26 1.35 1.47	0 22 28 35	RIP2004-901
O2/S/02 ES-41053 Lebrija, Cadiz 13.05.2004	Palomino	1) Jan. 1968 2) 20.04.-10.05.02 3) 20.08.02	0.6	785	0.075	23.07.02	BBCH 79-81	grapes	0.18 0.12 0.19 0.11	0 20 27 34	RIP2004-902
2003/1001357 FTL/18/02 FR-31620 Fronton FR-South	Negrette	1) 15.03.72 2) 12.-22.06.02 3)	0.6	800	0.075	14.08.02	BBCH 81	grapes	1.14 0.34 0.32 0.30	0 21 28 35	RIP2004-901
2004/1015915 FBD/01/03 FR- 26600 Pont de I'Isére FR-South 05.01.2006	Syrah	1) 01.02.82 2) 04.05.-21.05.03 3) 01.09.-03.09.03	0.6	800	0.075	06.08.03	BBCH 85	grapes	0.69 0.78 0.58 0.34	0 21 28 35	RIP2005-2259
2004/1015915 ITA/02/03 IT- 15058 Viguzzolo 05.01.2006	Barbera	1) -- 2) 01.06.-15.06.03 3) 05.09.-15.09.03	0.6	800	0.075	07.08.03	BBCH 83	grapes	0.98 0.76 0.88 0.42	0 21 28 35	RIP2005-2259

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity / Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg as / ha	Water l / ha	kg as / hL						
	(a)	(b)				(c)		(a)		(d)	(e)
2004/1015915 ALO/02/03 ES- 41710 Utrera (Sevilla) 05.01.2006	Cardenal	1) 15.02.87 2) 05.05.- 17.05.03 3) 17.07.- 21.07.03	0.6	800	0.075	16.06.03	BBCH 79	grapes	0.40 0.47 0.50 0.34	0 21 28 35	RIP2005-2259
2004/1015915 ALO/13/03 ES- 41720 Los Palacios (Sevilla) 05.01.2006	Airen	1) 15.02.96 2) 30.04.- 10.05.03 3) 11.08.- 12.08.03	0.6	800	0.075	07.07.03	BBCH 81	grapes	0.22 0.16 0.28 0.09	0 21 28 35	RIP2005-2259

Remarks:
(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Note: All entries to be filled in as appropriate

MRL calculation grapes
In the tables all results which are used for MRL calculation are underlined.
PHI:28 d (if at later PHIs higher residues were found this values were chosen for calculation).

Northern Europe
Supporting residue data according critical GAP:

0.23, 0.26, 0.39, 0.41, 0.48, 0.51, 0.78, 0.91 mg/kg

STMR: 0.45 mg/kg HR: 0.91 mg/kg
Rmax = 1.26 mg/kg Rber = 1.43 mg/kg

Southern Europe
Supporting residue data according critical GAP:

0.19, 0.21, 0.23, 0.28, 0.32, 0.50, 0.58, 0.88, 1.47 mg/kg

STMR: 0.32 mg/kg HR: 1.47 mg/kg
Rmax = 1.80 mg/kg Rber = 1.46 mg/kg

Rmax and Rber are calculated according EU-document7039/VI/95 EN of 22/07/97

A MRL of 2 mg/kg grapes is proposed.

B.7.8 Livestock feeding studies (Annex IIA 6.4; Annex IIIA 8.3)

Report: Stewart J. 2002(RIP2006-46)
A meat and egg magnitude of the residue study with BAS 510 F in laying hens
BASF Corporation Agro Research; Princeton NJ 08543-0400; United States of America
unpublished
BASF DocID 2002/5002466
GLP: Yes (laboratory certified by United States Environmental Protection Agency)

Material and methods

Test System
56 white Leghorn hens (Gallus gallus), in the age of about 42 weeks old, in the weight range from 1311 g to 1953 g were used in the study. The average total egg production data were considered normal and during the quarantine and test periods, no statistically significant differences in egg production or egg quality were noted

Feeding and husbandry
All birds were individually housed in 18’ x 12’ x 16' metabolism cages. Feed consumption was recorded for each bird daily.

Selection of dose levels

This feeding study was designed and performed in the US and was based on the calculation of the feed burden due to the US situation, taking into account canola, peas, sunflower, and peanuts and estimated tolerance levels.

Based on these calculations, nominal dose levels were 1.0 mg/kg (1x dose level), 5.0 mg/kg (5x dose level) and 20 mg/kg (20x dose level).

Dose preparation

Animals were dosed via capsules. The bottom-half of the gelatin capsules were loosely packed with corn starch. The appropriate amount of a solution of the test substance was transferred into the capsule and the capsules were allowed to air-dry prior to sealing the capsules by moistening the rim of top half of the capsule with a wet cotton swab and placing the two halves together. The control capsules each contained corn starch only. The capsules were prepared weekly and were stored frozen prior to use. To confirm the concentration of the dose solutions, aliquots from the two dosing solutions were diluted with acetonitrile and analyzed by LC/MS/MS.

Dose administration

The animals were orally dosed via gelatin capsule once daily. The achieved daily intake is calculated in terms of mg/kg feed and absolute intake in mg/day and animal. Residue concentration in the diet [mg/kg] are listed in Table B.7.8-1:

Table B.7.8-1: Summary of Boscalid Dose Levels

Group Number	Dose Level	Nominal Residue Concentration in the Diet [mg/kg]
I	Control (12 hens)	NA
II	1x (12 hens)	1.0
III	5x (12 hens)	5.0
IV	20x (20 hens)	20.0

The dosing period was of 29 days duration. Beginning on test day -1, samples of eggs were collected twice daily. Overall, the birds appeared normal and active throughout the study. The hens were sacrificed within 24 hours after administration of the last dose. For each hen, representative samples of liver, fat and muscle were collected for analysis.

Sampling:

Beginning on test day -1, samples of eggs were collected on Study Days –1, 1, 3, 5, 7, 10, 14, 17, 21, 24, 28, 31, 35 and 38. The eggs were pooled within each subgroup. Egg yields were recorded; no treatment related effects upon egg production were observed.

Terminal procedures

The birds were humanely sacrificed via decapitation followed immediately by exanguination within 24 hours after the last dose. For each bird, the liver and samples of muscle and fat were collected. All samples were frozen immediately and were shipped frozen to BASF for analysis.

Findings:

Bodyweight

Many animals lost weight over the course of the treatment period. However, this occurred in all dose groups including the controls.

Residue analysis

Analysis of egg and tissue samples was carried out according to BASF Analytical Method No. 471/0 to determine residues of boscalid and its metabolite M510F01 (including its conjugates). These analytes were determined to be the relevant residue in eggs and tissues in the hen metabolism study. BASF Analytical Method No. 471/0 is based on several liquid/liquid partitions, a SPE-purification on C_{18} material and quantification by LC/MS/MS. The limit of quantitation for parent and the metabolite M510F01 is 0.01 mg/kg in egg and 0.025 mg/kg in tissues. During the study, procedural recovery data were analyzed for each matrix. The overall recovery at the LOQ for the analyses of parent averaged 69 ± 5 % (n = 5) for the egg sample recoveries, 66 % (65 %, 66 %, n = 2) for the muscle sample recoveries, 66 % (66 %, 66 %, n = 2) for liver sample recoveries and 74 % (64 %, 83 %, n = 2) for fat sample recoveries. The overall recovery at the LOQ for the analyses of M510F01 averaged 81 ± 12 % (n = 5) for the egg sample recoveries, 87 % (94 %, 79 %, n = 2) for the muscle sample recoveries, 86 % (98 %, 74 %, n = 2) for liver sample recoveries and 96 % (96 %, 95 %, n = 2) for fat sample recoveries. Fortifications ranged from 0.01 to 0.1 mg/kg for the egg matrices, and from 0.025 to 0.5 mg/kg for liver. Muscle, and fat matrices were fortified with 0.025 mg/kg. Samples from control test chickens were fortified with boscalid for these experiments.

Residues in eggs and tissues

As shown in Table B.7.8-2 and Table B.7.8-3 at the 1.0 mg/kg (1x) and 5.0 mg/kg (5x) dose levels, all egg samples resulted in residues < 0.02 mg/kg, Only the 20x treatment demonstrated enough residue to show a time dependence of the residue levels, egg residues were < 0.02 mg/kg through test Day 3, then increased at Day 5 to 7, and reached a plateau within the first two weeks of dosing. At the 20.0 mg/kg dose level (20x) the highest residue was 0.06 mg/kg. The remaining residues from this group ranged from < 0.02 mg/kg (six days depuration) to 0.03 mg/kg (2 days depuration. Chicken liver, fat and muscle tissues were analyzed for residues of BAS 510 F and M510F01. There were no detectable residues > LOQ in any muscle samples from the three treatment groups. In liver, residues were < 0.05 mg/kg for the 1x dose group. Residues ranged from 0.11 to 0.18 mg/kg and from 0.32 to 0.47 mg/kg for the 5x and the 20x dose group, respectively. In fat, residues were < 0.05 mg/kg for the 1x dose group. In this matrix, residues ranged from 0.05 to 0.12 mg/kg and from 0.14 to 0.20 mg/kg for the 5x and the 20x dose group, respectively. The residues in all matrices were < LOQ after a depuration period of three days. All residue data for egg and tissue samples are summarized Table B.7.8-2 and Table B.7.8-3.

Table B.7.8-2: Summary of Group Mean Egg Results (Residues of Boscalid and the Metabolite M510F01 (including its Conjugates) Determined by BASF Analytical Method No. 471/0)

Day of Study	Group Mean Boscalid Residues in Eggs (mg/kg)			
	Control	Group II 1 x	Group III 5 x	Group IV 20 x
-1	< 0.02	< 0.02	< 0.02	< 0.02
1	< 0.02	< 0.02	< 0.02	< 0.02
3	< 0.02	< 0.02	< 0.02	< 0.02
5	< 0.02	< 0.02	< 0.02	0.283
7	< 0.02	< 0.02	< 0.02	0.046

Day of Study	Group Mean Boscalid Residues in Eggs (mg/kg)			
	Control	Group II 1 x	Group III 5 x	Group IV 20 x
10	< 0.02	< 0.02	< 0.02	0.046
14	< 0.02	< 0.02	< 0.02	0.05
17	< 0.02	< 0.02	< 0.02	0.044
21	< 0.02	< 0.02	< 0.02	0.054
24	< 0.02	< 0.02	< 0.02	0.036
28	< 0.02	< 0.02	< 0.02	0.054
Depuration phase				
31	n.a.	n.a.	n.a.	0.03
35	n.a..	n.a.	n.a.	<0.02
38	n.a.	n.a.	n.a.	<0.02

If residue levels were below the level of quantitation then the LOQ value (0.02 mg/kg) was used in averaging
n.a. not analysed

Table B.7.8-3: Summary of Residue Levels in Tissues (Boscalid and its Metabolite M510F01 (including its conjugatees) Determined by BASF Analytical Method No. 476/0)

	Group Mean Boscalid Residue (mg/kg)		
	Muscle	Liver	Fat
Control (Group I)	< 0.05	< 0.05	< 0.05
Group II (1 x)	< 0.05	< 0.05	< 0.05
Group III (5 x)	< 0.05	0.14	0.08
Group IV (20 x)	< 0.05	0.41	0.18

The deep freeze stability of residues of boscalid in hen matrices was demonstrated.

Conclusion:
A residue transfer study with boscalid was conducted in hens. The animals were dosed with 1.0, 5.0 and 20 mg/kg feed (dry matter) for a period of 28 days. At the 1.0 mg/kg (1 x) and 5.0 mg/kg (5 x) dose levels, all egg samples resulted in residues < 0.02 mg/kg. At the 20 x dose level, the residues reached a plateau of about 0.05 mg/kg within 2 weeks of dosing. After a depuration of 7 days, all residues in eggs are < 0.02 mg/kg. Chicken liver, fat and muscle tissues were analyzed for boscalid residues. No residues accumulated in any of those matrices at a dose level of 1.0 mg/kg (1x). At the 5x and 20x dose level, all residues of boscalid were < 0.05 mg/kg in muscle. At the 5x dose level, the highest amounts of detected residues were 0.18 mg/kg and 0.12 mg/kg for liver and fat, respectively. At the 20x dose level, the highest residues were 0.47 mg/kg and 0.20 mg/kg for liver and fat, respectively. In all investigated matrices, the residue levels were under the limit of quantitation after the depuration phase of 3 days.

Calculation of residues to be expected in livestock

Livestock feeding studies are very expensive experiments which involves the consumption of animals. It is as well from the economical as from the ethical point of view unjustifiable to repeat such studies without strong necessity.
Therefore it is not only acceptable but also advisable to consider foreseeable developments in the near future when calculating the dietary burden and the dose level for feeding studies. Taking only into account the limited number of crops included in the DAR (“one safe use” concept) the dietary burden would be unrealistic and the results of an adequate feeding study would not cover the use of the active substance already registered in Europe.

Therefore the following calculation of the dietary burden (Table B.7.8-4) was done on basis of all available information including knowledge from the German national registration process.

B.8 Environmental fate and behaviour

B.8.1 Route and rate of degradation in soil (Annex IIA 7.1.1; Annex IIIA 9.1.1)

B.8.1.3 Soil accumulation study

Annex Point:	IIA-7.1.1.2.2/1
Author:	Kellner, O. Grote, C. and Platz, K.
Title:	Accumulation behaviour of BAS 510 F under field conditions over a 5-year-period (1998-2003) after application onto grapes in a vineyard
Date:	07.09.2004
Doc ID:	2004/1003851; BOD 2005-906
Guidelines:	SETAC, BBA IV, 4-1, IVA-Leitlinie
GLP:	yes
Valid:	yes

The accumulation behaviour of BAS 510 F under field conditions was investigated over a 5-year-period from 1998 to 2003 after application onto grapes in a vineyard. The trial was conducted at a site in Germany in Rhineland Palatinate (Rheinland-Pfalz). The soil was a loamy sand/sandy loam with a pH value of 7.5, an organic carbon content of 1.2 %, a cation exchange capacity of 15 meq/100 g dry soil and a maximum water holding capacity of 40 g water/100 g dry soil.

The nominal application rates were 3 times 700 g active substance/ha sprayed onto grapes at BBCH growth stages 67, 77 and 81. The amounts of products actually applied were determined by measuring the volumes in the tank before and after application. The rates were always between 680 and 735 g as/ha and therefore very near to the nominal rates.

BAS 510 KA F (1998) or BAS 510 01 F were always applied onto grapes with a gasoline powered mistblower with nominal amounts of spray mixture of 600, 700 and 800 L/ha at the respective growth stages (Table B.8.1-1).

Table B.9.3-1: Application parameters of BAS 510 F in grapes

Appl. No.	Date	DAFT	Formulation	BBCH	Spray mixture L/ha	Product L/ha or kg/ha	as nominal g/ha
1	19.06.1998	0	BAS 510 KA F	67	598	1.39	700
2	28.07.1998	39	BAS 510 KA F	77	694	1.39	695
3	18.08.1998	60	BAS 510 KA F	81	777	1.36	680
4	17.06.1999	363	BAS 510 01 F	67	584	1.36	680
5	27.07.1999	403	BAS 510 01 F	77	693	1.39	695
6	18.08.1999	425	BAS 510 01 F	81	841	1.47	735
7	16.06.2000	728	BAS 510 01 F	67	605	1.41	705
8	24.07.2000	766	BAS 510 01 F	77	723	1.45	725
9	16.08.2000	789	BAS 510 01 F	81	835	1.46	730
10	20.06.2001	1097	BAS 510 01 F	67	616	1.44	720

11	26.07.2001	1133	BAS 510 01 F	77	712	1.42	710
12	23.08.2001	1161	BAS 510 01 F	81	803	1.41	705
13	26.06.2002	1468	BAS 510 01 F	67	590	1.38	690
14	29.07.2002	1501	BAS 510 01 F	77	711	1.42	710
15	21.08.2002	1524	BAS 510 01 F	81	832	1.46	730
16	12.06.2003	1819	BAS 510 01 F	67	619	1.45	725
17	16.07.2003	1853	BAS 510 01 F	77	694	1.39	695
18	05.08.2003	1873	BAS 510 01 F	81	822	1.44	720

DAFT = days after first treatment

The precipitation and distribution of the spray broth on the plots at the time of application was determined at the first application with a method using Petri dishes filled with soil. It can be concluded from the results that the spray broth reaching the soil via application is uniformly distributed throughout the plots. Additionally, the volume of the spray broth was kept small to avoid the formation of droplets rinsing off the leaves. Therefore it was decided, to take the soil cores from 1998 to 2000 as 3 replicates within a subplot at random, but for practical reasons not closer than 45 cm to the vines. In April 2000 the distribution of the soil residues within the subplots was determined after 3 years of BAS 510 F application and cultivation according to good agricultural practice. The results revealed that the soil residue were lowest right in the middle between the grape vines rows. Therefore, from the season 2001 on, the sampling pattern within the subplots was modified. The core area between the rows of ca. 70 cm was not sampled. All samples were taken at a maximum distance of 60 cm from the trunk of the vine.

Soil samples (soil cores) were taken down to a depth of 25 cm routinely three times a year, once before the first application, once after the last application in August and once in October. Results up to sampling 16 in June 2003 are reported. The samples were separated in layers of 0 to 10 and 10 to 25 cm (until sampling 9) and in layers of 0 to 10, 10 to 20 and 20 to 25 cm from sampling 10 onwards. The leaves and the plant material that was cut off the vines due to agricultural management were left on the plots. The grapes were harvested.

Replicate samples were analysed for BAS 510 F by BASF method 408/1. No corrections, neither for recoveries nor blanks, have been made, but all results were corrected for moisture content of the soil. The recoveries from n = 42 measurements of fortified samples had a mean value of 98.9 % with a relative standard deviation of 14 %. This proves the quality and repeatability of the method.

Control samples from untreated plots were analysed from sampling before application. As expected, all the soil samples from replicates 1 and 3 were free of residues of BAS 510 F. However, the 2 samples from replicate 2 (also prior to the first application) contained BAS 510 F, especially in the 10 to 25 cm layer. This was explained by accidental contamination of the samples. Overall, the data demonstrate that no interferences of the sample material with the analytical procedure occurred and that the control plots were free of residues of BAS 510 F.

By far the highest amounts of residues of BAS 510 F were detected in the 0 – 10 cm soil layers. Up to sampling no. 4, only very minor quantities above the LOQ were found in the 10 - 25 cm soil layer. At later samplings, the residue level in the 10 - 25 cm layer increased slightly due to agricultural engineering of the plots. Therefore, it was decided to separate the soil cores into increments of 0 - 10, 10 - 20 and 20 – 25 cm starting with the season 2001 to get a clearer picture of the distribution of BAS 510 F with respect to soil depth.

The residues observed in the different soil layers were converted from mg/kg to kg/ha under consideration of the following equation. Residues lower than the determination limit (< 0.01 mg/kg) were treated as 0 mg/kg.

$$c_{kg/ha} = c_{mg/kg} * 10^{-6} * d * \sigma * A$$

where

d = depth of the considered soil layer (0.1 or 0.15 or 0.05) [m]
σ = soil bulk density (1500 kg/m^3) [kg/m^3]
A = considered area (1 ha) [m^2]

The residues of the associated soil layers of each soil core converted to kg/ha were summed up. The mean values of the different replicates of each sampling date were calculated and used for the estimation approach. The model data used for the estimation approach are given in Table B.8.1-2.

Table B.9.1: Analytical results: BAS 510 F residues in soil (sum of the different layers of each soil core, given in kg as/ha)

Sampling date	DAFT	Replicate 1	DAFT	Replicate 2	DAFT	Replicate 3	mean of replicates used for estimation
20.08.1998	62	0.480	62	0.443	62	0.552	0.492
26.10.1998	129	0.386	129	0.498	129	0.497	0.460
09.06.1999	355	0.612	355	0.824	355	0.661	0.699
19.08.1999	426	1.884	426	1.993	426	1.799	1.892
27.10.1999	495	1.312	495	1.918	495	0.895	1.375
15.06.2000	727	1.457	727	1.932	727	0.977	1.455
29.08.2000	802	2.174	802	1.879	802	1.931	1.994
25.10.2000	859	2.231	859	2.430	8.59	1.518	2.060
07.06.2001	1084	2.017	1084	2.600	1084	1.683	2.100
24.08.2001	1162	2,848[1)]	1162	3.478	1162	2.428[1)]	2.918
22.10,2001	1221	3.167	1221	3.811	1221	1.916	2.964
12.06.2002	1454	2.834	1454	3.138	1454	2.267	2.746
22.08.2002	1525	6.317	1525	7.083	1525	4.445	5.948[2)]
28.10.2002	1592	2.824	1592	2.822	1592	2.811	2.819
05.06.2003	1812	2.312	1812	3.218	1812	1.880	2.470

DAFT =day after first treatment

[1)] As no samples for the soil layers 10 cm - 20 cm and 20 cm - 25 cm were taken at replicates 1 and 3, the analysed residues of the comparable layers of replicate 2 are considered.

[2)] The residue observed at sampling time 22.08.2002 was assessed to be an outlier. Because of steady dissipation between the single applications and likely crop interception, the expected increase should be clearly less than the nominal annual application rate, whereas the measured increase was nearly the double of the nominal annual application rate. The measured residue was therefore not considered for the modelling approach.

A simple biphasic estimation model was established using of the software tool ModelMaker (v.3 patch 3.0.4), in order to investigate if the residue in soil has reached its steady state concentration (steady state level) within the study period.

As the field accumulation study was executed with a regular application procedure with similar application rates and similar application times each year, one can expect a steady increase of the soil concentration up to the maximum level. When the plateau concentration is reached, the annual dissipation rate corresponds to the annual application rate of the pesticide. The chosen biphasic estimation model describes this accumulation behaviour in principle. It reflects the initial concentration at the day of first application, a time period with a linear increase of the residue concentration and a hinge point were the maximum concentration is reached and remains at steady state. The initial concentration, a constant b that describes the linear increase and the hinge point a (time point at steady state) were estimated/optimised under consideration of the observed residues.

$$c(t) = \begin{cases} c_0 + b * t & \text{for } 0 \leq t \leq a \\ c_{plateau} = c_0 + b * a & \text{for } t > a \end{cases}$$

where

$c(t)$	=	concentration at time t	[kg/ha]
c_0	=	initial concentration after the first application	[kg/ha]
b	=	linear slope constant	[kg/ha/d]
a	=	time point of steady state (“hinge point”)	[d]
$c_{plateau}$	=	plateau concentration at steady state	[kg/ha]
t	=	time	[d]

The hinge point a (time to reach steady state) was estimated with 1220 days. The related standard deviation of 138 days and type-I error rate of < 0.001 are low and give evidence of a successful and significant estimation of the hinge point (see also Figure 8.1-1). The last sampling point was taken at day 1812 after first treatment (DAFT), whereas the estimated hinge point is calculated much lower with 1220 DAFT. It was thus concluded that the steady state level was reached within the study period.

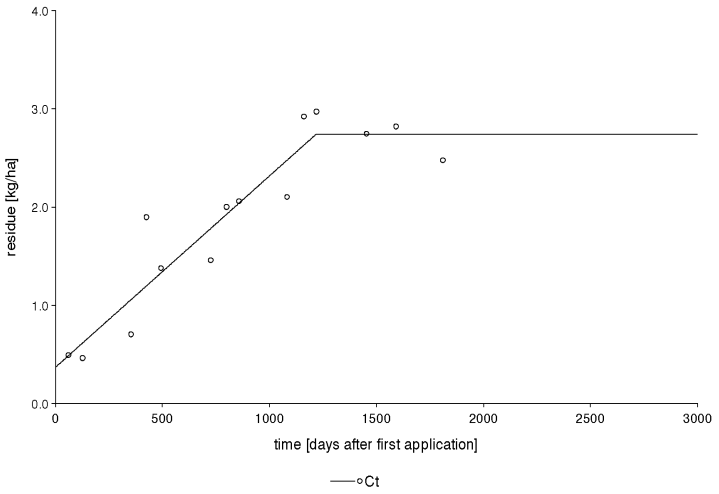


Figure 8.1- 1: Result of fitting a biphasic curve to the observed residue data

A second modelling approach was established to estimate the minimum and maximum soil concentrations of the field accumulation study. Those are mainly influenced by the application rates, interception of the cultivated crop (grapevine) and pesticide re-entry into the soil layer through residues in or on leaves. The dissipation behaviour in soil does also play a significant role for the accumulation behaviour of BAS 510 F. All those influences are considered in this modelling approach. To prevent an over-parameterisation of the estimation model, the dissipation rate was fixed to a realistic average amount deduced from a previous dissipation study. The model entry values that consider the different application rates and application times were deduced from the actual application procedure. As the amount and time point of pesticide re-entry due to leaf residues varies over the whole study period, an average value was estimated. The re-entry (fraction of intercepted amount) was estimated under consideration of the observed residues by use of the software tool ModelMaker (v.3

patch 3.0.4). As the input parameters of the model are based on mean values and as the actual daily climatic conditions were not considered, this modelling approach describes the average accumulation behaviour of BAS 510 F.

It was assumed that the whole pesticide entry occurs at the day of the application event. The interception amount depends on the different growth stages of the cultivated crop. The interception amounts considered for this estimation approach are based on recommendations of FOCUS. The resulting pesticide soil entry considered in this estimation approach is the sum of the nominal application rate minus the respective crop interception plus the estimated fraction of re-entry of the intercepted amount due to leaf residues.

$$c(t_1) = c(t_2) + A - (A * f_{\text{int}}) + (A * f_{\text{int}} * f_{re-entry})$$

where

$c(t_1)$	=	concentration at time after application	[kg/ha]
$c(t_2)$	=	concentration at time before application	[kg/ha]
A	=	nominal application rate (fixed)	[kg/ha]
f_{int}	=	FOCUS crop interception (fixed)	-
$f_{\text{re-entry}}$	=	fraction of re-entry of the intercepted amount (estimated)	-

The application rates and the application times considered for the modelling approach are given in Table B.8.1-1. The respective crop interception amounts for BBCH 67, 77 and 81 are set as 0.7, 0.7 and 0.85, respectively.

Dissipation according to single first order kinetics was considered for this modelling approach. The trial site of the field accumulation study was located in Grünstadt/Rhineland Palatinate. Therefore the dissipation behaviour investigated in a field dissipation study Schifferstadt/Rhineland Palatinate with comparable climatic conditions was considered for the modelling approach. As the respective half-life of 212 d was normalised to a standard temperature of 20° C, it had to be adapted to a realistic mean temperature of 10 °C of the accumulation study. The half-life was thus recalculated using the Arrhenius equation as recommended by FOCUS with a Q10 value of 2.2.

$$HL_{10°C} = HL_{20°C} * Q_{10}^{(20°C - 10°C)/10}$$

The resulting half-life considered for the modelling approach was 466 d (degradation rate constant 0.0015 d^{-1}).

The second modelling approach yielded minimum and maximum plateaus of 2000 g as/ha and 3100 g as/ha, respectively (as graphically depicted in Table B.8.1-2). However, these amounts cannot be used directly for the risk assessment, since the accumulation study was performed with a higher number of applications and dose rates for BAS 510 F in grapes (3 × 700 g as/ha) than relevant for the EU risk assessment now (1 × 600 g as/ha).

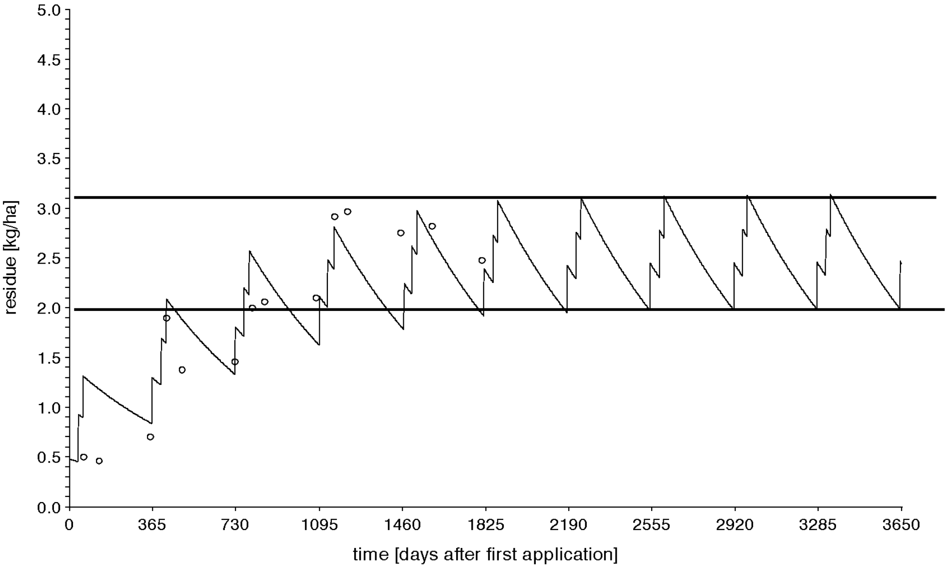


Figure 8.1-2: **Result of fitting a soil residue dynamics curve to the observed residue data (vines)**

Conclusion:

A concentration plateau in soil was reached in an accumulation study in grapes over 5 years with annual application of 3 × 700 g as/ha. According to a simple biphasic model, this plateau was reached at about 1220 days (40 – 41 months) after the first treatment. A more sophisticated assessment of the data using ModelMaker yielded minimum and maximum plateaus of 2000 g as/ha and 3100 g as/ha, respectively. In relation to the tested annual application rate of 2100 g as/ha, this is equivalent to an accumulation factor of 95 % for the background areic concentration directly before the annual application and to an accumulation factor of 148 % for the expected maximum areic concentration after the application of the compound.

However, closer inspection of the modelled concentration curve and the individual measured data-points reveals some aspects that must be considered when applying the results of the study for PEC_{soil} calculations. First, the measured concentrations of boscalid directly before application of the compound in June 2002 and June 2003 (i.e. after the plateau should have been reached) are both higher than the modelled level with 2746 and 2470 g as/ha, respectively (mean 2608 g as/ha, n = 2; i.e. 124 % of annual application rate). Second, the modelled maximum concentration levels exceed the modelled background concentration by more than 50 %, although for an average interception of 0.75 (mean of 0.7, 0.7 and 0.85 for the individual application events), only 25 % exceedance could have been expected. This emphasises the great impact of compound 're-entry' into soil (most probably with falling leaves) in the model. However, such effects are not considered in standard PEC_{soil} calculations.

As regards the maxima reached within a year, the concentrations obtained two months after the 3rd annual application in October 2001 and October 2002 are virtually as high as the concentrations measured directly after that 3rd application in August 2002. The mean of those measured maximum concentrations is 2.900 g as/ha (n = 3; i.e. 138 % of annual application rate) and thus lower than the modelled level of 148 %. This might be seen as a confirmation for the maximum plateau as obtained from the ModelMaker evaluation.

Annex Point:	IIA-7.1.1.2.2/2
Author:	Grote, C. and Platz; K.
Title:	Accumulation behaviour of BAS 510 F under field conditions over a 7-year-period (1998-2004) after applications onto vegetables
Date:	31.05.2005
Doc ID:	2005/1013964; BOD 2005-907
Guidelines:	SETAC, BBA IV, 4-1, IVA-Leitlinie
GLP:	yes
Valid:	yes

The accumulation behaviour of BAS 510 F under field conditions in vegetables has been investigated over a six-year-period from 1998 to 2004. (The report title suggests that accumulation behaviour had been observed over a period of seven years. However, results are available for a period of six years only.) The trial was conducted at a site in Germany in Rhineland Palatinate (Rheinland-Pfalz). The soil was a loamy sand with an organic carbon content of 1.0 %, a pH value of 7.8, cation exchange capacity of 13 mVal/100 g dry soil and a maximum water holding capacity of 43 g water/100 g dry soil.

BAS 510 F was applied in 1998 onto lettuce (nominal 2 × 300 g as/ha) and green beans (nominal 3 × 500 g as/ha) and in 1999 onto carrots (nominal 3 × 300 g as/ha) and cauliflower (nominal 2 × 400 g as/ha). The total amounts of BAS 510 F applied were nominally 2100 g in 1998 and 1700 g in 1999. In the year 2000, spring wheat was grown on the plots and no product containing BAS 510 F was applied to these plots. In general, cultivation of vegetables in two consecutive years with cultivation of cereals in the third year stands for a rather common crop rotation in agricultural practice in Germany. It also represents a reasonable worst case for the application of BAS 510 F in a crop rotation.

The three-year crop rotation with its crops and applications of BAS 510 F as previously described in detail was repeated. In 2001, BAS 510 F was applied onto lettuce (nominal 2 × 300 g as/ha) and green beans (nominal 3 × 500 g as/ha) and in 2002 onto carrots (nominal 3 × 300 g as/ha) and cauliflower (nominal 2 × 400 g as/ha). In 2004, the cycle was started again with application onto lettuce (nominal 2 × 300 g as/ha) and green beans (nominal 3 × 500 g as/ha). The total amounts of BAS 510 F nominally applied per ha were 2100 g as in 2001, 1700 g as in 2002, none in 2003 and again 2100 g as in 2004.

The actual amounts of BAS 510 F applied onto the field as determined by spray broth calculation differ only slightly. A summary of the application parameters including dates of applications, formulation, crops, growth stages and product and spray mixture applied is given in Table B.8.1-3.

Table B.9.1: Application parameters of BAS 510 F in vegetables

Application No.	Date	DAFT	Formulation	Crop	Growth stage [BBCH]	Spray mixture [L/ha]	Product [L/ha or kg/ha]	as nominal [g/ha]
1	14.05.98	0	BAS 510 KA F	Lettuce	17	595	0.595	298
2	03.06.98	20	BAS 510 KA F	Lettuce	43	811	0.608	304
3	25.08.98	103	BAS 510 KA F	Green bean	61	589	0.982	491
4	07.09.98	116	BAS 510 KA F	Green bean	65	799	0.999	500
5	17.09.98	126	BAS 510 KA F	Green bean	67	823	1.029	515
6	20.05.99	371	BAS 510 01 F	Carrot	14	395	0.593	297
7	07.06.99	389	BAS 510 01 F	Carrot	41	575	0.575	288
8	22.06.99	404	BAS 510 01 F	Carrot	47	756	0.567	284
9	02.09.99	476	BAS 510 01 F	Cauliflower	19	617	0.822	411
10	17.09.99	491	BAS 510 01 F	Cauliflower	41	781	0.781	391

11	04.05.01	1086	BAS 510 01 F	Lettuce	17	600	0.60	300
12	23.05.01	1105	BAS 510 01 F	Lettuce	43	814	0.61	305
13	23.07.01	1166	BAS 510 01 F	Green bean	61	593	0.99	495
14	02.08.01	1176	BAS 510 01 F	Green bean	65	767	0.96	480
15	21.08.01	1195	BAS 510 01 F	Green bean	67	774	0.97	485
16	15.05.02	1462	BAS 510 01 F	Carrot	16	419	0.63	315
17	27.05.02	1474	BAS 510 01 F	Carrot	41	586	0.59	295
18	17.06.02	1495	BAS 510 01 F	Carrot	45	806	0.60	300
19	02.09.02	1572	BAS 510 01 F	Cauliflower	19	608	0.81	405
20	13.09.02	1583	BAS 510 01 F	Cauliflower	41	784	0.78	390
21	26.05.04	2204	BAS 510 01 F	Lettuce	17	618	0.62	310
22	08.06.04	2217	BAS 510 01 F	Lettuce	42	800	0.60	300
23	23.08.04	2293	BAS 510 01 F	Green bean	61	605	1.01	505
24	03.09.04	2304	BAS 510 01 F	Green bean	65	806	1.01	505
25	17.09.04	2318	BAS 510 01 F	Green bean	67	794	0.99	495

DAFT = days after first treatment

Soil samples were taken twice a year in 3 replicates, once before application and once after harvest. Initially, the soil cores were divided into 0 - 10, 10 - 25 and 25 – 50 cm segments. From 2001 onwards, the increments for analysis were changed to 0 - 10, 10 - 20, 20 - 30, 30 - 40 and 40 – 50 cm to give a more detailed overview of the distribution of the residues within the soil layers. Results up to sampling no. 13 in spring 2004 are reported.
Replicate samples were analysed for BAS 510 F by BASF method 408/1. No correction, neither for recoveries nor blanks, has been made, but all results were corrected for moisture content of the soil. The recoveries from n = 55 measurements of fortified samples had a mean value of 95.9 % with a relative standard deviation of 11.7 %. This proves the quality and repeatability of the method.
Control samples from untreated plots were analysed from sampling before application. They were free of residues. These data demonstrate that no interferences of the sample material with the analytical procedure occurred and that the control plots were free of residues of BAS 510 F.

The results of the first six years of the vegetable accumulation study confirm the results that were found after application of BAS 510 F on bare soil. After application in the growth season, significant residues of BAS 510 F can be detected in soil in the spring of the following year. In contrast to the field soil dissipation studies, BAS 510 F was found in this study also in deeper layers of the soil horizon. This was caused by the tillage of the soil including ploughing once a year down to 35 cm depth. However, the highest amounts of residues were detected from 0 to 30 cm depth.
The residues observed in the different soil layers were converted from mg/kg to kg/ha as described above for the soil accumulation study in vines. These areic concentrations were then summed up per soil core and the mean of the three replicates calculated. The model data used for the estimation approach are given in Table B.8.1-4.

Table B.9.1: Residue data of the accumulation study of BAS 510 F in vegetable

DAFT	BAS 510 F [kg/ha]			
	Replicate 1	Replicate 2	Replicate 3	mean
-14	0	0	0	
151	0.619	1.006	2.483	1.369
298	0.604	1.01	0.491	0.701
538	1.602	1.871	1.077	1.516

669	1.088	0.93	0.802	0.940
830	1.219	1.084	0.941	1.081
1056	0.470	0.620	0.546	0.545
1272	1.515	1.886	1.631	1.677
1386	1.185	1.344	1.286	1.265
1650	2.696	2.421	2.519	2.545
1768	0.815	1.001	0.764	0.860
1925	1.685	2.285	1.694	1.888
2132	1.025	1.140	1.124	1.096

DAFT days after first application

The analytical results were further investigated by modelling. The dates of the different application events, the respective application rates of BAS 510 F to the cultivated crops, the growth stages of the crops, and crop interception as given by FOCUS were taken into account for estimating the minimum and maximum residue levels in soil after repeated application. The FOCUS crop interception values at the different application events vary between 25 % and 80 %. The nominal application rates were 2100 g as/ha in the first year, 1700 g as/ha in the second year and no application in the third year and so on. This application pattern results in an average annual application rate of BAS 510 F of 1270 g as/ha.

The effective soil loads of BAS 510 F at the respective application events were deduced from the nominal application rates, the crop interception and the fraction of crop residues of BAS 510 F that finally reaches the soil after harvest or with falling leaves. As suitable information of this reload fraction is not available, the amount was estimated under consideration of the residue data of the accumulation study. To prevent an over-parameterisation of the estimation model the modelling approach is based on the simple assumption that the reload entry of BAS 510 F takes place at the time of the application event.

The dissipation behaviour of BAS 510 F in the accumulation study could not be estimated independently from the fraction of BAS 510 F that finally reaches the soil with crop residues after harvest or with falling leaves. For that reason the dissipation time of BAS 510 F in the accumulation study was not estimated but fixed to a realistic value. In doing so, the average dissipation behaviour of BAS 510 F in soil as observed in different field dissipation studies of BAS 510 F was considered. The respective half-lives at these trial sites when standardised to a reference temperature of 20 °C are in a very close range. The mean half-lives of the different trial sites vary between 98 d and 212 d. The vegetables were irrigated according to GAP. Thus, fair dissipation behaviour of BAS 510 F can be expected and the arithmetic mean half-life of 139 d was considered as a realistic input parameter for the estimation approach. The mean half-life of 139 d valid for a reference temperature of 20 °C was converted to the average annual temperature of the accumulation study of about 10 °C. The conversion was made with a derivation of the Arrhenius equation as recommended by FOCUS. The mean field half-life in soil of BAS 510 F standardised (converted) to the experimental average annual temperature of 10 °C is 305.8 d.

The observed residues of the accumulation study were fitted under consideration of the varying application pattern and dissipation according to first order kinetics. As explained above, the modelling approach is based on simple assumptions with respect to reload of previously intercepted amounts of BAS 510 F into soil (at the time of the application event) and temperature dependence of dissipation (described by the annual mean temperature instead of actual daily temperatures of the field experiment). For that reason the fitted curve (see Figure B.8.1-3) does only reflect the formation of the soil residues in general, but not the individual observed values.

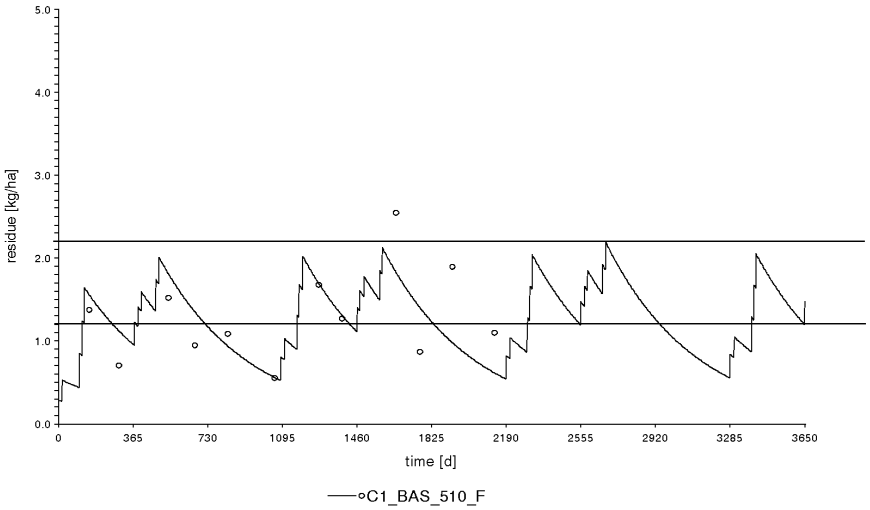


Figure 8.1-3: **Result of fitting a soil residue dynamics curve to the observed residue data (vegetables)**

Because of the varying annual application rates of BAS 510 F (as is true for a realistic crop rotation scenario), the minimum and maximum plateau concentrations at steady state vary, too. The reported minimum plateau amount of BAS 510 F is the maximum estimated concentration in springtime before the first annual application event in the second of two consecutive years with application of BAS 510 F. In order to reflect worst-case conditions, the minimum value in springtime following the year without application of BAS 510 F was not considered. The reported maximum plateau concentration is the estimated maximum value (peak amount) at steady state. The minimum and maximum estimated plateau concentration of BAS 510 F following multiple applications onto vegetables are 1200 g as/ha and 2200 g as/ha, respectively. However, these amounts cannot be used directly for the risk assessment, since the accumulation study was performed with a higher number of applications and dose rates for BAS 510 F in vegetables than relevant for the EU risk assessment now. The current supported use for carrots treated with BAS 510 F is 2 × 267 g as/ha instead of 3 × 300 g as/ha as in the accumulation study. For lettuce, the current supported use consists of 2 × 400 g as/ha (instead of 2 × 300 g as/ha), for beans 2 × 500 g as/ha (instead of 3 × 500 g as/ha) and for cauliflower 3 × 267 g as/ha (instead of 2 × 400 g as/ha).

Conclusion:

The RMS has noticed that the study report is actually an interim report. It was confirmed by the notifier that the study is on-going for at least one further crop rotation cycle to allow a more reliable fitting of the soil residue dynamics curve to the experimental data.

The minimum plateau concentration of 1200 g as/ha according to the current fitted curve would represent an accumulation of 95 % in relation to the average treatment rate over three years of 1270 g as/ha (i.e mean of 2100, 1700 and 0 g as/ha). Likewise, the maximum plateau concentration of 2200 g as/ha would represent an accumulation of 174 %.

It is obvious from the modelled concentration curve and the individual measured data-points that three out of the four last measured concentrations in soil are significantly higher than predicted. In contrast, the fit appears to be quite satisfactory for the first four years of the study. No final conclusion on the actual plateau levels is possible as long as no measured data for a third crop rotation cycle are available. It is in principle agreed that the risk assessment should consider the measured/modelled accumulation within the 2-year period of actual treatments, rather than the concentration levels obtained after a year without any treatment. However, measured values for that time-point are only available one year (plateau definitely not reached) and four years after the first treatment. Furthermore, like in the soil accumulation study in vines, it is obvious from the modelling results that the reload of initially intercepted residues of the active substance significantly contributes to the actual concentrations in soil. This effect is not considered in standard PEC_{soil} calculations.

Nevertheless, an evaluation based on selected measured concentrations in the study is considered to provide a reliable value for a preliminary risk assessment. Due to regular ploughing as a part of soil treatment in vegetable and cereal cultivation, it can be assumed that the background concentration level, as soon as it is reached, will be evenly distributed over the 0 - 30 cm soil horizon. It can further be assumed that this level is well represented by the measured concentrations in the 10 - 20 cm soil layer in samples taken before ploughing. Those concentrations reflect the input through application and reload from previous, but not from the current year. The 10 - 20 cm soil layer is preferred over the 20 - 30 cm soil layer, because the mixing effect of ploughing is considered to be highest in that medium layer and because the results from the deeper 20 - 30 cm soil layer may be biased by edge/border effects. For the selection of sampling dates, the following considerations were made: In samples taken between the start of the study in April 1998 and March 2000, definitely no plateau could have been reached. The sampling dates August 2000 and March 2001 follow a year without application of boscalid (cultivation of cereals). In November 2001, the first application after the break had not yet been incorporated into the soil. The samples from February 2002, November 2002 and March 2003 (numbered 9 to 11) appear suitable. The concentrations remain fairly constant over the year, indicating that some plateau (i.e. equilibrium between input and degradation) could have already been reached. The subsequent sampling dates (August 2003 and March 2004) again follow a year without application of boscalid and thus cannot be considered. The individual results for sampling dates 9 to 11 are summarised in Table B.8.1-5. The overall mean of the concentrations amounts to 0.345 mg/kg.

Table B.9.1: Measured concentrations of boscalid in the 10 – 20 cm soil layer

Sample No.	soil depth [cm]	sampling date	BAS 510 F [mg/kg]	mean [mg/kg]
9	10 - 20	28.02.2002	0,440	0,439
			0,438	
			0,439	
10	10 - 20	19.11.2002	0,429	0,413
			0,335	
			0,474	
11	10 - 20	17.03.2003	0,168	0,185
			0,217	
			0,169	
Overall				0,345

As a preliminary surrogate for a maximum plateau, the concentration at 1650 d after initial treatment (November 2002) can be taken. As shown above for the vineyard study, this value will also cover the reload to soil of initially intercepted amounts of the active substance. The areic concentration at 1650 DAFT is 2545 g as/ha. In relation to the corresponding application rate of 1700 g as/ha (i.e. the maximum is considered to reflect the last application before sampling), this would represent an accumulation of 150 %. This value can be used in the calculation of PEC_{soil} values resulting from application of boscalid on a soil that already contains a background plateau concentration of the active substance.

B.8.2 Adsorption, desorption and mobility in soil (Annex IIA 7.1.2, 7.1.3; Annex IIIA 9.1.2)

B.8.2.1 Adsorption and desorption

It was stated in the monograph that on the basis of the findings of the adsorption/desorption study, BAS 510 F could be classified as 'non-mobile' in soil. However, with a K_{OC} in the range 500 – 1000, the compound must in fact be classified as 'slightly mobile'.

B.8.3 Predicted environmental concentrations in soil (PEC_S) (Annex IIIA 9.1.3)

Annex Point:	IIIA-9.1.3/6
Author:	Platz, K.
Title:	Predicted environmental concentrations in soil after long-term use of BAS 5100 F (Boscalid) under consideration of a bean and grapevine crop scenario
Date:	21.05.2005
Doc ID:	BASF DocID 2005/11014172; BOD 2005-908
Guidelines:	FOCUS (2000)
GLP:	No, not subject to GLP regulations
Valid:	n.a. (modelling exercise)

This modelling calculation estimates the overall predicted environmental concentrations in soil ($PEC_{lt,overall}$) of BAS 510 F after long-term application onto beans and grapevine. In a first step the soil concentrations at steady state after long-term use ($PEC_{plateau,min}$) of BAS 510 F were estimated by using a percentage rate deduced from two accumulation field studies and by using the following parameters:

	grapevine scenario	bean scenario
total annual application rate	600 g as/ha	1000 g as/ha
minimum accumulation factor in soil as derived from a field accumulation study	95 %	95 %
depth of the considered soil cultivation layer	10 cm	30 cm
considered density of the soil layer	1.5 g/cm^3	1.5 g/cm^3
$PEC_{plateau,min}$	0.38 mg/kg (570 g/ha)	0.21 mg/kg (950 g/ha)

In a second step, the short-term soil load (PEC_{ini}) of BAS 510 F was estimated for the upper soil layer before the next soil cultivation procedure using the following parameters:

	grapevine scenario	bean scenario
total annual application rate	600 g as/ha	1000 g as/ha
fraction of crop interception	85 %	80 %
mixing depth	5 cm	5 cm
considered density of the soil layer	1.5 g/cm^3	1.5 g/cm^3
PEC_{ini}	0.12 mg/kg (90 g/ha)	0.27 mg/kg (200 g/ha)

The overall (maximum) PEC values in soil after long-term application of BAS 510 F are estimated as:

	grapevine scenario	bean scenario
$PEC_{lt,overall}$ (= $PEC_{plateau,min} + PEC_{ini}$)	0.50 mg/kg	0.48 mg/kg

Conclusion:

As argued before in the assessment of the two accumulation field studies, the RMS has reservations against using the “minimum plateau accumulation factor” of 95 % from those studies in a standard PEC_{soil} calculation for two reasons. First, there is some degree of uncertainty in the vineyard study and even more in the vegetables study whether the level of 95 % actually represents the long-term plateau concentration in soil. Second, the PEC_{ini} from the standard PEC_{soil} calculation does not account for the amount of boscalid that is initially intercepted, but then ‘reloaded’ in the soil most probably via falling leaves. However, it has become clear from the descriptive modelling of the soil accumulation study that this entry path will contribute significantly to the actual concentrations of boscalid in soil. Consequently, the $PEC_{lt,overall}$ values above cannot be used for the risk assessment.

Annex Point:	IIIA-9.2.1/3, also relevant for IIIA-9.1.3
Author:	Jene, B.
Title:	Predicted environmental concentrations of BAS 510 F in groundwater (PEC_{gw}) and soil accumulation ($PEC_{soilaccu}$) under worst case degradation conditions for France
Date:	July 2003
Doc ID:	BASF DocID 2003/11009266; BOD 2005-909
Guidelines:	-/-
GLP:	No, not subject to GLP regulations
Valid:	n.a. (modelling exercise)

This study consists of two parts, calculating PEC_{soil} and $PEC_{groundwater}$ separately. Here, only the PEC_{soil} calculation is summarised. This new modelling study was performed, because it was concluded with RMS to use the maximum field DT_{50} of 212 d as worst case scenario. Simulations were carried out for the two scenarios Hamburg and Châteaudun with the modelling tool FOCUS-PEARL 1.1.1. For PEC_{soil} calculation the following parameters have been used:

	grapevine scenario	vegetable scenario (cabbage, beans)
scenarios	Châteaudun, Hamburg	Châteaudun, Hamburg
application rate	600 g as/ha	2 × 500 g as/ha
application date	28 days before harvest	7, 14 days before harvest
crop interception	50 %	70 %
amount reaching soil	0.3 kg/ha/a	2 × 0.15 kg/ha/a
DT_{50}	212 d	212 d
Moisture Dependency	switched off	switched off

The $PEC_{soil,Accu}$ plateau values for the grapevine and the vegetables scenario are as follows:

Grapevine	Châteaudun		Hamburg	
	Areic mass kg/ha	Concentration mg/kg	Areic mass kg/ha	Concentration mg/kg
Average min	0.29	0.39	0.39	0.52
Average max	0.59	**0.79**	0.68	**0.91**

TWA	0.45	0.60	0.55	0.73

Vegetables	Châteaudun		Hamburg	
	Areic mass kg/ha	Concentration mg/kg	Areic mass kg/ha	Concentration mg/kg
Average min	0.30	0.40	0.39	0.52
Average max	0.59	**0.78**	0.68	**0.90**
TWA	0.44	0.58	0.53	0.71

These concentrations are calculated on basis of a minimum worst case soil depth of 5 cm. If tillage is carried out, the residues in the soil will be mixed within the tillage layer. For a representative mixing depth of 20 or 30 cm, the calculated concentrations would be reduced a by factor of 4 or 6, respectively.

For the assessment of the $PEC_{groundwater}$ calculation, please see **Fehler! Verweisquelle konnte nicht gefunden werden.**.

Conclusion:

This modelling study is a modification of the study by Hauck (2001) (IIIA-9.1.3/3, already assessed in the monograph). Modified parameters include the maximum field DT_{50} value of 212 d (instead of the mean field DT_{50}), an interception of 50 % for grapevines and 70 % for beans (instead of 0 %) and deactivation of moisture correction in modelling. The latter was justified by the fact that the also the relevant DT_{50} had been calculated without considering moisture correction factors. These modifications are considered acceptable for a higher-tier modelling approach.
It was argued by the notifier that actual concentrations in the upper 5 cm soil layer would be reduced by tillage. This is true from a long-term perspective. However, tillage would not reduce the concentration peak in the upper soil layer directly after application of the plant protection product. It should also be considered that the FOCUS scenarios were defined to represent a worst case with respect to leaching. Downward movement of the modelled compound in the soil column will thus be more prominent than under worst-case conditions for accumulation in soil.

Annex Point:	IIIA-9.1.3
Author:	Calculation by RMS

The notifier had proposed to calculate $PEC_{lt,overall}$ values by adding a $PEC_{plateau,min}$ as derived by modelling from the two soil accumulation studies and a PEC_{ini} considering FOCUS interception values. As explained above, the RMS cannot accept those values for a risk assessment, since the reload of initially intercepted boscalid to soil (most probably due to falling leaves) is not considered. Instead, an alternative approach is proposed that directly makes use of the measured or modelled minimum and maximum concentrations from the soil accumulation studies.
For the vineyard study, the approach relies on the following assumptions: The background plateau concentration over the whole soil column of 30 cm can be represented either by the modelled minimum plateau concentration of 2000 g as/ha (95 % of the annual application rate in the study) or by the measured concentration levels in June 2002 and 2003 directly before the respective annual application (mean 2608 g as/ha, i.e. 124 % of the annual application rate in the study). The annual input is reflected in either the modelled maximum plateau

concentration of 3100 g as/ha (148 % of the annual application rate in the study) or by the measured concentration levels in October 2001, August, 2002 and October 2002 (mean 2900 g as/ha, i.e. 138 % of the annual application rate in the study). For the purpose of PEC_{soil} calculation, it is assumed that the difference between background and maximum of 53 % (ModelMaker evaluation) or 14 % (measured concentrations) is completely located in the upper 5 cm soil layer. The relevant PEC_{soil} for the risk assessment is the sum of the background concentration in mg/kg for 30 cm soil depth and the annual input in mg/kg for 5 cm soil depth (Table B.8.1-6).

Table B.8.3-1: PEC_{soil} in the upper 5 cm soil layer resulting from accumulated background concentration and annual application in vineyards

Vineyard 1 × 600 g as/ha		Areic concentration [g as/ha]	Mass-related concentration for 30 cm soil depth [mg/kg]	Mass-related concentration for 5 cm soil depth [mg/kg]
Modelled minima and maxima				
Background	95 %	570	0.127	
Maximum	148 %	888		
Annual input (maximum – background)		318		0.424
PEC_{soil} (0-5 cm)		**413**		**0.551**
Measured minima and maxima				
Background	124 %	744	0.165	
Maximum	138 %	828		
Annual input (maximum – background)		208		0.112
PEC_{soil} (0-5 cm)		**208**		**0.277**

For beans, no reliable maximum plateau concentration can be derived from the ModelMaker evaluation of the currently available data. Consequently, the maximum is derived from the highest measured concentration in the study (2545 g as/ha, equivalent to 150 % accumulation as related to the corresponding application rate of 1700 g as/ha). The background plateau concentration over the whole soil column of 30 cm can be represented either by the modelled minimum plateau concentration of 1200 g as/ha (95 % of the mean annual application rate over three years in the study) or by the mean of the measured concentration levels in the 10 - 20 cm soil layer in February 2002, November 2002 and March 2003 of 0.345 mg/kg (for the average treatment rate over three years of 1270 g as/ha). If that concentration is normalised to the intended treatment rate of 1000 g as/ha in beans, a value of 0.272 mg/kg is achieved. The principle of the PEC_{soil} calculation is the same as explained for the vineyard study. The results are given in Table B.8.1-7.

Table B.8.3-2: PEC_{soil} in the upper 5 cm soil layer resulting from accumulated background concentration and annual application in beans

Beans 2 × 500 g as/ha		Areic concentration [g as/ha]	Mass-related concentration for 30 cm soil depth [mg/kg]	Mass-related concentration for 5 cm soil depth [mg/kg]
Modelled minimum and measured maximum				
Background	95 %	950	0.165	
Maximum	150 %	1500		
Annual input (maximum – background)		550		0.733

PEC_{soil} (0-5 cm)		**708**		**0.944**
Measured minima and maxima				
Background		1224	0.272	
Maximum	150 %	1500		
Annual input (maximum – background)		276		0.368
PEC_{soil} (0-5 cm)		**480**		**0.640**

The chosen approach accounts for the fact that the minimum plateau concentration might have been underestimated by the model, particularly in the case of the vegetables study. The annual input is calculated from the difference between the minimum plateau concentration and maximum measured or modelled concentration in the respective studies. Provided the measured maximum concentrations will not exceed the maximum plateau (which is considered confirmed for the vineyard study and preliminary assumed for the vegetables study), any underestimation of the minimum plateau concentration would result in an overestimation of the annual input and thus also an overestimation of the resulting PEC_{soil} for the upper 5 cm layer.

Conclusion:

Concentrations of boscalid in soil reflecting accumulation as well as the annual application on top of that background concentration were calculated by means of $FOCUS_{gw}$ modelling and by using measured and modelled minimum and maximum plateau concentrations from two soil accumulation studies. For an annual application of 600 g as/ha to vines, the calculated concentrations for the upper 5 cm soil layer range from 0.277 to 0.910 mg/kg (208 to 683 g as/ha). For an application of 2 × 500 g as in beans as a part of a three year crop rotation including cereals, the respective concentrations are 0.640 to 0.944 mg/kg (480 to 708 g as/ha).

B.8.6 Predicted environmental concentrations in surface water and in ground water (PEC_{SW}, PEC_{GW}) (Annex IIIA 9.2.1, 9.2.3)

B.8.6.2 PEC in surface water

Annex Point: IIIA-9.2.3
Author: Calculation by RMS

The concentrations in surface water resulting from spray drift after application of 1 × 600 g as/ha in vines and 2 × 500 g as/ha in beans were recalculated by the RMS considering the 90th percentile and 82nd percentile drift values according to Ganzelmeier, respectively. The recalculated PEC_{act} and PEC_{twa} values from 1 to 100 days after the final application consider the DT50 of 9 d in water from the non-irradiated laboratory water/sediment study.

Table B.8.6-1: PEC_{sw} calculation for application of 1 × 600 g as/ha boscalid to vines, spray drift exposure (90th percentile; scenario grapevine, late)

Time/integration period [d]	3 m buffer		5 m buffer		10 m buffer	
	PEC_{act} [µg/L]	PEC_{twa} [µg/L]	PEC_{act} [µg/L]	PEC_{twa} [µg/L]	PEC_{act} [µg/L]	PEC_{twa} [µg/L]
0	16.04	16.04	7.24	7.24	2.46	2.46
1	14.85	15.44	6.70	6.97	2.28	2.37
2	13.75	14.87	6.21	6.71	2.11	2.28
3	12.73	14.32	5.75	6.46	1.95	2.20
4	11.79	13.81	5.32	6.23	1.81	2.12
7	9.36	12.40	4.22	5.60	1.43	1.90
14	5.46	9.82	2.46	4.43	0.84	1.51
21	3.18	7.95	1.44	3.59	0.49	1.22
28	1.86	6.58	0.84	2.97	0.28	1.01
42	0.63	4.76	0.29	2.15	0.10	0.73
100	0.01	2.08	0.00	0.94	0.00	0.32

Table B.8.6-2: PEC_{sw} calculation for application of 2 × 500 g as/ha boscalid to beans, spray drift exposure (82nd percentile, scenario arable crops)

Time/integration period [d]	1 m buffer	
	PEC_{act} [µg/L]	PEC_{twa} [µg/L]
0	6.28	6.28
1	5.81	6.05
2	5.38	5.82
3	4.98	5.61
4	4.61	5.41
7	3.66	4.86
14	2.14	3.84
21	1.25	3.11
28	0.73	2.58
42	0.25	1.87
100	0.00	0.82

Since the risk assessment is based on the long-term effects on the rainbow trout, *Oncorhynchus mykiss* in a 93-day flow-through test where effects became obvious after day 40, the $PEC_{twa,42\,d}$ is the relevant endpoint from this section. For vines, the respective values range from 4.76 µg/L (3 m buffer) to 0.73 µg/L (10 m buffer). For beans, the $PEC_{twa,42\,d}$ with the averaging period starting directly after the second application is 1.87 µg/L (1 m buffer). However, due to the short half-life of 9 d of boscalid in water, the time-weighted average starting directly after the first application and thus covering both individual application peaks is more relevant. Considering the minimum buffer zone of 1 m, this value amounts to 2.32 µg/L.

B.8.6.3 PEC in sediment

Annex Point:	IIIA-9.2.4/4
Author:	Platz, K.
Title:	Kinetic evaluation of the accumulation behaviour in sediment after long-term application of BAS 510 F (Boscalid) under consideration of different water sediment studies

Date:	21.10.2004
Doc ID:	BASF DocID 2004/1022502; WAS 2005-367
Guidelines:	-/-
GLP:	No, not subject to GLP regulations
Valid:	n.a. (modelling exercise)

The kinetic evaluation was performed in order to estimate the accumulation behaviour in sediment after long-term application of BAS 510 F (boscalid). The accumulation behaviour was estimated on the basis of a standard laboratory study conducted in the dark and on the basis of an outdoor water sediment study performed under natural sunlight.

The standard water sediment study was conducted in the laboratory at 20 °C in the dark. The study includes two aquatic test systems from different origins, one representing a pond (Kellmetschweiher) and the other a river (Berghauser Altrhein). In both test systems, no significant amounts of metabolites were found in the water phases or in the sediments. Only bound residues could be detected in sediment. The highest amounts in sediment of BAS 510 F were observed in test system B (Berghauser Altrhein). To consider worst-case conditions system B was therefore used for the modelling approach of the standard laboratory water sediment study.

The higher-tier outdoor water sediment study was initiated to investigate the degradation and transformation of BAS 510 F in a water/sediment system under more realistic outdoor conditions. Since in natural water/sediment systems (rivers, lakes), photolysis and sediment sorption may influence the degradation of BAS 510 F simultaneously, this supplementary outdoor study was carried out, where both factors were combined. The outdoor study uses a pond (Kellmetschweiher) water/sediment system. In this outdoor water sediment study an additional metabolite M510E64 was observed in the water phase.

In the present evaluation, two different compartment models were chosen for the standard laboratory and the outdoor water sediment study to achieve a successful fit of the observed residues.

As a principle of these approaches, compartments are defined which represent the compounds and different matrices. Experimental data are allocated to the individual compartments and transitions between these compartments are then postulated and described mathematically based upon scientific considerations. The mathematical model consists of a system of differential equations and involves several free parameters that shall be adjusted to the specific degradation data by non-linear parameter estimation procedures. The initial concentrations of BAS 510 F in the water compartment were estimated as well.

The quality of the estimations was checked with statistical items like the standard deviation and the type I-error rates of the estimated parameters. The modelled curves to the observed residues in water and sediment were evaluated visually and the determination coefficients were given.

The development of the amounts of BAS 510 F in sediment was extrapolated under consideration of one seasonal treatment (application period 365 days) with identical application rates. The extrapolated amounts of active substance in sediment are expressed in percent of the seasonal applied application rate.

Laboratory study

As no metabolite could be observed in the standard laboratory study conducted in the dark, the loss of BAS 510 F in the water phase was attributed to the sorption processes onto the sediment. That means the dissipation flow rate of BAS 510 F in the water phase (F12) corresponds to the formation rate to sediment. As the sorption and desorption processes of

BAS 510 F in the water sediment system couldn't be satisfactorily described by single first-order kinetic flow-rates, a bi-phasic kinetic model according to Gustafson Holden was used to describe the dissipation behaviour in the water phase of BAS 510 F. The formation of the bound residues was attributed to the degradation flow of BAS 510 F in sediment (F23). The degradation of BAS 510 F in sediment could be explained by single first-order kinetics. A graphical description of the 3-compartment model is shown in Figure B.8.6-1.

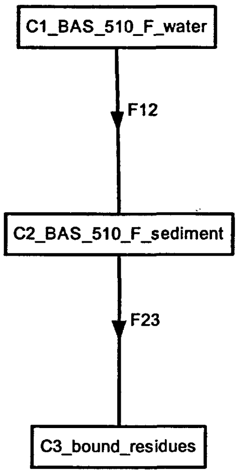


Figure 8.6-1: **3-compartment model for the fate and behaviour of boscalid in a non-irradiated laboratory water/sediment study**

The observed residues of BAS 510 F in water and sediment were fitted as described above. Low standard deviations, low type-I error rates and a high coefficient of determination confirmed the correctness of estimation model and estimated parameters. It is concluded that an extrapolation of the amount of BAS 510 F in sediment after long-term application is thus based on reliable assumptions. The comparison of the fitted curves to the observed residues in water and sediment are given in Figure B.8.6.-2. The visual check shows an excellent fit of the observed residues in water and sediment.

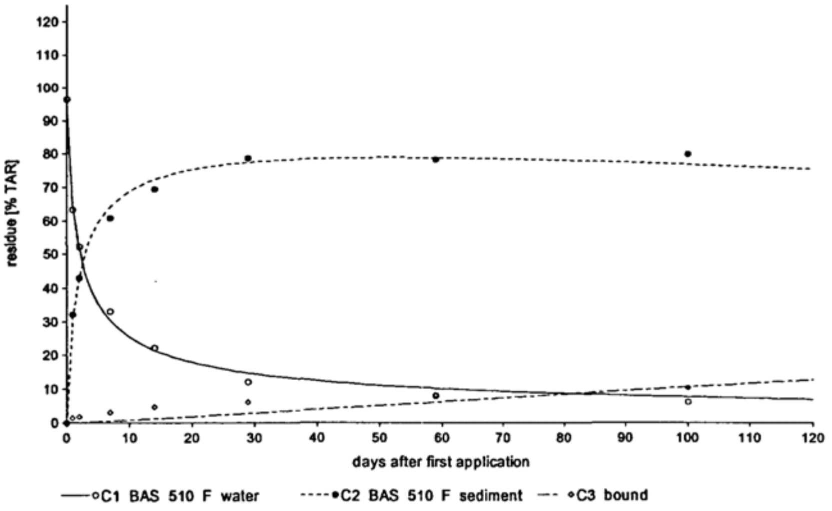


Figure 8.6-2: **Fitted curves to the observed residues in water and sediment of the non-irradiated laboratory water/sediment study**

The maximum amount of BAS 510 F in sediment after long-term application estimated on the basis of the standard laboratory study is reached at about 8 years after first application. The estimated maximum plateau amount of BAS 510 F in sediment at steady state is 217 % of the seasonal applied application rate. The extrapolated residues of BAS 510 F after long-term application in sediment under consideration of the standard laboratory study and the resulting maximum plateau amount of BAS 510 F at steady state are illustrated in Figure B.8.6-3.

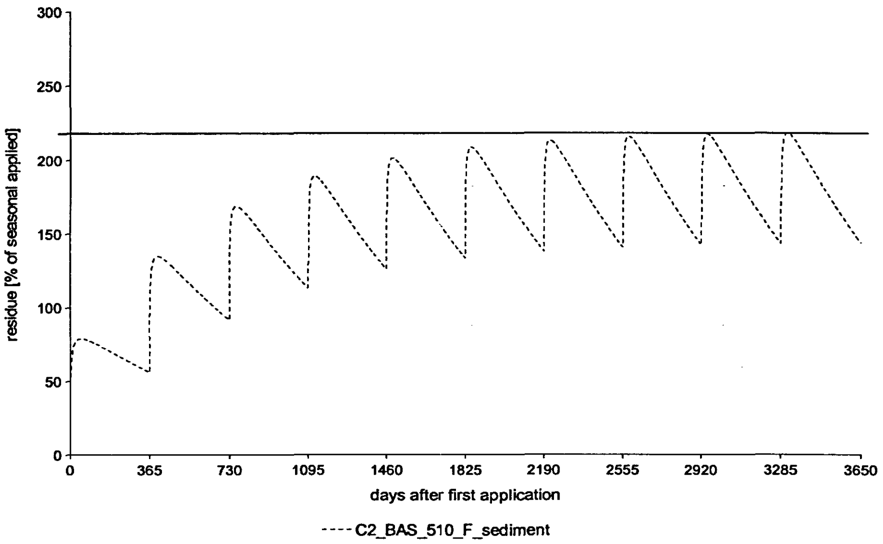
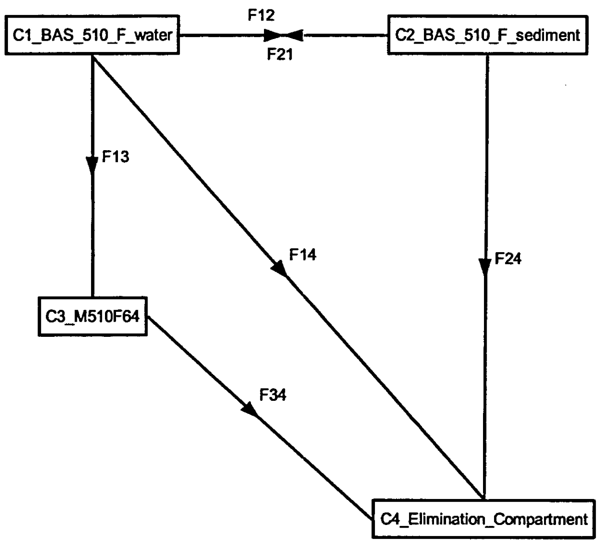


Figure 8.6-3: **Modelled concentration curve for boscalid in the sediment of a non-irradiated laboratory water/sediment study**

Outdoor study

The observed residues in the water and in the sediment phase are fitted with help of a compartment model that considers the dissipation of BAS 510 F in water as well as the sorption and desorption processes of BAS 510 F in the sediment phase and formation and degradation of M510F64 in the water phase. The observed residues in water and sediment could be well described by single first-order kinetics. The compartment model as implemented in ModelMaker is given in Figure B.8.6-4.

Figure 8.6-4: **multi-compartment model for the fate and behaviour of boscalid in an outdoor water/sediment study**



The observed residues of BAS 510 F in water and sediment were fitted as described above. During optimisation, the degradation rate constant k24 (degradation in sediment) became $< 10^{-10}$ 1/d and was set to 0. A high type-I error rate of k14 (degradation in water) was considered negligible for the overall result, because the value of k14 is relatively small as compared to the other rate constants. The coefficient of determination gives evidence of a successful fit. It is concluded that the extrapolation of the amount of BAS 510 F in sediment under consideration of similar seasonal treatments is thus based on reliable assumptions. The comparison of the fitted curves to the observed residues in water and sediment are given in Figure B.8.6-5. The visual check shows an excellent fit of the observed residues in water and sediment.

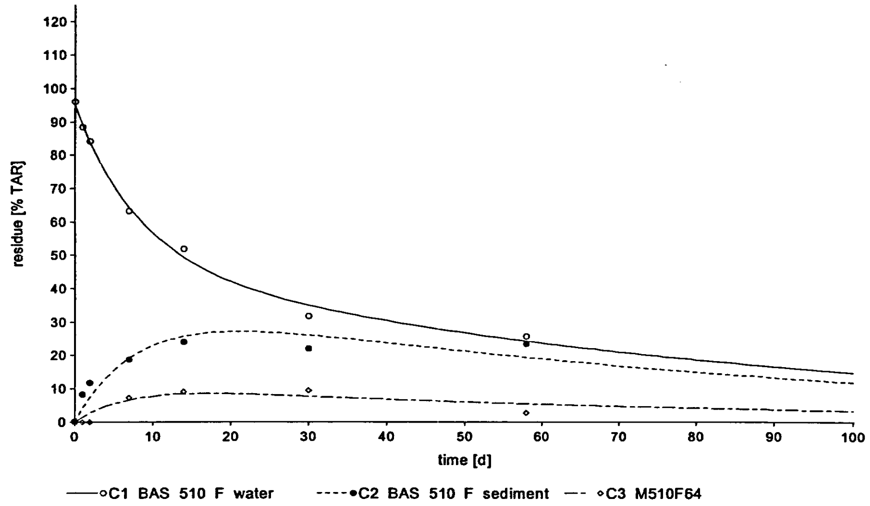


Figure 8.6-5: **Fitted curves to the observed residues in water and sediment of the outdoor water/sediment study**

The modelled concentration curve of BAS 510 F after long-term application estimated on the basis of the higher tier outdoor water sediment study shows that there is no accumulation risk of the parent compound in sediment. The maximum amount in sediment after long-term application of BAS 510 F was estimated with 27.2 % of the seasonal application rate. The extrapolated residues of BAS 510 F after long-term application in sediment under consideration of the standard laboratory study and the resulting maximum plateau amount of BAS 510 F at steady state are illustrated in Figure B.8.6-6

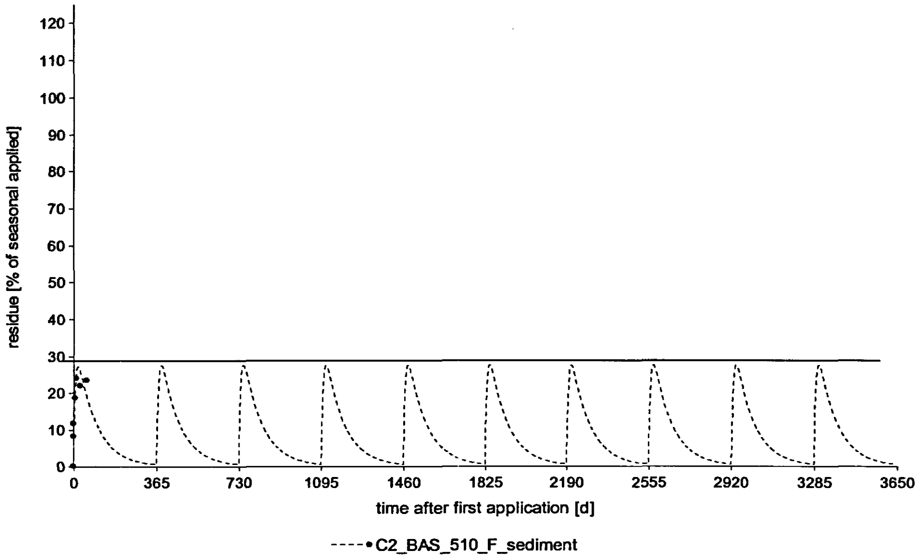


Figure 8.6-6: **Modelled concentration curve for boscalid in the sediment of a non-irradiated laboratory water/sediment study**

Conclusion:

Residue dynamics and distribution of boscalid in a water/sediment system could be modelled with sufficient accuracy for a non-irradiated standard laboratory study as well as for an outdoor study. The results are considered a reliable basis for assessing the potential of boscalid to accumulate in sediment and of the corresponding accumulation plateaus. These are 217 % for the laboratory study and 27.2 % for the outdoor study. No agreed guidance exists as yet for the inclusion of results from outdoor water/sediment studies in a risk assessment; therefore the value obtained for the laboratory study is used.

Annex Point:	IIIA-9.2.4/5
Author:	Platz, K.
Title:	Predicted environmental concentrations in sediment after long-term application of BAS 510 F (Boscalid)
Date:	21.05.2005
Doc ID:	BASF DocID 2005/1014173; WAS 2005-368
Guidelines:	-/-
GLP:	No, not subject to GLP regulations
Valid:	n.a. (modelling exercise)

This study predicts the environmental concentration in sediment after long term application of boscalid. The calculation study uses the maximum accumulation value of 217 % in sediment as calculated by Platz (2004), see above.

As drift entry is the main entry route into surface water it was taken into account for the PEC_{sed} calculation. The PEC in sediment was calculated for a 1 cm and a 5 cm sediment layer depth. In available guidance, a sediment layer depth of 1 cm is recommended as conservative approach for a PEC_{sed} calculation. Since a sediment layer depth of 5 cm seemed to be more realistic for a long-term assessment, this was additionally considered. The considered density of the sediment layer was 1.3 kg/L.

The drift values used for the grapevine scenario at buffer zones of 3 m (standard FOCUS buffer zone), 5 m and 10 m (overall 90th percentile valid for single application) were 8.02 %, 3.62 % and 1.23 % of the application rate, respectively. Application of BAS 510 F at a late growth stage of grapevine was taken into account (worst-case). The drift values used for the beans scenario at buffer zones of 1 m (standard FOCUS buffer zone), 5 m and 10 m (82nd percentile valid for double applications, equivalent to overall 90th percentile) were 2.38 %, 0.47 % and 0.24 % of the application rate, respectively.

The maximum predicted environmental concentrations in sediment at steady state of BAS 510 F after long-term application was calculated as described in the following equation. The results are listed in Table B.8.6-3.

$$PEC_{sed,accu,\max} = \frac{A \cdot f_{drift} \cdot f_{plateau}}{depth * bd}$$

where

$PEC_{sed,accu,max}$	=	maximum PEC in sediment of BAS 510 F (boscalid) after long-term application	[mg/kg]
A	=	total annual application rate	[mg/m^2]
f_{drift}	=	drift fraction	[-]
$f_{plateau}$	=	estimated maximum plateau amount at steady state (217 % of yearly application rate)	[-]
depth		depth of the considered sediment layer (0.01 m and 0.05 m)	[m]
bd		density of the considered sediment layer (1.3 g/cm^3 = 1300 kg/m^3)	[kg/m^3]

Table B.8.6-3: Predicted environmental maximum plateau concentrations in sediment at steady state ($PEC_{sed,accu,max}$) after long-term application of boscalid

	sediment layer depth: 1 cm		sediment layer depth: 5 cm	
	grapevines (1 × 600 g as/ha) [mg/kg]	beans (2 × 500 g as/ha) [mg/kg]	grapevines (1 × 600 g as/ha) [mg/kg]	beans (2 × 500 g as/ha) [mg/kg]
0 m	-	-	-	-
1 m	-	0.397	-	0.079
3 m	0.803	-	0.161	-
5 m	0.363	0.078	0.073	0.016
10 m	0.123	0.040	0.025	0.008

B.8.6.4 PEC in groundwater

Annex Point:	IIIA-9.2.1/3
Author:	Jene, B.
Title:	Predicted environmental concentrations of BAS 510 F in groundwater (PECgw) and soil accumulation (PECsoilaccu) under worst case degradation conditions for France
Date:	July 2003

Doc ID:	BASF DocID 2003/1009266; WAS 2005-366
Guidelines:	-/-
GLP:	No, not subject to GLP regulations
Valid:	n.a. (modelling exercise)

The following predictions are an extension of the PEC_{gw} calculations as described in the monograph. These additional PEC_{gw} calculations were made upon the request to use the worst-case field half-life as a high end benchmark reflecting an extreme leaching scenario.

The degradation behaviour of BAS 510 F had been investigated in five field soils as shown in Table B.8.6-4. Standardisation of the field values was performed for temperature but not for soil moisture. Standardisation was only possible for three out of the five studies, but not for the Spanish sites Huelva and Sevilla due to scattering of the data and high uncertainty of the estimated degradation rate. Nevertheless, the 'best fit' DT_{50} values indicate that the half-lives in the Huelva and Sevilla trials are in the lower range of the observed field half-lives. The longest field half-life of the Schifferstadt study is larger by a factor of 2 than the second longest half-life (Stetten). This DT_{50} of 212 d was used to assess leaching in the two sensitive scenarios Piacenza and Châteaudun as to model a worst-case situation.

Table B.8.6-4: DT_{50} of BAS 510 F in the field and half-lives standardised to reference temperature of 20°C

Code	Location	DT_{50} (best fit) [d]	DT_{50} (1st order, standardised to 20 °C) [d]
DU2/15/97	Stetten DE	55.7	106
DU3/06/97	Schifferstadt DE	176.7	212
D05/03/98	Grossharrie DE	144	98
ALO/05/98	Huelva ES	78	n.c.*
ALO/06/98	Sevilla ES	27	n.c.*
Arithmetic mean		96.3	139

* not calculated due to experimental conditions – a reasonable half life cannot be derived, because of the high standard deviation of the degradation rate

Calculations were carried out for the scenario Piacenza using the model FOCUS-PEARL 1.1.1 as well as for the macropore scenario Châteaudun using the model FOCUS-MACRO 3.3.1. The parameterisation of the scenarios Piacenza and Châteaudun was taken according to the implementation in the models and shown in the FOCUS groundwater report. For the Piacenza scenario, only natural precipitation was simulated and no additional irrigation for vine was considered, because irrigation is mostly not allowed in viticulture in France (the study was initially prepared for the purpose of a national authorisation in France) and the inclusion of irrigation would result in unrealistically high groundwater recharge.

Except the half-life in soil, the parameters used for the calculations are identical with the earlier calculations described in the monograph (B.8.6.1, Table B.8.6-3). The worst-case half-life of 212 days was taken from the Schifferstadt field study. To be consistent with the evaluation method of the study that considered temperature but not moisture dependency of the degradation rate, the moisture dependency in the model was switched off (moisture exponent = 0).

Application scenario

The simulations are carried out for grapevine. The application rate is 1 × 600 g as/ha and crop interception was set to 50 % (relevant for grapevine during flowering, will increase during later growth stages). In order to consider a worst-case application date, 1st October as the latest possible application time in the year was simulated.

Piacenza scenario with FOCUS-PEARL 1.1.1

Despite the very high groundwater recharge rates between 150 and 935 mm/year (mean = 470 mm/year), the 80th percentile as well as the maximum annual leachate concentration is clearly below the groundwater threshold of 0.1 µg/L. The average concentration of boscalid closest to the 80th percentile is 0.031 µg/L This value occurs in period from 01-Jan-1918 to 31-Dec-1918.

Chateaudun scenario with FOCUS-MACRO 3.3.1

Despite the consideration of macroporosity, the 80th percentile of 0.0012 µg/L as well as the maximum annual leachate concentration of 0.0015 µg/L is clearly below the groundwater threshold of 0.1 µg/L.

Conclusion:

Using the worst-case field half-life of 212 days, the simulations with FOCUS-PEARL 1.1.1 for the most vulnerable Piacenza scenario as well as calculations with FOCUS-MACRO 3.3.1 for the Châteaudun scenario with macropores show that the groundwater threshold of 0.1 µg/L is not exceeded.

As compared to the earlier study reported in the monograph, the calculated 80th percentile concentrations are lower in the Piacenza (0.031 µg/L in new vs. 0.042 µg/L in old study) as well as in the Châteaudun scenario (0.0012 µg/L in new vs. 0.005 µg/L in old study). This is most likely due to the impact of 50 % crop interception in the new study, whereas the earlier study considered no crop interception and thus had reflected an absolute worst case in that respect. Switching off moisture correction in FOCUS modelling when using the Schifferstadt degradation data was justified by the notifier with uncommonly dry conditions in that trial. According to Table B.8.1-18 in the monograph, the accumulated rainfall for Schifferstadt amounted to 194 mm 0-90 d after treatment and to 712 mm 0-545 d after treatment. This indicates that the annual rainfall most probably was below 600 mm. Thus, underestimation of degradation in the FOCUS$_{gw}$ scenarios Piacenza (750 mm annual rainfall) and Châteaudun (600 mm annual rainfall) is not to be expected.

The new results are in accordance with the results from the previous calculations as reported in the monograph. The potential of boscalid to reach groundwater under vulnerable conditions is low. The risk of unacceptable groundwater concentrations after use in vines according to good agricultural practice is negligible.

B.8.10 References relied on

Annex point/ reference number	**Author(s)**	**Year**	**Title** **source (where different from company)** **report no.** **GLP or GEP status (where relevant), published or not** **BVL registration number**	**Data protection claimed** **Y/N**	**Owner**
IIA-7.1.1.2.2/1	Kellner, O. et al.	2004	Accumulation behaviour of BAS 510 F under field conditions over a 5-year-period (1998 – 2003) after application onto grapes in a vineyard BOD 2005-906	Y	BASF
IIA-7.1.1.2.2/2	Grote, C. Platz, K.	2005	Accumulation behaviour of BAS 510 F under field conditions over a 7-year-period (1998 – 2004) after application onto vegetables BOD 2005-907	Y	BASF
IIIA-9.1.3/6	Jene. B.	2003	Predicted environmental concentrations of BAS 510 F in groundwater (PECgw) and soil accumulation (PECsoilaccu) under worst case degradation conditions for France BOD 2005-909	Y	BASF
IIIA-9.2.1/3	Jene, B.	2003	Predicted environmental concentrations of BAS 510 F in groundwater (PECgw) and soil accumulation (PECsoilaccu) under worst case degradation conditions for France WAS 2005-366	Y	BASF
IIIA-9.2.4/4	Platz, K.	2004	Kinetic evaluation of the accumulation behaviour in sediment after long-term application of BAS 510 F (Boscalid) under consideration of different water sediment studies WAS 2005-367	Y	BASF
IIIA-9.2.4/5	Platz, K.	2005	Predicted environmental concentrations in sediment after long-term application of BAS 510 F (Boscalid) WAS 2005-368	Y	BASF

B.9 Ecotoxicology

B.9.1 Effects on birds (Annex IIA 8.1; Annex IIIA 10.1)

B.9.1.3 Summary of effects on birds

Data are listed in Table B.9.1-1 in the context of the additionally submitted risk assessment according to SANCO/4145/2000. The respective studies have already been assessed in the monograph.

Table B.9.1-1: Summary of effects of BAS 510 F on birds

Test species	Test system	Results
Colinus virginianus	Acute oral toxicity	LD_{50} > 2000 mg as/kg bw NOED = 2000 mg as/kg bw
Colinus virginianus	short-term dietary toxicity	LC_{50} > 5000 mg as/kg diet NOAEC = 5000 mg as/kg diet LDD_{50} > 1094.3 mg as/kg bw/d *)
Anas platyrhynchos	short-term dietary toxicity	LC_{50} > 5000 mg as/kg diet NOAEC = 625 mg as/kg diet LDD_{50} > 1413.2 mg as/kg bw/d *)
Colinus virginianus	sub-chronic toxicity and reproduction	NOAEL = 300 mg a.s./kg diet NOAEDD = 24.1 mg as/kg bw/d *)
Anas platyrhynchos	sub-chronic toxicity and reproduction	NOAEL = 1000 mg a.s./kg diet NOAEL = 128.6 mg as/kg bw/d *)

*) Daily Dose (mg/kg bw/d) calculated based on mean food consumption and body weight data.

B.9.1.6 Risk assessment

B.9.1.6.1 Risk assessment for the active substance

Annex Point:	IIIA-10.1
Author:	Welter, K.
Title:	Formulation Cantus (BAS 510 01 F) – use in oilseed rape, bush beans and vines in Germany. Assessment of the potential risk to birds (M-III, 10.1)
Date:	November 2005
Doc ID:	BASF DocID 2005/1029947; -/-
Guidelines:	-/-
GLP:	n.a.
Valid:	n.a.

An extensive risk assessment for birds according to SANCO/4145/2000 was submitted by the notifier in the context of a national application for registration of a plant protection product. For the EU assessment, such assessment had not been required in the Peer Review. In formal terms, with respect to a decision on Annex I inclusion of boscalid, the risk assessment for birds as described in the monograph is still considered valid. Nevertheless, the RMS has decided to include the additionally submitted risk assessment in this addendum to make the underlying data and assumptions available to all Member States and to provide an aid for national evaluations of plant protection products containing boscalid after an inclusion of the compound in Annex I of Directive 91/414/EEC.

Exposure assessment for the active substances

According to SANCO/4145/2000, the estimated daily uptake of a compound is given by the following equation:

$$ETE = (FIR / bw) \times C \times AV \times PT \times PD \text{ (mg/kg bw/d)}$$

where
ETE = Estimated daily uptake of compound (= estimated theoretical exposure)
FIR = Food intake rate of indicator species (gram fresh weight per day)
bw = Body weight (g)
AV = Avoidance factor (1 = no avoidance, 0 = complete avoidance)
PT = Fraction of diet obtained in treated area (number between 0 and 1)
PD = Fraction of food type in diet (number between 0 and 1; one type or more types)

In case of multiple applications and/or long-term considerations, the concentration C may be expressed as
$C = C_0 \times MAF \times f_{twa} \times DF$

where
C_0 = Initial concentration after a single application calculated from RUD (= Residue Unit Dose) multiplied by the application rate (kg a.s./ha)
MAF = Multiple application factor (concentration immediately after the last application compared to a single application)
f_{twa} = Time-weighted-average factor (average concentration during a certain time interval compared to the initial concentration after single resp. last application)
DF = Deposition factor (1 - Interception)

Both equations can be combined and converted to the following form, which will be used in this assessment.

$$ETE = (FIR / bw) \times RUD \times AV \times PT \times PD \times MAF \times f_{twa} \times DF \times \text{Appl. Rate (mg/kg bw/d)}$$

Tier 1 risk assessment (calculation of TER values)

An assessment is conducted for the application of 1 × 600 g as/ha in vines (Table B.9.1-3) and 2 × 500 g as/ha in beans (Table B.9.1-4). The assessment of the application in winter rape (named in the title of the study) is not documented, since it is not relevant for the EU assessment.

Table B.9.1-2: Exposure assessment for BAS 510 F in vines (Tier 1)

Crop stage	Indicator species	FIR (fresh) / body weight	Food type	RUD [mg as/kg]	PT	PD	DF	f_{twa}	MAF	Use Rate [kg as/ha]	ETE [mg as/kg]
Acute											
Early / late	Insectiv. bird	1.04	Small insects	52	1	1	1	-/-	n.a.	0.6	32.45
Short-term											
Early / late	Insectiv. bird	1.04	Small insects	29	1	1	1	-/-	n.a.	0.6	18.10
Long-term											
Early / late	Insectiv. bird	1.04	Small insects	29	1	1	1	n.a.	n.a.	0.6	18.10

Table B.9.1-3: Exposure assessment for BAS 510 F in beans (Tier 1)

Crop stage	Indicator species	FIR (fresh) / body weight	Food type	RUD [mg as/kg]	PT	PD	DF	f_{twa}	MAF	Use Rate [kg as/ha]	ETE [mg as/kg]
Acute											
Early / late	Medium herbiv bird	0.76	Leafy crops	87	1	1	1	-/-	1.4	0.5	46.28
Early / late	Insectiv. bird	1.04	Small insects	52	1	1	1	-/-	n.a.	0.5	27.04
Short-term											
Early / late	Medium herbiv bird	0.76	Leafy crops	40	1	1	1	-/-	1.6	0.5	24.32
Early / late	Insectiv. bird	1.04	Small insects	29	1	1	1	-/-	n.a.	0.5	15.08
Long-term											
Early / late	Medium herbiv bird	0.76	Leafy crops	40	1	1	1	0.53	1.6	0.5	12.89
Early / late	Insectiv. bird	1.04	Small insects	29	1	1	1	n.a.	n.a.	0.5	15.08

The resulting TER values (shown in Table B.9.1-5 and Table B.9.1-6) show an acceptable risk on the acute and short-term time-scale for both applications and all indicator species. For the long-term time scale, the TER values are below the Annex VI acceptability criterion of 5. A refined risk assessment is required.

Table B.9.1-4: Toxicity/exposure ratios for BAS 510 F in vines (Tier 1)

Crop stage	Indicator species	Food type	TER
Acute			
Early / late	Insectiv. bird	Small insects	TER_a > 2000 / 32.45 > 61.63
Short-term			
Early / late	Insectiv. bird	Small insects	TER_{st} = 1094.3 / 18.10 = 60.46
Long-term			

Early / late	Insectiv. bird	Small insects	TER_{lt} = 24.07 / 18.10 = 1.33

Table B.9.1-5: Toxicity/exposure ratios for BAS 510 F in beans (Tier 1)

Crop stage	Indicator species	Food type	TER
Acute			
Early / late	Medium herbiv. bird	Leafy crops	TER_a > 2000 / 46.28 > 43.22
Early / late	Insectiv. bird	Small insects	TER_a > 2000 / 27.04 > 73.96
Short-term			
Early / late	Medium herbiv. bird	Leafy crops	TER_{st} = 1094.3 / 24.32 = 45.00
Early / late	Insectiv. bird	Small insects	TER_{st} = 1094.3 / 15.08 = 72.57
Long-term			
Early / late	Medium herbiv. bird	Leafy crops	TER_{lt} = 24.07 / 12.89 = 1.86
Early / late	Insectiv. bird	Small insects	TER_{lt} = 24.07 / 15.08 = 1.60

B.9.1.6.2 Refined risk assessment

Application in vines – insectivorous bird scenario

Focal species: A survey on the birds inhabiting vineyards has been conducted at four study sites in south-western Germany from April to August 2003 by territory mapping (Pedall, I. et al. 2003). The study sites differed in structure from richly structured small-scale vineyards to large scale monotonous vineyards. Among the insectivorous guild, the yellowhammer and the blackbird were those species identified as characteristic, i.e. they were encountered regularly feeding in the vineyards by Pedall, I. et al. (2003). The representative status of the yellowhammer for Central European vineyards was corroborated by a comprehensive study in southern Germany on birds of vineyards (Seitz, B.J. 1989). The yellowhammer was considered to be the most common bird species in vineyards in southern Germany (Braun, M. 1985; Seiler,W. 1986). Therefore, the yellowhammer (*Emberiza citrinella*) is chosen as focal species for the insectivorous scenario in grapevine. The FIR/bw ratios for arthropod and seed food were calculated according to Crocker, D.R. et al. (2002) to be 0.77 and 0.26, respectively.

PT (Proportion of diet obtained from the treated area): Due to their mobility, birds are capable of extending their foraging habitat beyond the borders of a single treated field. It was shown for the skylark (Green, R.E. 1978), the starling (Tinbergen, J.M. 1976) and the redshank (Goss-Custard, J.D. 1970) that foraging birds make use of suboptimal areas to a considerable extent as well. This might be due to the reason that such behaviour would allow the birds to gain information on new potential food sources. This might be especially important on farmland where, as a result of mechanised agriculture, abundant food sources can appear or disappear within few hours (Green, R.E. 1978). This underlines that exclusive foraging on one single treated field is highly unlikely.

This is corroborated by data from CSL Report PN0915 (Crocker, D.R. et al., 2001). In this radio-telemetry study, the habitat use of different bird species (blackbird, linnet, skylark, yellowhammer) was evaluated in summer and winter on mixed arable land. The mean active tracking time, which is the relevant number for refining a long-term exposure assessment, was found to be highest in off-crop habitat elements (set-asides/hedges). For single arable habitat elements (oil seed rape, beets, potatoes, cereals), the vast majority of mean active tracking times were clearly below 30 %. The only exception is the active time for blackbirds in oil seed rape, which was found to be 60 % in summer.

To conclude, literature and recent telemetry data indicate that the mean active time spent in arable crops would be clearly below the default value of 1.0. Hence, for scenarios which cannot be justified by specific PT data, it is still considered conservative to apply a factor PT = 0.5 for refinement.

PD (Proportion of diet): The yellowhammer is known to feed on seeds, especially of grasses, while invertebrates are preyed in the breeding season and casually throughout remainder of the year (Perrins, C.M. 1998).

A field study on the diet of the yellowhammer was conducted in an intensively managed and richly structured agricultural area in Schleswig-Holstein, Germany between 6th June and 8th August 1987-90 (Lille, R. 1996). The prey items of adult yellowhammers (12 pairs) were studied (1416 foraging flights of the adults) by means of photographical documentation (1691 photos) and direct observations. The prey items consisted of almost 84 % animal and 16 % vegetable items. Main components of the diet were 47 % dipteran larvae (particularly Syrphid larvae), 16 % cereal grains (especially oats), 12 % lepidopteran larvae. Further items were arachnids (8 %), coleopterans (6 %), dipteran imagines (4 %), lepidopteran adults (2 %). Approximately 4 % of the items could not be determined (Lille, 1996).

This study also revealed data on the size of the prey items of yellowhammers. According to the results, the prey size and prey weight ranged from 3 mm/5 mg in case of harvestmen (*Opiliones*) to 30 mm/380 mg for craneflies (*Tipulidae*).

The majority of the nestling diet of yellowhammers (42 % of 4764 prey items) consists of small prey items with an average weight between 5 and 20 mg. This prey size class was dominated by small syrphid larvae (8 mm/20 mg) (Lille, R. 1996). The next prey size class included objects of 20-40 mg fresh weight (such as cereal grains) and of 40-60 mg fresh weight. 82 % of the analysed food items had a fresh weight between 5 mg and 60 mg. 58 % of the prey weight was above 20 mg. The fresh weight per load delivered to the nestlings was found to range between 5 mg and 1150 mg, but 95 % of the loads had a weight below 580 mg (average weight 194 mg ± 187 mg, n = 1416) (Lille, R. 1996).

In the guidance document SANCO/4145/2000, the residue estimate for ‘small’ insects is derived from Kenaga, E.E. (1973) on the basis of residues in weed seeds, which would typically measure 1-2 mm. The residue estimate for ‘large’ insects comes from Kenaga, E.E. (1973) as well. This value was based on residues on wheat seeds, which are typically 4-5 mm in length. Hence, it is proposed to include a working definition of ‘large’ insects being ≥ 5 mm and ‘small’ insects being < 5 mm. From the results of the comprehensive study by Lille, R. (1996) on diet of yellowhammers, it is obvious that the bulk of the food items of yellowhammer nestlings (which represent the worst case scenario for such risk assessments) is equivalent to or exceeds the size of cereal grains (5 mm). Thus, as a realistic approach in a tier 2 assessment, the use of default residues of large insects (size of cereal grain or larger) would be justified for the bulk of arthropod prey species.

As a conclusion and synopsis of the results obtained by Lille, R. (1996) and presented above, a realistic diet composition of the yellowhammer is estimated to comprise 15 % weed seeds (cereal grains are not expected to be available in vineyards), 75 % large insects and 10 % small insects. In fact, the amount of typical small insects such as aphids and collembolans reported to be eaten was rather small (Bösenberg, K. 1958 refers to “few individuals of aphids”; Moreby, S.J. and Stoate, C. , 2000) give a figure of 1.2 % percentage in diet for aphids and collembolan, respectively; Lille, R. 1996 does not mention this size-class at all). Thus, the suggested composition of diet is considered to be a realistic but still conservative estimate of the diet of yellowhammers foraging in vineyards.

DF (Deposition factor): The yellowhammer almost exclusively forages on the ground (Snow & Perrins, 1998). Thus, the inclusion of a deposition factor of 0.3 (according to FOCUS interception factor of 0.7 for vines at the stage of flowering) is deemed valid.

The refined long-term exposure assessment, accounting for aforementioned refinement options for the yellowhammer in vineyards is summarised in Table B.9.1-7.

Table B.9.1-6: Refined long-term exposure assessment (insectivorous birds) for BAS 510 F in vines (Tier 2)

Crop stage	FIR (fresh) / body weight	Food type	RUD [mg as/kg]	PT	PD	DF	f_{twa}	MAF	Use Rate [kg as/ha]	ETE per diet fraction [mg as/kg]	ETE Sum [mg as/kg]
Yellowhammer – vines											
Early / late	0.77	Arthropods (small)	29	0.5	0.1	0.3	n.a	n.a	0.6	0.20	0.61
	0.77	Arthropods (large)	5.1	0.5	0.75	0.3	n.a.	n.a.	0.6	0.27	
	0.26	Weed seeds	4	0.5	0.15	0.3	n.a	n.a	0.6	0.14	

Application in beans – insectivorous bird scenario

Focal species: In an evaluation paper in 2004, the PPR Panel chose the yellow wagtail as focal species for the insectivorous scenario in potatoes and tomatoes. It is assumed that, due to structural similarities, the yellow wagtail would also be the relevant species in bush beans. This is corroborated by data published by Schümperlin (1994). In a study on the breeding population of the yellow wagtail in north-eastern Switzerland, yellow wagtail territories were found in beans, though other leafy crops (potatoes, sugar beet) were preferred. Based on that, the yellow wagtail (*Motacilla flava*) is considered as key focal species for the insectivorous scenario in bush beans. The FIR/bw ratio for arthropod and food was calculated according to Crocker et al. (2002) to be 0.88.

PT (Proportion of diet obtained from the treated area): PT is set to 0.5, based on the same rationale as for the insectivorous bird scenario in vines.

PD (Proportion of diet): In a study on the foraging behaviour of yellow wagtails in the UK, the diet of solitary foraging yellow wagtails was examined on non-flooded areas of a meadow (Davies, N.B. 1977). The predominant prey types of foraging yellow wagtails were flies, which were caught around dung pats. The availability of the individual prey types was estimated by counting the number of prey individuals per 100 dung pat transects. The size distribution of available insects and ingested insects (from assessment of faecal material) was ascertained (see Table B.9.1-8). The insects are presented in a range of sizes, from which the prey size preference of yellow wagtails is determined. This research result can be used for the risk assessment.

Table B.9.1-7: The prey types eaten by solitary foraging yellow wagtails (adopted from Davies, N.B. 1977)

Prey type	Body length [mm]	Availability [%]	Remains in droppings [%]
Scatophagidae	5-10	77.1	35.1
Sphaeroceridae	1-2	6.9	2.3
Sphaeroceridae	3-4	10.1	41.3
Sepsidae	3-4	0.7	0.0
Coleoptera	2-3	5.1	6.4
Others	--	0.1	14.9

Scatophagidae vary from 5 mm to 10 mm in body length with females being smaller. On the dung pats, males outnumbered females by 3.7 to 1.0. Yellow wagtails preferred flies having about 7 mm in length. Prey up to this size is swallowed immediately in a very short period of time (< 1 sec). Larger prey, 10 mm in length, is bashed against a perch, sometimes dropped and took 5 – 10 sec to handle (Davies, N.B. 1977). From caloric specific values and the handling times for each size of prey, the energy intake per unit handling time was calculated. It became obvious that the size of the prey selected by wild wagtails corresponds to the optimum prey size they can handle. Thus, small prey items (1 – 2 mm) were ignored, because although quick to handle, the ratio between energy used for foraging and energy gained from successful prey was too unfavourable for the bird. On the other end of the scale, the largest *Scatophagidae* were rejected, because although worth very much energy, they took too long to handle (Davies, N.B. 1977).

Based on the data presented by Davies, N.B. (1977), which is the most comprehensive study on the yellow wagtail diet currently available, the majority of prey items collected by yellow wagtails are 3 - 4 mm and greater. As argued above for the yellowhammer in vines, it is proposed to include a working definition of 'large' insects being ≥ 5 mm and 'small' insects being < 5 mm. Employing the results from Table B.9.1-8, the proportion of large insects (5-10 mm category) in the diet of yellow wagtails is 35 % ($PD_{\text{large insects}} = 0.35$), and the PD for small insects is set as to represent the remaining proportion of the diet ($PD_{\text{small insects}} = 0.65$).

Foraging technique: The foraging technique of nine yellow wagtails in an agricultural landscape was subject of a comprehensive study in the German state of Brandenburg, eastern Germany. According to the results of this study, the most common foraging technique was picking from the soil while running on the ground. Capturing prey from a perch or collecting arthropods from vegetation were of minor importance only (Stiebel, 1996). This was corroborated by the already mentioned study on prey selection and foraging behaviour of pied and yellow wagtails in Britain (Davies, N.B. 1977). That author distinguished three types of foraging techniques:

1. Picking (84%): The birds walk and pick up prey items from the ground surface.
2. Run-picking (9%): The wagtails make quick darting runs at a prey item and pick it up either from the ground or as it takes off.
3. Fly-catching (7%): The birds make a short sally up off the ground and catch prey mid-air.

Based on that information, the notifier proposes a subdivision of yellow wagtails' prey items into two groups: the first group comprises soil-dwelling insects ($PD_{\text{soil-dwelling}} = 0.93$), the second group consists of insects obtained by fly-catching, which clearly cannot be attributed to soil-dwelling insects ($PD_{\text{flying}} = 0.07$). The RMS agrees that differentiation between soil-dwellers and other arthropods constitutes in principle a suitable approach for a refined risk assessment. However, not all prey items picked up directly from the ground are necessarily ‘soil dwellers’ in the narrower sense. The article of Davies, N.B. (1977) describes the technique used for catching dung flies as follows: a wagtail will perform a darting attack on flies on a dung pat causing the insects to escape and will then pick up from the soil surface those flies returning to the dung pat. However, dung flies should certainly not be seen as ‘soil dwellers’. Since no information is currently available on the distribution of prey items between actual soil dwellers and other arthropods temporarily resting or feeding on the soil surface, the RMS proposes not to include such differentiation quantitatively in the risk assessment.

DF (Deposition factor): In SANCO/4145/2000, the effect of crop interception on residues on soil-dwelling invertebrates is only considered in tall-growing crops (orchards, vines, hops). However, it is deemed appropriate to account for that exposure-mitigating effect also for other cultures. Deposition rates for beans corresponding to the interception factors according to focus are as follows,

100 %	BBCH 00-09 (Bare - emergence)
75 %	BBCH 10-19 (Leaf development)
60 %	BBCH 20-39 (Stem elongation)
30 %	BBCH 40-89 (Flowering)
20 %	BBCH 90-99 (Senescence, Ripening)

BAS 510 F will be applied twice in beans between growth stage BBCH 60 and 69 with an application interval of 7-10 d. This use pattern correlates with a deposition rate of 30 % of the applied amount on the ground. Based on that, a DF of 0.3 is proposed by the notifier. However, as mentioned above, the RMS does not agree with the assumption that the proportion of actual soil dwellers in a yellow wagtail’s diet can be directly deduced from the bird’s foraging technique. Consequently, no setting of a DF for a certain fraction of the arthropod diet is possible.

The refined long-term exposure assessment, accounting for aforementioned refinement options for the yellow wagtail in beans is summarised in Table B.9.1-9.

Table B.9.1-8: Refined long-term exposure assessment (insectivorous birds) for BAS 510 F in beans (Tier 2)

Crop stage	FIR (fresh) / body weight	Food type	RUD [mg as/kg]	PT	PD	DF	f_{twa}	MAF	Use Rate [kg as/ha]	ETE per diet fraction [mg as/kg]	ETE Sum [mg as/kg]
Yellow wagtail – beans											
Early / late	0.88	Arthropods (small)	29	0.65	0.5	1	n.a.	n.a.	0.5	4.15	4.54
	0.88	Arthropods (large)	5.1	0.35	0.5	1	n.a.	n.a.	0.5	0.39	

Application in beans – herbivorous bird scenario

PT (Proportion of diet obtained from the treated area): PT is set to 0.5, based on the same rationale as for the insectivorous bird scenario in vines.

DF (Deposition factor): BAS 510 F is intended to be applied in beans at BBCH 60-69 (flowering). In general, herbivorous birds prefer young leaves and plant shoots, disregarding older green plant material. Based on that, it is assumed that herbivorous birds will not eat bean plants at this stage. Furthermore, the canopy of the crop is very broad at this stage, and it is therefore unlikely that weeds may grow within the crop. However, to take a conservative approach, it is assumed that in some fields the crop will grow sparser, thereupon allowing the growth of some weeds which might be consumed by birds.
Under these conditions the deposition of the product on the weeds will be relatively low because of the interception by the crop. According to the prescriptions of $FOCUS_{gw}$, the inclusion of a Deposition Factor (DF) of 0.3 is valid for BBCH growth stages between 40 and 89 of beans.

The refined long-term exposure assessment for herbivorous birds in beans is summarised in Table B.9.1-10.

Table B.9.1-9: Refined long-term exposure assessment (herbivorous birds) for BAS 510 F in beans (Tier 2)

Crop stage	FIR (fresh) / body weight	Food type	RUD [mg as/kg]	PT	PD	DF	f_{twa}	MAF	Use Rate [kg as/ha]	ETE per diet fraction [mg as/kg]	ETE Sum [mg as/kg]
Herbivorous default bird species											
BBCH 60-69	0.76	Weed plants	40	0.5	1	0.3	0.53	1.6	0.5	1.93	1.93

Tier 2 risk assessment (calculation of refined TER values)

The TER_{lt} values resulting from a refined risk assessment (shown in Table B.9.1-11) show an acceptable risk on the long-term time-scale for all applications and indicator species.

Table B.9.1-10: Refined long-term toxicity/exposure ratios for BAS 510 F in vines and beans (Tier 2)

Crop	Focal species	Food type	TER_{lt}
Vines	Yellowhammer	Insects / weed seeds	24.07 / 0.61 = 39.45
Beans	Yellow wagtail	Insects	24.07 / 4.54 = 5.30
Beans	Herbivorous bird	Weed plants	24.07 / 1.93 = 12.47

Conclusion:

The risk to birds resulting from uptake of boscalid through diet after application of the active substance in vines or beans can be considered acceptable in the acute scenario as well as on the short-term and the long-term time-scale.

B.9.1.6.3 Bioaccumulation and food chain behaviour

The log P_{OW} of the active substance BAS 510 F was determined to be 2.96, hence roughly 3.0, which triggers an assessment as to the potential risk of secondary poisoning.
The risk assessment for earthworm-eating birds (…) and fish-eating birds (…) is depicted below in short tabular form.

Table B.9.1-11: Risk to earthworm-eating birds

Parameter	Boscalid (BAS 510 F)	Comment
PEC_{soil} (twa, 21 days) [mg/kg soil]	0.912	derived from maximum plateau in vegetable soil accumulation study, recalculated to application of 2 × 500 g as/ha to beans, $PEC_{soil,max}$ = 0.944 mg/kg, $DT_{5ß}$ = 212 d
K_{OW}	915	-/-
K_{oc}	507	minimum (lowest binding to soil – worst case for accumulation in earthworms)
f_{oc}	0.02	default
BCF_{worm}	0.985	$BCF_{worm} = (PEC_{worm} / PEC_{soil}) = (0.84 + 0.01 \times K_{OW}) / f_{oc} \times K_{oc}$
PEC_{worm}	0.899	$PEC_{worm} = PEC_{soil} \times BCF$
Daily dose [mg/kg bw]	0.988	$ETE = PEC_{worm} \times 1.1$
NOEDD [mg/kg bw]	24.07	See 9.1.3
TER_{lt}	24.35	> 5

Table B.9.1-12: Risk to fish-eating birds

Parameter	Boscalid (BAS 510 F)	Comment
PEC_{sw} (twa, 21 days) [mg/L]	0.00318	
BCF_{fish}	125	whole fish, maximum of unchanged boscalid (normalised to 6 % lipid content)
PEC_{fish}	0.398	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dose [mg/kg bw]	0.083	$ETE = PEC_{fish} \times 0.21$
NOEDD [mg/kg bw]	24.07	See 9.1.3
TER_{lt}	288.35	> 5

Conclusion:

The risk to birds resulting from secondary poisoning through accumulation of boscalid in possible prey items can be considered acceptable.

B.9.2Effects on aquatic organisms (Annex IIA 8.2; Annex IIIA 10.2)

B.9.2.1 Toxicity data

B.9.2.1.1 Sediment-dwelling organisms

Annex Point:	IIA-8.2.7/1
Author:	Dohmen, P.
Title:	Effects of BAS 510 F on the development of sediment dwelling larvae of *Chironomus riparius* in a water-sediment system.
Date:	2001

Doc ID:	2000/1018538; WAT 2001-381
Guidelines:	-/-
GLP:	Yes
Valid:	Yes

The study had already been validated and assessed in the monograph. Following a re-evaluation requested in the WG Evaluation on 15.07.2004, the NOEC from this study was set to 1 mg as/L (nominal) instead of the initially proposed value of 2 mg/L.
The reduction of the emergence rate at 2 mg/L amounts to 20 %. Although this value has not been found statistically significant, the variation coefficient at this concentration is high. Therefore, the effect should not be neglected.

Annex Point:	IIA-8.2.7/2
Author:	Weltje L.
Title:	Chronic toxicity of Boscalid (BAS 510 F) to the non-biting midge *Chironomus riparius* exposed via spiked-sediment
Date:	31.08.2005
Doc ID:	Study No. 232363; BASF DocID 2005/1022464; WAT 2005-733
Guidelines:	OECD 218: Sediment-water chironomid toxicity test using spiked sediment (Feb. 2004)
GLP:	Yes
Valid:	Yes

Material and methods:

Test substance:	BAS 510 F (Reg. No. 300 355), batch no. 81/1 (= BB81/1); purity: 98.4 %; specification (Document J).
Test species:	*Chironomus riparius*, egg masses obtained from in-house cultures, larvae less than 3 days old at test initiation.
Test design:	**Static system containing spiked artificial sediment and water (Elendt, M4-medium); test duration 28 days; 6 test concentrations, each with 4 replicates plus a control and solvent control with 6 replicates; 20 larvae per vessel; assessment of emergence ratio (number of emerged insects divided by the number of introduced larvae), development rate (proportion of larval development per day).**
Test concentrations:	**Solvent control, solvent free control, 1.87, 3.75, 7.50, 15.0, 30.0 and 60.0 mg/kg dry sediment (nominal).**
Test conditions:	Glass vessels with ca. 100 g wet spiked artificial sediment and ca. 400 mL M4 water (Elendt medium), pH 7.89 - 8.63, oxygen content 7.30 - 9.36 mg/L, total hardness 2.40 - 2.79 mmol/L, ammonium 0.156 - 38.395 mg/L, conductivity 693 µS/cm (bulk M4 water), feeding with TetraMin, gentle aeration, water temperature 19.0 - 20.1 °C, photoperiod: 16 h light : 8 h dark; light intensity 511 – 963 lux.
Analytics:	Analytical measurements of test substance concentrations in overlaying water, pore water and sediment were conducted during the course of the study using GC/MS.

Statistics: Standard procedures, analysis of variance, Bonferroni’s test, Dunnett's test, Williams’-test ($\alpha = 0.05$).

Findings:

Analytical measurements: Analysis of sediment by GC/MS at DAT 2 yielded recovery of 77.6 to 136.6 %. Overlaying water concentrations, measured on DAT 2, showed a linear relation with those in sediment and ranged from 0.0196 to 0.5672 mg/L. The pore water concentrations measured in the nominal 15 and 60 mg/kg treatments on DAT 2 were somewhat higher than those in overlaying water. At DAT 30, sediment concentrations in the nominal 15 and 60 mg/kg treatments had decreased to ca. 52 % of the nominal values, while the corresponding overlaying water concentrations slightly increased. The results are based on initially (= DAT 2) measured sediment concentrations.

Biological results: On day 15 after insertion of the larvae (= DAT 17), the first emerged midges were observed, which is normal under the conditions of our test system. Males always emerge earlier than females, which is a natural phenomenon in *C. riparius*. There was no indication for different effects on males and females, therefore male and female data were pooled for the calculations. In the nominal 3.75 mg/kg treatment, one replicate was excluded from further consideration, since a female midge, which had escaped from the breeding stock, laid an egg mass in this vessel.
No significant effects of BAS 510 F were detected on emergence ratio (ANOVA, followed by Bonferroni’s, Williams’ or Dunnett's test, $p > 0.05$). The development rate was significantly affected by BAS 510 F in the highest treatment (ANOVA, followed by Bonferroni’s, Williams’ or Dunnett's test, $p < 0.05$).

Table B.9.2-1:

Concentration (nominal) [mg a.s./kg]	Solvent control	Solvent free contr.	1.87	3.75	7.5	15.0	30.0	60.0
Concentration (initially measured) [mg a.s./kg dry weight]	< LoQ	< LoQ	1.69	3.13	10.25	13.124	23.26	47.75
Emergence rate	0.9756	0.9333	0.9375	0.9000	0.9424	0.9625	0.9750	0.9750
Development rate	0.0591	0.0603	0.0586	0.0596	0.0595	0.0592	0.0592	0.0575*
	Endpoints [mg/kg dry sediment (initially measured)]							
EC_{50}	> 47.75							
NOEC $_{\text{development rate}}$	23.26							
LOEC $_{\text{development rate}}$	47.75							

* significantly different from the pooled controls ($p < 0.05$)

Conclusion:

The NOEC for the development rate was 23.26 mg/kg dry sediment (based on initially measured concentrations). Consequently, the LOEC for the development rate was 47.75 mg/kg dry sediment (initially measured). For both endpoints, the EC_{50} is > 47.75 mg/kg dry sediment (initially measured).

B.9.2.2 Summary of aquatic toxicity data

Data are listed in Table B.9.2-2 in the context of the revised risk assessment due to recalculated PEC values. Except for *Chironomus riparius*, the respective studies have already been assessed in the monograph.

Table B.9.2-2: Laboratory toxicity data for aquatic species (most sensitive species of each group)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L)
O. mykiss	boscalid	static – 96 h	LC_{50}	2.7
O. mykiss		flow-through – 97 d (ELS)	NOEC	0.125
D. magna		static – 48 h	EC_{50}	5.33
D. magna		semi-static – 21 d	NOEC	1.31
P. subcapitata		static – 96 h	E_rC_{50}	3.75
			E_bC_{50}	1.34
C. riparius		static – 28 d spiked water	NOEC	1.0
C. riparius		static – 28 d spiked sediment	NOEC	23.26 mg/kg
Activated slugde		static – 0.5 h	Respiration rate	> 1000

B.9.2.3 Risk assessment

Due to recalculation of the PEC_{sw} values and due to the revised database for *Chironomus riparius*, a revision of the risk assessment for aquatic organisms became necessary. Except for the long-term effects on fish and on sediment organisms (with respect to accumulation of boscalid in the sediment), the risk assessment is based on initial PEC_{sw} values resulting from drift. The TER values for long-term effects on fish are calculated on the basis of a $PEC_{twa,42\,d}$ (see explanation in monograph). The TER values reflecting the risk to sediment dwellers from accumulation of boscalid in the sediment are based on a calculated $PEC_{sed,plateau}$ value. All relevant figures are compiled in Table B. 9.2-3.

Table B.9.2-3: Relevant PEC values for aquatic systems

Scenario	Distance			
	1 m	3 m	5 m	10 m
vines, 1 × 600 g as/ha				
PEC_{ini} [µg/L]	-/-	16.04	7.24	2.46
$PEC_{twa,42\,d}$ [µg/L]	-/-	4.76	2.15	0.73
$PEC_{sed,plateau}$ [mg/kg]	-/-	0.803[1] / 0.161[2]	0.363[1] / 0.073[2]	0.123[1] / 0.025[2]
beans, 2 × 500 g as/ha, 7 d interval				
PEC_{ini} [µg/L]	6.28	-/-	-/-	-/-
$PEC_{twa,42\,d}$ [µg/L]	1.87[3] / 2.32[4]	-/-	-/-	-/-
$PEC_{sed,plateau}$ [mg/kg]	0.397[1] / 0.079[2]	-/-	0.078[1] / 0.016[2]	0.040[1] / 0.008[2]

[1] sediment depth 1 cm
[2] sediment depth 5 cm
[3] twa-interval 7-49 d (averaging starts after 2nd application)
[4] twa-interval 0-42 d (averaging starts after 1st application)

The TER values compiled in Table B.9.2-4 relate to the respective highest PEC values, i.e. distance 3 m and 1 m for grapes and beans, respectively, twa-interval 0-42 d for $PEC_{twa,42\,d}$ in beans and sediment depth 1 cm for $PEC_{sed,plateau}$ in both cultures.

Table B.9.2-4: Toxicity/exposure ratios for the most sensitive aquatic organisms

Application rate (kg as/ha)	Crop	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger
1 × 0.600	grapevines	*O. mykiss*	acute	3	168	100
		O. mykiss	long-term	3	26	10
		D. magna	acute	3	332	100
		D. magna	long-term	3	82	10
		P. subcapitata	short-term	3	84	10
		C. riparius spiked water	long-term	3	62	10
		C. riparius spiked sediment	long-term	3	29	10
2 × 0.500	beans	*O. mykiss*	acute	1	430	100
		O. mykiss	long-term	1	54	10
		D. magna	acute	1	849	100
		D. magna	long-term	1	209	10
		P. subcapitata	short-term	1	213	10
		C. riparius, spiked water	long-term	1	159	10
		C. riparius, spiked sediment	long-term	1	59	10

Conclusion:

All calculated TER values are all well above the respective Annex VI acceptability criteria alreeady at the lowest distance (vines 3 m, beans 1 m) of treated area to surface water body. Thus, no unacceptable effects are expected for aquatic organisms as a result of the proposed uses of boscalid.

B.9.3 Effects on other terrestrial vertebrates (Annex IIIA 10.3)

B.9.3.1 Summary of terrestrial vertebrate toxicity data

The selection of the appropriate endpoint for assessing the long-term effects on mammals was discussed in the Peer Review Process (point 5(3) in Reporting Table, resulting in Open point 3.1 in the Evaluation Table). After reassessment of the data, the RMS now agrees with the proposal to use the endpoint of 1000 ppm (67 mg/kg bw/d) as derived from the reproduction study in rat in the risk assessment.

The overall database shows that changes in liver and thyroid were observed after two years in rat and after one year in dogs as well as after 28 days in rats. Such effects on thyroid are potentially population relevant and should be considered in the risk assessment. However, the effects observed at a concentration level of 100 ppm after two generations in the reproduction study in rat were not pronounced.

The earlier RMS argumentation for using the 100 ppm (6.7 mg/kg bw/d) endpoint from the reproductive study in rat was based on the reasoning that effects on body weight are usually population relevant. At 1000 ppm in the two generation rat study, reductions of body weight (up to 8.7 %) as well as body weight gain (up to 19%) were observed. However, according to SANCO/4145/2000, these effects should be above 20 % to be of relevance for natural populations.

The argumentation of the notifier to use 10000 ppm (1183 mg/kg bw/d) from the two generation rat study is not accepted. Potentially relevant effects were already observed in other studies at this concentration level.

B.9.3.2 Risk assessment

B.9.3.2.1 Risk assessment for the active substance

As a consequence of the revised endpoint for long-term effects to mammals, i.e. NOEAEC = 1000 ppm instead of NOEC = 100 ppm from the two-generation study in the rat, the corresponding TER values (Table B.9.3-1) are increased by a factor of 10.

Table B.9.3- 2:

Application rate (kg as/ha)	Crop	Category (*e.g.* insectivorous bird)	Time-scale	TER	Annex VI Trigger
0.6	Grapes	Insectivorous mammal	long-term	80	5
0.5	Field crops	Herbivorous mammal	long-term	120	5

B.9.6 Effects on earthworms (Annex IIA 8.4; Annex IIIA 10.6.1)

B.9.6.1 Risk assessment

Considering the results from the submitted accumulation studies in soil and the correspondding PEC_{soil} values, the risk assessment for earthworms was revised. For the assessment of the chronic risk to earthworms following an use of boscalid over many consecutive years, the long-term PEC_{soil} values (see B.8.3 above) are compared to the biological threshold rate of 1000 g as/ha (equivalent to 1.333 mg/kg soil according to standard parameters 5 cm soil layer and soil density of 1.5 g/cm^3), which is considered to be the NOEAEC (No Observed Environmentally Adverse Effect Concentration).

Two different sets of PEC_{soil} data are available: either directly deduced from measured and/or modelled concentrations in the soil accumulation studies or modelled with the groundwater leaching model FOCUS-PEARL 1.1.1 for the two intended uses in the scenarios Hamburg and Châteaudun. The respective data and the resulting TER values are compiled in Table B.9.6.1.

Table B.9.6-1: TER-values for long-term exposure of earthworms to Boscalid

	PEC_{soil}		TER_{lt}
	mg as/kg	kg as/ha	
vines (1 × 600 g as/ha)			
modelled concns.	0.551	413	2.42
measured concns.	0.277	208	4.81
FOCUS-PEARL 1.1.1 Hamburg	0.91	680	1.47
FOCUS-PEARL 1.1.1 Châteaudun	0.79	590	1.69
beans (2 × 500 g as/ha)			
meas. + mod. concns.	0.944	708	1.41
measured concns.	0.640	480	1.56
FOCUS-PEARL 1.1.1 Hamburg	0.90	680	1.47
FOCUS-PEARL 1.1.1 Châteaudun	0.78	590	1.69

Conclusion:

The calculated TER values are higher than 1 for all crop scenarios and all plateau estimations considered. Since the ecotoxicological endpoint was deduced as a NOEAEC from two field studies, i.e. under conditions highly relevant for actual use, no additional assessment factor (margin of safety) is considered necessary in this case. It is thus concluded that the risk to earthworm communities is acceptable for the two assessed crop scenarios vines and beans treated with boscalid (BAS 510 F) according to the label instructions.

B.9.11 References relied on

Annex point/ reference number	**Author(s)**	**Year**	**Title** **source (where different from company)** **report no.** **GLP or GEP status (where relevant), published or not** **BVL registration number**	**Data protection claimed** **Y/N**	**Owner**
IIA-8.2.7/1	Dohmen, P.	2001	Efects of BAS 510 F on the development of sediment dwelling larve of *Chironomus riparius* in a water-sediment system BASF DocID 2000/1018538 WAT 2001-381	Y	BASF
IIA-8.2.7/2	Weltje, L.	2005	Chronic toxicity of Boscalid (BAS 510 F) to the non-biting midge *Chironomus riparius* exposed via spiked-sediment BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. Study code 232363; BASF DocID 2005/1022464 WAT 2005-733	Y	BASF
IIIA-10.1	Anonymous	2004	Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request from the Commission related to the evaluation of methamidophos in ecotoxicology in the context of the Council Directive 91/414/EEC. The EFSA Journal (2004), 144, 1-50	N	-/-

Annex point/ reference number	**Author(s)**	**Year**	**Title** **source (where different from company)** **report no.** **GLP or GEP status (where relevant), published or not** **BVL registration number**	**Data protection claimed** **Y/N**	**Owner**
			AVS 2006-34		
IIIA-10.1	Bösenberg, K.	1958	Zur Nestlingsnahrung der Goldammer. Der Falke 5:58-61. AVS 2006-43	N	-/-
IIIA-10.1	Braun, M.	1985	Die Veränderung der Vogelwelt in einem ehemaligen Weinbaugebiet (1975/1985). Naturschutz und Ornithologie in Rheinland-Pfalz 4:38-46 AVS 2006-39	N	-/-
IIIA-10.1	Crocker, D.R., Hart, A., Gurney, J., McCoy, C.	2002	Methods for estimating daily food intake of wild birds and mammals. Central Science Laboratory, Project PN0908. Final Report. AVS 2006-29	N	-/-
IIIA-10.1	Crocker, D.R., Prosser, P., Bone, P., Irving & K. Brookes	2001	Project PN0915: Improving estimates of wildlife exposure to pesticides in arable crops. Milestone 03/03 - Radio-tracking progress report AVS 2006-33	N	-/-
IIIA-10.1	Davies, N.B.	1977	Prey selection and social behaviour in wagtails. Journal of Animal Ecology 46: 37-57 AVS 2006-35	N	-/-
IIIA-10.1	Goss-Custard, J.D.	1970	Responses of redshank (*Tringa totanus* L.) to spatial variations in the density of their prey. Journal of Animal Ecology 39: 91-113 AVS 2006-32	N	-/-
IIIA-10.1	Green, R.E.	1978	Factors affecting the diet of farmland skylarks, *Alauda arvensis*. Journal of Applied Ecology 47: 913-928 AVS 2006-30	N	-/-
IIIA-10.1	Kenaga, E.E.	1973	Factors to be considered in the evaluation of toxicity of pesticides to birds in their environment. Environmental Quality and Safety. Academic Press, New York, II: 166-181 AVS 2006-36	N	-/-
IIIA-10.1	Lille, R.	1996	Zur Bedeutung von Bracheflächen für die Avifauna der Agrarlandschaft: Eine nährungs-ökologische Studie an der Goldammer *Emberiza citrinella*. Verlag Paul Haupt, Bern Stuttgart Wien. AVS 2006-42	N	-/-

Annex point/ reference number	**Author(s)**	**Year**	**Title** **source (where different from company)** **report no.** **GLP or GEP status (where relevant), published or not** **BVL registration number**	**Data protection claimed** **Y/N**	**Owner**
IIIA-10.1	Moreby, S. J., Stoate, C.	2000	A quantitative comparison of neck-collar and faecal analysis to determine passerine nestling diet. Bird Study 47:320-331 AVS 2006-44	N	-/-
IIIA-10.1	Pedall, I.., Storch, V., Riffel, M.	2003	Vogelcoenosen südwestdeutscher Weinberge. Pollichia 90:353-367 AVS 2006-37	N	-/-
IIIA-10.1	Perrins, C.M.	1998	Cramp's the complete book of the western Palearctic. in Optimedia. AVS 2006-41	N	-/-
IIIA-10.1	Schümperlin, W.	1994	Die Brutpopulation der Schafstelze Motacilla flava im unteren Thurgau und im angrenzenden Zürcher Weinland. In: Ornithol. Beob., Bd. 91, Nr. 1, S. 52-56.	N	-/-
IIIA-10.1	Seiler, W.	1986	Sommervogelgemeinschaften von flurbereinigten und nicht bereinigten Weinbergen im württembergischen Unterland. Ökologie der Vögel 8:95-107. AVS 2006-40	N	-/-
IIIA-10.1	Seitz, B.-J.	1989	Beziehungen zwischen Vogelwelt und Vegetation im Kulturland - Untersuchungen im südwestdeutschen Hügelland. Beihefte zu den Veröffentlichungen für Naturschutz und Landschaftspflege in Baden-Württemberg 54:1-236 AVS 2006-38	N	-/-
IIIA-10.1	Snow, D. W., Perrins, C. M.	1998	The birds of the western Palearctic, vol. 2. Passerines. Oxford University Press, Oxford, UK	N	-/-
IIIA-10.1	Stiebel, H.	1996	Untersuchungen zur Habitatwahl und Habitatnutzung der Schafstelze (Motacilla flava L. 1758) in einer Agrarlandschaft. Diplomarbeit, Univ. Göttingen.	N	-/-
IIIA-10.1	Tinbergen, J.M.	1976	How starlings (*Sturnus vulgaris* L.) apportion their foraging time in a virtual single prey situation on a meadow. Ardea 64: 155-170 AVS 2006-31	N	-/-

(=> Jahreszahl im Addendum muss demnach kortrigiert werden)

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Addendum 2

to the Draft Assessment Report

of 08 November 2002

(relating to Volume 1 + 3)

This Addendum cancels and replaces the one which was distributed in January 2006. This is necessary to correct a number of editorial errors as well as to include some new data and other changes triggered by comments received after the WG evaluation of February 2006. All changes have been done in tracked changes mode.

Boscalid

24 May 2006

Rapporteur Member State: Germany

Contents

To Volume 1:

2.3 Impact on human and animal health

2.3.1 Effects having relevance to human and animal health arising from exposure to the active substance or to impurities contained in the active substance or to their transformation products

2.3.1.6 Reproductive toxicity

The reproductive toxicity of boscalid was investigated in a two-generation reproduction study in rats as well as in developmental toxicity studies in rats and rabbits. Since actual food consumption data were available these have been used throughout to calculate the exposure levels for the two-generation study. The dose information in mg/kg bw/d which was given based on a conversion factor of 15 in Volume 1 of the DAR has been replaced by the values based on actual consumption in this Addendum.

Boscalid had no adverse effects on reproductive performance or fertility of the F0 or F1 parental animals of all substance-treated groups up to a dose of 10000 ppm (1165 mg/kg bw/d). Signs of general toxicity/systemic effects occurred in both parental generations at 1000 and 10000 ppm. The effects at 10000 ppm were characterised by decreased food consumption and reduced body weights during parts of the administration period. Pathology showed statistically significantly increased liver weights, centrilobular hypertrophy of liver cells and centrilobular liver cell degeneration in single or all male and/or female animals. Systemic effects at 1000 ppm were confined to an increased incidence of centrilobular hepatocellular hypertrophy, which occurred in few F0 and F1 parental animals. No substance-related effects were noted at 100 ppm. Substance-induced signs of developmental toxicity were observed in progeny of the F0 and F1 parents at 1000 and 10000 ppm. At 10000 ppm a slightly increased pup mortality of the F2 litters was noted between days 0 and 4 post partum only. Pup body weight development was impaired in both F1 and F2 litters. At 1000 ppm, slightly decreased body weight gains were recorded for the male F2 pups only. 100 ppm did not induce any indication of developmental toxicity. The NOAEL for parental toxicity of the test substance was established at 100 ppm (11 mg/kg bw/d) for the F0 and F1 parental males and females. The NOAEL for developmental toxicity was 1000 ppm (113 mg/kg bw/d) for the male and female F1 and female F2 progeny and 100 ppm (11 mg/kg bw/d) for the male F2 progeny.

In the developmental toxicity study in rats, incomplete ossification of the thoracic centrum was observed at the highest dose tested (1000 mg/kg bw/d) in the absence of overt maternal toxicity. At this limit dose level there were also no signs of maternal toxicity. However, results from the 90-day oral feed study in rats indicate that liver toxicity would have been detected in dams at 1000 mg/kg bw/d. The NOAEL for developmental toxicity in rats was established at 300 mg/kg bw/d.

In the rabbit developmental toxicity study, incomplete ossification of the thoracic centrum was also observed at significantly increased incidences at the highest dose level (1000 mg/kg bw/d). At this dose level there was overt maternal toxicity (clinical signs of toxicity, reduced body weight and body weight gain). At 300 mg/kg bw/d clinical signs (abortion and discoloured/reduced faeces) were observed in a single animal only. Thus, the NOAELs for maternal and for developmental toxicity were 100 mg/kg bw/d and 300 mg/kg bw/d, respectively.

Results of all reproduction toxicity studies are summarised in Table 2.3-3.

Table 2.3-3: Summary of reproductive toxicity studies with boscalid

Study **dose levels** **purity**	**Target**	**NOAEL mg/kg bw/d**	**LOAEL mg/kg bw/d**	**Effects**
Rat 2-generation study 0–100–1000–10000 ppm purity: 94.4 %	Parental tox.	11 (100 ppm)	113 (1000 ppm)	≥ 1000 ppm: ↑ hepatocell. hypertrophy 10000 ppm: ↓ bw gain & feed intake ↑ liver wt & hepatocyte degeneration
	Fertility	1165 (10000 ppm)	–	No effects observed
	Offspring tox.	11 (100 ppm)	113 (1000 ppm)	≥ 1000 ppm: ↓ bw gain 10000 ppm: ↑ Male F2 pup mortality during days 0–4 p.p.
Rat teratogenicity 0–100–300–1000 mg/kg bw/d purity: 94.4 %	Maternal tox.	1000	–	No effects observed
	Developmental tox.	300	1000	1000 mg/kg bw/d: ↑ Incomplete ossification of the thoracic centrum
Rabbit teratogenicity 0–100–300–1000 mg/kg bw/d purity: 94.4 %	Maternal tox.	100	300	300 mg/kg bw/d: 1 doe with abortion and reduced / discoloured faeces 1000 mg/kg bw/d: 4 does with abortion ↓ feed intake, bw & bw gain
	Developmental tox.	300	1000	1000 mg/kg bw/d: ↑ Incomplete ossification of the thoracic centrum

2.3.1.8 Further toxicological studies

Concerns regarding a possible immunotoxic effect of boscalid based on reduced spleen weights of parents and offspring in the 2-generation study in rats have been addressed by the applicant with an additional immunotoxicity study. Boscalid did not have an effect on cellular or humoral immune functions in male rats as evidenced by analysis of subsets of thymic and splenic lymphocytes and of sheep red blood cell-specific IgM antibody formation.

2.3.3 AOEL

The calculation of a systemic AOEL using the NO(A)EL from the 1-year toxicity study in the dog corrected with the oral bioavailability in the rat has been criticized as not being a scientifically sound procedure and it has been suggested that the NO(A)EL from the 90-day rat study is used instead.

The studies in the dog were chosen to derive the point of departure on the scientific grounds that they supported a much more precise estimate of the NOAEL and LOAEL than any of the rat studies. ADME data from rats indicated that gastrointestinal absorption can be saturated in mammals. In rats this appeared to be the case at a dose of 50 mg/kg bw where oral bioavailability was only about 45 % and became even more prominent at a dose of 500 mg/kg bw where gastrointestinal absorption decreased to about 12 % of administered dose. No information about the shape of the bioavailability curve was available in the dose range below 50 mg/kg bw so that there is no scientific basis to assume that a gastrointestinal absorption value of 44 % is more valid for rats at a dose of 34 mg/kg bw/d than it is for dogs at a dose of 22 mg/kg bw/d. Because of these uncertainties, the lack of ADME data in dogs, and in order to achieve adequate protection for operators the RMS considered it prudent to assume that gastrointestinal absorption at the NOAEL could have been saturated to some extent in dogs as well as in rats.

2.3.4 Acute Reference Dose (ARfD)

The question has been raised whether an ARfD should be set for boscalid on the basis that a reduction in the ossification of vertebral structures (thoracic centra and to a lesser extent sacral arches) was noted at a dose of 1000 mg/kg bw/d in rat and rabbit developmental toxicity studies. This finding is considered to be of minor toxicological relevance as such variations, although often indicative of generalised embryofoetal toxicity, represent only a difference of a few hours in relative development of foetuses at the time of sacrifice. Moreover, in the absence of malformations of the underlying cartilaginous structures, no true adversity would be associated with this type of change. Retardations of skeletal ossification could fulfill the criteria for the derivation of an ARfD when they are elicited by a single dose of a toxicant. In the case of boscalid there are insufficient data to decide whether the developmental retardation was induced on a single occasion during the embryofoetal period or whether it was a consequence of repeated exposure of the dam and the conceptus. The sensitive period for skeletal ossification changes is much broader than for malformations for which a limited time window of sensitivity can be assumed. In humans this process continues for several months and is thus less likely to be notably affected by a single dose above the ADI than it would be the case in the common animal models.
Based on the low acute toxicity of boscalid and the lack of concern regarding developmental toxicity in humans allocation of an ARfD is not considered necessary.

Acute dietary risk assessment

Since there is from the toxicological point of view no need to set an ARfD there is no need to conduct an acute dietary risk assessment.
An acute dietary risk for consumers is highly unlikely.

2.4 Residues

2.4.1 Definition of residues relevant to MRLsPlants

Plants

The metabolism of boscalid was investigated in grapes, lettuce and beans. Unchanged parent compound formed the major part of the residue in these studies. The cleavage products M510F62 (chlorophenylaminobenzene) and M510F47 (chloronicotinic acid) and in addition hydroxy-parent and sugar conjugates were identified in beans. All metabolites were of minor importance. Therefore parent only is included in the residue definition.

Residue definition plant**: Boscalid**

Animals

Metabolism studies performed on goats and hens show that residues in products of animal origin derive from the parent compound as well as from the hydroxylated metabolite M510F01 including its conjugates. Further metabolites result from a substitution of the chlorine of the 2-chloropyridine moiety by the thiol group of glutathione to create metabolites as the cysteine conjugate. Boscalid derived residues were also bound in liver based on this substitution (most likely SH-groups from cysteine containing protein). The amide bond of boscalid was very stable under metabolic conditions in goats and hens.
The results of the goat and hen metabolism studies selects the following compounds that are listed differentiated in residues for monitoring purposes and residues for risk assessment:

Residue definition for monitoring:	**Boscalid, M510F01 (including its conjugates) calculated as boscalid**
Residue definition for risk assessment:	**Nicobifen, M510F01 (including its conjugates) conjugates) calculated as boscalid** **M510F53 (for bound residues in liver and minor metabolites in milk)**

2.4.2 Residues relevant for consumer safety

Chronic dietary intake levels were estimated using the proposed MRL values derived from supervised residue trials in the EU-monograph as well as from German national registration process and from the livestock feeding studies in cows and hens. The results obtained on the basis of the German (VELS) and WHO European regional diet were compared with the ADI value of 0.04 mg/kg. A chronic dietary consumer risk is unlikely.

TMDI (WHO European diet 1998):	0.022 mg/kg bw/day – 54 % of the ADI
TMDI (German diet, child 16.15 kg):	0.025 mg/kg bw/day – 63 % of the ADI

Since it is not necessary to set an ARfD an acute risk for consumers can be excluded.

2.8.3.3 Appendix III.3: Chapter 3 (impact on human and animal health)

Absorption, distribution, excretion and metabolism in mammals (Annex IIA, point 5.1)

Rate and extent of absorption	Approx. 44 % (based on bile excretion within 48 h and urinary exretion within 6 h, low dose)
Distribution	Widely distributed. Highest residues in liver and adipose tissue (8-h, low dose) In high-dose females, highest residues were observed in thyroid and kidney
Potential for accumulation	No evidence
Rate and extent of excretion	Complete excretion of low dose within 48 h (approx. 20 % via urine and 80 % via faeces)
Metabolism in animals	Extensive (< 1 % of absorbed dose excreted as parent via urine or bile), 38 metabolites identified in rat matrices. Major pathway was hydroxylation at the diphenyl moiety and subsequent O-glucuronidation
Toxicologically significant compounds (animals, plants and environment)	Parent and metabolites

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral	> 5000 mg/kg bw
Rat LD_{50} dermal	> 2000 mg/kg bw
Rat LC_{50} inhalation	> 6.7 mg/l air (nose-only dust exposure)
Skin irritation	Non-irritant
Eye irritation	Non-irritant
Skin sensitization (test method used and result)	Not a skin sensitiser (M&K test)

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Liver, thyroid
Lowest relevant oral NOAEL / NOEL	Dog 1-yr: 800 ppm (22 mg/kg bw/d)
Lowest relevant dermal NOAEL / NOEL	Rat 28-day: 1000 mg/kg bw/d
Lowest relevant inhalation NOAEL / NOEL	No studies submitted, not required.

Genotoxicity (Annex IIA, point 5.4)

	No genotoxic potential

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target / critical effect	Liver, thyroid
Lowest relevant NOAEL / NOEL	Rat 2-yr: 100 ppm (4.4 mg/kg bw/d)
Carcinogenicity	Slight increase of thyroid follicular cell adenomas; not relevant to man. No classification and labelling necessary.

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect	Slightly reduced viability and decreased pup wt during lactation in the presence of parental adverse effects
Lowest relevant reproductive NOAEL / NOEL	100 ppm (11 mg/kg bw/d)
Developmental target / critical effect	Delayed ossification in rabbits and rats in the presence of maternal toxicity at the limit dose
Lowest relevant developmental NOAEL / NOEL	Rat & rabbit: 300 mg/kg bw/d

Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 5.7)

	No evidence from oral acute and 90-d neurotoxicity studies. No evidence from developmental neurotoxicity study

Other toxicological studies (Annex IIA, point 5.8)

Toxic effects of metabolites	Para-chlorobenzoic acid (degradation product in aquatic environment): literature survey data indicates that para-chlorobenzoic acid exhibits higher acute oral toxicity than boscalid. No concern from limited in-vitro genotoxicity data
Mechanistic studies	Boscalid is an inducer of cytochrome P450; T3 and T4 levels are decreased and TSH is increased. The increased metabolism of T4 via hepatic enzyme conjugation appeared to be responsible for the increased TSH.
Immunotoxicity	No toxic potential on cellular and humoral immune functions

Medical data (Annex IIA, point 5.9)

	No data (new compound)

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI	0.04 mg/kg bw	Rat 2-yr oral feed	100
AOEL systemic	0.1 mg/kg bw/d	Dog 1-yr oral feed; corrected for 44 % oral absorption	100 x [44 %]
ARfD (acute reference dose)	Not allocated	Not necessary, based on low acute toxicity and lack of developmental toxicity concerns	

Dermal absorption (Annex IIIA, point 7.3)

	Rat in vivo: 7 %; rat/human in-vitro dermal penetration ratio: 1 => 7 % human dermal absorption proposed for use in exposure calculations

Acceptable exposure scenarios (including method of calculation)

Operator	Intended uses acceptable (operator exposure < systemic AOEL; German model: without PPE and UK-POEM: with PPE)
Workers	Intended uses acceptable
Bystanders	Intended uses acceptable

3.1 Background to the proposed decision

Residue data

The metabolism of boscalid in plants was investigated in grapes, lettuce and beans. The metabolic pattern is similar in all three crop groups. Therefore the metabolism in plants is considered to be proofed.
The residue definition for plants is proposed as parent compound only

The metabolism and distribution of radioactive labelled boscalid was investigated in lactating goats and laying hens.
For monitoring purposes the residue definition for food of animal origin is proposed as boscalid and metabolite M510F01 (including its conjugates) calculated as boscalid.
For risk assessment bound residues in liver and minor metabolites in milk (M510F53) should be considered too.

The residue situation for the intended uses of boscalid in grapes, beans, peas and rape seed is covered by a sufficient number of residue trials. On basis of these data, of additional data submitted in the German national registration process and of possible residues in succeeding crops the possible intake of residues by consumers was calculated. In a chronic risk assessment no unacceptable risk for consumers could be identified. An acute risk is not to be expected since there was no necessity to set an Acute Reference Dose (ARfD).

Due to its persistent nature in soil and its ability to be transported systemically in plants the parent compound boscalid may occur in crops grown in rotation. A confined rotational crop study as well as field trials indicate that residue levels above 0.05 mg boscalid/kg are possible in crops grown in rotation. Therefore a MRL of 0.5 mg/kg is proposed for those crops not covered by residue or rotational crop studies.

3.2 Proposed decision concerning inclusion in Annex I

The inclusion of the active substance boscalid in Annex I of Directive 91/414/EEC is recommended.

To Volume 3:

B.1.2 Identity of the plant protection product (Annex IIA 3.1; Annex IIIA 1) (Dossier Documents J, K-II, L-II, K-III and L-III) (to be included for each preparation for which an Annex III dossier was submitted)

B.1.2.1 Current, former and proposed trade names and development code numbers (Annex IIIA 1.3)

Trade Name: "BAS 510 01 F" (preliminary designator)
(country specific alternatives are under consideration)

Code Number:
Plant Protection Product: BAS 510 01 F
Active Substance: BAS 510 F
proposed common name: boscalid
(formerly known as nicobifen)

BASF internal No. Reg. No. 300355

B.1.2.2 Applicant (Annex IIIA 1.1)

Headquarter/Germany
BASF Aktiengesellschaft
Agricultural Center
Product Registration Management
P.O. Box 120
67114 Limburgerhof
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B.5.3 Analytical methods (residue) plants, plant products, foodstuffs of plant and animal origin, feedingstuffs (annex IIA 4.2.1; Annex IIIA 5.2)

B.5.3.1 Plant material

Corrigendum to the draft assessment report:
Reporting table 1(x):
The method of Reichert (2001) is considered not acceptable for hops due to low recoveries for this matrix.

B.5.3 Analytical methods (residue) soil, water, air (annex IIA 4.2.2 to 4.2.4; Annex IIIA 5.2)

B.5.3.1 Soil

Reference: Grote, C (2003): Report Amendment No.1 to Validation of analytical method No. 408/1. GC-MS determination of BAS 510 F active ingredient residues in soil and sediment after methanol extraction; BASF Doc ID 2003/1000977; BASF, MET2003-355

The uncorrected values for the recoveries were missing in the original study. A report amendment to the method of Keller(1998a) was submitted. For soil the uncorrected recoveries are in the range of 70 –110 % and the blank values < 30% of the lowest fortification level. The study is considered acceptable.
The uncorrected values are included in table B.5.3-1.

Table B.5.3-1: Validation data for the analytical methods for the determination of boscalid in soil and sediment

Reference	Sample matrix	Test substance	Fortific. level [ppm]	Mean recovery uncorrected [%]	Mean recovery corrected* [%]	RSD [%]	No. of replicates
Keller (1998 a)	Standard soil 2.2	Boscalid	0.01 0.1 1.0	99 90 84	79 88 84	5.9 3.5 3.3	5 5 5
	US soil	Boscalid	0.01 0.1 1.0	97 90 92	82 89 91	3.2 1.6 5.3	5 5 5
	Sediment	Boscalid	0.01 0.1 1.0	113 90 98	77 86 98	6.3 4.2 3.6	5 5 5

* for blank values corrected recoveries

B.5.3.1 Water

Reference: Grote, C (2003): Report Amendment No.1 to Validation of analytical method No. 411. Determination of BAS 510 F ai residues in water; BASF Doc ID 2003/1000976; BASF, MET2003-356

The uncorrected values for the recoveries were missing in the original study. A report amendment to the method of Keller(1998b) was submitted.

The uncorrected recoveries for water are in the range of 70 –110 % for the fortification levels of 0.5 µg/kg and 5.0 µg/kg. At the fortification level of 0.05 µg/kg the uncorrected recoveries are significantly higher due to high blank values. The blank value for tap water is 55% and for leachate water 43% of the lowest fortification level. However, if calculated for the drinking water limit of 0.1 µg/L the blank values are below 30%. The study is considered acceptable.
The uncorrected recoveries are included in table B.5.3-2.

Reference:	Grote, C (2003): Report Amendment No.1 to Validation of analytical method No. 411/0. GC/MS determination of BAS 510 F ai residues in surface water; BASF Doc ID 2003/1000975; BASF, MET2003-357

The uncorrected values for the recoveries were missing in the original study. A report amendment to the method of Grote (2001) was submitted. It is stated there that no blank values were observed for surface water. Therefore the uncorrected values are the same as the corrected values of the recoveries. The study is considered acceptable.

Table B.5.3-2: Validation data for analytical methods for the determination of boscalid residues in water

Reference	Sample matrix	Test substance	Fortific. level [µg/kg]	Mean recovery uncorrected [%]	Mean recovery corrected* [%]	RSD [%]	No. of replicates
Keller (1998 b)	Tap water	Boscalid	0.05** 0.5 5.0	133 90 89	77 84 88	2.2 3.9 2.4	5 5 5
	Leachate water	Boscalid	0.05** 0.5 5.0	140 100 102	97 96 102	7.6 6.5 2.1	5 5 5
Grote (2001)	Surface water	Boscalid	0.05 0.5** 5.0	114 105 99	114 105 99	0.7 4.4 4.6	5 5 5

* for blank values corrected recoveries
** LOQ

B.5.5 Evaluation and assessment

B.5.5.2 Residue analysis

Reporting table 1 (i) and (vii):
Regarding MRLs which were used for evalution of residue analytical methods in the draft assessment report: Since the MRLs were altered during the evaluation process see latest list of endpoints for proposed MRLs.

B.5.6 References

Annex point/ reference number	Author(s)	Year	Title source (where different from company) report no. GLP or GEP status (where relevant), published or not BBA registration number	Data protection claimed Y/N	Owner
AIIA-4.2.2	Grote, C	2003	Report Amendment No.1 to Validation of analytical method No. 408/1. GC-MS determination of BAS 510 F active ingredient residues in soil and sediment after methanol extraction; BASF Doc ID 2003/1000977 unpublished MET2003-355	Y	BAS
AIIA-4.2.3	Grote, C	2003	Report Amendment No.1 to Validation of analytical method No. 411. Determination of BAS 510 F ai residues in water; BASF Doc ID 2003/1000976 unpublished MET2003-356	Y	BAS
AIIA-4.2.3	Grote, C	2003	Report Amendment No.1 to Validation of analytical method No. 411/0. GC/MS determination of BAS 510 F ai residues in surface water BASF Doc ID 2003/1000975 unpublished MET2003-357		

B.3.5 Further information on the plant protection product (Annex IIIA 4)

B.3.5.1 Packaging (type, materials, size, etc.), compatibility of the preparation with proposed packaging materials (Annex IIIa 4.1)

B.3.5.1.1 Description of packaging (Annex IIIA 4.1.1)

A second type of packaging was added to the already existing square block bottom paper bag. BAS 510 01 F is also to be marketed in high-density polyethylene containers. They are sealed by foil seals, protected by screw caps of polyethylene or polypropylene.

0.25 litre bottle: material: HDPE
shape/size: cylindrical / approx. 62.5 mm diameter x 126 mm
opening: 42 mm inner diameter
closure: polypropylene screw cap
seal: H F-seal

1 litre bottle: material: HDPE
shape/size: cylindrical / approx. 91 mm diameter x 234 mm
opening: 42 mm inner diameter
closure: polypropylene screw cap
seal: H F-seal

2.2 litre bottle: material: HDPE
shape/size: rectangular / approx. 140 mm x 96 mm x 220 mm
opening: 54 mm inner diameter
closure: polypropylene screw cap
seal: H F-seal

5 litre container: material: HDPE
shape/size: rectangular / approx. 190 mm x 140 mm x 318 mm
opening: 54 mm inner diameter
closure: polyethylene screw cap
seal: H F-seal

10 litre container: material: HDPE
shape/size: rectangular / approx. 230 mm x 165 mm x 375 mm
opening: 54 mm inner diameter
closure: polyethylene screw cap
seal: H F-seal

B.3.5.1.2 Suitability of packaging (Annex IIIA 4.1.2)

Reference number: PHY2005-1126
Report: Schreiner (2004)
EU Performance Tests
BASF AG,
Ludwigshafen, Germany
unpublished
Guidelines: None
GLP: No

The packaging is suitable according to ADR Method 3552 (drop test) for transporting solids.

B.3.5.1.3 Resistance of Packaging material to its contents (Annex IIIA 4.1.3)

During the handling or storage of BAS 510 01 F, corrosiveness of the formulation towards containers or the packaging material (Lupolen) was not observed. Thus, it is anticipated that the square block bottom paper bag, laminated with polyethylene on the inner side, and the high-density polyethylene containers won't be impaired by any corrosion.

B.3.6 References relied on

Annex point/ reference number	Author(s)	Year	Title source (where different from company) report no. GLP or GEP status (where relevant), published or not BBA registration number	Data protection claimed Y/N	Owner
AIIIA-4.1.2	Schreiner	2004	EU Performance Tests BASF DocID 2004/1016332 not GLP, unpublished PHY2005-1126	Y	BAS

B.6 Toxicological and Metabolism Studies

B.6.3 Short-term toxicity (Annex IIA 5.3)

B.6.3.2 Dermal studies

B.6.3.2.1 Rat, 28 Days

Report:	Mellert W. et al., 2000 (TOX2001-718) BAS 510 F - Repeated dose dermal toxicity study in Wistar rats - Administration for 4 weeks BASF AG, Ludwigshafen/Rhein, Germany BASF RegDoc# 2000/1013240, unpublished

Supplementary comment:

Stauber F., 2005
BASF Doc# 2005/1015024, unpublished

In addition to the findings described in the DAR, a slight increase in the number of female animals with gastric erosion or ulcers was noted in this dermal study at the dose of 1000 mg/kg bw/d (4/10 vs. 1/10 in the control group). No similar observations were made in high dose males. The applicant has submitted a response regarding a possible relationship of this finding to dermal treatment with boscalid.

No mechanistic explanation for these gastric lesions could be discovered. Since no comparable, dose-related findings were made in the 90-day oral study (Mellert W. et al., 2000 BASF RegDoc# 2000/101219) with daily doses up to 1225 mg/kg bw in females, the lesions are obviously not elicited by a direct contact of the gastric epithelia with the test substance. Indirect mechanisms related to stress phenomena could be envisaged. However, no indications for a specifically higher stress in female rats treated dermally with a dose of 1000 mg/kg bw were noted. Therefore, a chance occurrence is considered the most likely explanation. In accordance with the original evaluation in the DAR the dose of 1000 mg/kg bw/d is considered to be the NOAEL in this study.

B.6.8 Further toxicological studies (Annex IIA 5.8)

B.6.8.2 Supplementary studies with the active substance

Report:	Kosaka T. 2003 (TOX2005-2345) BAS 510 F: 4-week oral feeding immunotoxicity study in rats The Institute of Environmental Toxicology (IET); Uchimoriya-machi 4321, Mitsukaido-shi, Ibaraki 303-0043; Japan Study Code IET 03-0018 BASF RegDoc# 2003/1025755, unpublished (Experimental work from April 2003 - June 2003)
GLP:	Yes (laboratory certified by Agricultural Production Bureau, Ministry of Agriculture, Forestry and Fisheries, Japan (MAFF))
Guideline:	EPA immunotoxicity test guideline OPPTS 870.7800, 1998
Deviations:	None
Acceptability:	The study is considered to be acceptable.

Material and Methods:

Test material:	Boscalid; batch No. N37, purity: 94.4 %.
Test animals:	Male Wistar rats (Crj:Wistar; Charles River Japan)

Boscalid was administered to groups of 16 male Wistar rats at dietary concentrations of 0, 100, 1000 and 10000 ppm for 4 weeks, corresponding to a substance intake of 0, 7.8, 76.3 and 769 mg/kg bw/d. The test substance concentrations were chosen in accordance with those of the 2-generation study in rats (refer to B.6.6.1 of the DAR). As positive control, cyclophosphamide was administered by gavage to 16 male Wistar rats per group at doses of 0 (0.5 % methyl cellulose solution as vehicle control) and 3 mg/kg bw/d. The animals were about six weeks old at initiation of test substance administration. Animals were observed for clinical signs, moribundity and death on a daily basis. Food consumption and body weight (twice a week) were recorded. Out of each group 8 animals were selected for organ weight determination (thymus, spleen) and flow cytometry analysis of lymphocytes. The remaining 8 animals were injected with sheep red blood cells as an antigen 6 days before the termination of the study and anti-SRBC immunoglobulin M (IgM) was measured after the test substance administration period.

Findings:
The stability and the homogeneity of test substance and positive control substance were verified by analysis of the diet and the dosing solution, respectively, and were found to be within acceptable limits.
One animal of the 10000 ppm group was killed during week 3 of the study due to deteriorating health unrelated to the test substance. No clinical signs were observed in the remaining animals. In the treatment groups as well as in the positive control group food consumption and body weights were comparable to those of the controls throughout the treatment period. There were no significant changes in the organ weight (absolute and relative) of spleen and thymus, number of cells in thymus and spleen, and cell numbers of lymphocyte subsets. A significant increase in the Pan T-cell subset of the 100 ppm group was noted as isolated finding; however, in the absence of similar results in the 1000 and 10000 ppm groups this finding was not considered to be test substance-related. In the cyclophosphamide group statistically significant decreases were found in organ weights, cellularity and splenic and thymic lymphocyte subsets.
In the groups treated with boscalid no significant differences in serum anti-SRBC IgM antibody titers were observed with respect to the control group whereas in the cyclophosphamide group, the anti-SRBC IgM antibody titer was significantly lower than that of the corresponding control.

Conclusion:
Following the administration of 100, 1000 and 10000 ppm of boscalid in the diet for a period of 28 days in male Wistar rats, there were no immuno-toxicological effects on lymphocyte subsets of thymic and splenic cells as well as SRBC-specific IgM antibody titers that could be related to the test substance. The immune-suppressive effects of cyclophosphamide were indicative of the reliability of the method and procedures used.

B. 6.10.1 Summary

Further toxicological studies
In an immunotoxicity study with male rats, boscalid did not have an effect on cellular or humoral immune functions in male rats as evidenced by analysis of subsets of thymic and splenic lymphocytes and of SRBC-specific IgM antibody titers.

B. 6.15 References relied on

Annex point(s)	Author(s)	Year	Title Source (where different from company) Report No. GLP or GEP status (where relevant), published or not BBA registration number	Data protection claimed Y/N	Owner
AII A 5.8.2/3	Kosaka T.	2003	BAS 510 F: 4-week oral feeding immunotoxicity study in rats 2003/1025755 GLP, unpublished TOX2005-2345	Y	BASF

B.7 Residue data

B.7.3 Definition of the residue (Annex IIA 6.7; Annex IIIA 8.6)

Products of animal origin

It is questioned whether to include the metabolites BAS510F53 or BA510F52 in the residue definition for risk assessment.

The difficulty of this question is that both metabolites are not present in animal matrices. They are the result of a chemical treatment which is necessary to liberate bound residues. Depending on the conditions of cleavage one or the other metabolite will be present.

Bound residues were cleaved under microwave treatment with formic acid to form BAS510F52 or with acetic acid to form BAS510F53. Since the cleavage with acetic acid is also described for milk, it was decided to take BAS510F53 as compound representing the bound residues in liver.

B.7.6 Residues resulting from supervised trials (Annex IIA 6.3; Annex IIIA 8.2)

Reports:	Beck, J.; Greener, N. Mackenroth, C., 2003 (RIP2004-901) Study on the residue behaviour of Boscalid (BAS F510 F) in grapes (wine) after application of BAS 510 01F under field conditions in Germany, France, Italy and Spain, 2002 BASF AG, Ludwigshafen/Rhein, Germany BASF RegDoc# 2003/1001357, unpublished
GLP:	Yes
	Moreno, S., 2003 (RIP2004-902) Study on the residue behaviour of Boscalid (BAS 510 F) in grapes (wine) after application of BAS 510 01F under field conditions in Spain, 2002 BASF AG, Ludwigshafen/Rhein, Germany BASF RegDoc# 2003/1001279, unpublished
GLP:	Yes
	Amendment with minor corrections: Moreno, S., 2003 (RIP2004-903) Report Amendment No. 1! Study on the residue behaviour of Boscalid (BAS 510 F) in grapes (wine) after application of BAS 510 01 F under field conditions in Spain, 2002 BASF AG, Ludwigshafen/Rhein, Germany BASF RegDoc# 2003/1009789, unpublished
GLP:	Yes
	Schulz, H.; 2004 (RIP2005-2259) Study on the residue behaviour of Boscalid (BAS 510 F) in vines after application of BAS 510 01 F under field conditions in France (N&S), Spain, Italy and Germany, 2003 BASF AG, Ludwigshafen/Rhein, Germany BASF RegDoc# 2004/1015915, unpublished
GLP:	Yes

The intended use for Boscalid in grapes was changed. Instead of 3 x 0.7 kg a.i./ha the critical GAP is now 1 x 0.6 kg a.i./ha. Since this new GAP was not covered by adequate residues trials, new trials were conducted in 2002/2003.

Material and methods:

During the growing seasons 2002 and 2003, a total of 17 field trials were conducted in different representative wine growing areas in Germany, Spain, France and Italy (8 in Northern EU, 9 in the South) to determine the residue levels of boscalid. The WG formulation BAS 510 01 F (trade name in Germany: ”Cantus”) was tested. It

was applied once at growth stages of 79 to 89 (BBCH code) about 28 days before expected harvest. Different varieties of both white and red wine were used. The application rate was 1.2 kg/ha (= 600 g a.i./ha). The product was applied with a spray volume of 800 l/ha.
In all trials, grape samples were taken directly after the last application (0 DALA) as well as about 3, 4 and 5 weeks thereafter.
The samples were analyzed with BASF method no. 445/0 which quantifies the parent compound boscalid (BAS 510) with a limit of quantitation of 0.05 mg/kg. The overall average results of procedural recovery experiments obtained with each analytical series were at about 82%. Fortification levels were between 0.05 mg/kg and 5.0 mg/kg.

Findings:
In the trials treated with BAS 510 01 F, the residues of boscalid (BAS 510 F) found directly after the last application ranged between 0.18 and 1.96 mg/kg. After about four weeks at the proposed PHI, the residues were between 0.13 and 1.35 mg/kg. After about 5 weeks residues between 0.09 and 1.47 mg/kg were left.
The trial details and results are list in the following tables.

Table B.7.6- 1 Residue trials grapes – Northern Europe

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Boscalid
Crop / crop group : Grapes

Federal Institute for Risk Assessment, Thielallee 88 - 92
D-14195 Berlin
Federal Republic of Germany

Content of as (g/kg or g/L) : 500 g/kg
Formulation (e.g. WP) : WG
Commercial product (name) : Cantus (submitted to WN1 **005116-00**)
Applicant : BASF Aktiengesellschaft

Indoors / outdoors : Outdoors (Northern Europe)
Other as in formulation (common name and content) : --
Residues calculated as : Boscalid

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity / Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg as / ha	Water l / ha	kg as / hL						
	(a)	(b)				(c)		(a)		(d)	(e)
2003/1001357 DU2/13/02 DE-74193 Stetten a.H. 13.05.2004	Spät-burgunder	1) 20.10.98 2) 14.-28.06.02 3) 02.10.02	0.6	800	0.075	03.09.02	BBCH 83	grapes	0.38 0.33 0.35 0.41	0 21 28 35	RIP2004-901
2003/1001357 DU4/14/02 DE-67157 Wachenheim 13.05.2004	Riesling	1) 12.10.90 2) 01.-14.06.02 3) 25.09.02	0.6	800	0.075	19.08.02	BBCH 79	grapes	0.85 0.71 0.48 0.45	0 22 28 35	RIP2004-901
2003/1001357 FAN/15/02 FR-67560 Rosheim, Alsace FR-North	Chardonnay	1) 01.04.95 2) 10.-25.06.02 3) 17.-18.09.02	0.6	800	0.075	14.08.02	BBCH 79	grapes	1.26 1.12 0.79 0.91	0 21 29 35	RIP2004-901

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity / Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg as / ha	Water l / ha	kg as / hL						
	(a)	(b)				(c)		(a)		(d)	(e)
13.05.2004											
2003/1001357 FBM/12/02 FR-49190 Saint Aubin de Luigné FR-North 13.05.2004	Grolleau	1) 12.03.63 2) 18.-26.06.02 3) 30.09.02	0.6	800	0.075	03.09.02	BBCH 83	grapes	0.26 0.24 0.13 0.26	0 23 28 35	RIP2004-901
2004/1015915 DU2/06/03 DE-69168 Wiesloch 05.01.2006	Riesling	1) 01.10.85 2) 06.06.-20.06.03 3) 10.10.03	0.6	800	0.075	01.09.03	BBCH 85	grapes	0.19 0.24 0.23 0.20	0 21 28 35	RIP2005-2259
2004/1015915 DU4/06/03 DE-76831 Eschbach 05.01.2006	Spätburgunder	1) 10.05.93 2) 10.05.-20.05.03 3) 25.09.03	0.6	800	0.075	01.09.03	BBCH 83	grapes	0.79 1.03 0.43 0.51	0 21 28 35	RIP2005-2259
2004/1015915 FAN/03/03 FR- 67560 Rosheim FR-North 05.01.2006	Chardonnay	1) 01.04.95 2) 03.06.-15.06.03 3) 10.09.-18.09.03	0.6	800	0.075	13.08.03	BBCH 83	grapes	0.65 0.50 0.78 0.61	0 21 28 35	RIP2005-2259

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity / Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg as / ha	Water l / ha	kg as / hL						
	(a)	(b)				(c)		(a)		(d)	(e)
2004/1015915 FBM/02/03 FR- 49540 Martigné-Briand FR-North 05.01.2006	Chenin	1) 05.03.93 2) 17.06.-23.06.03 3) 22.09.03	0.6	800	0.075	27.08.03	BBCH 83	grapes	0.80 0.36 0.39 0.35	0 21 28 35	RIP2005-2259

Remarks:
- (a) According to CODEX Classification / Guide
- (b) Only if relevant
- (c) Year must be indicated
- (d) Days after last application (Label pre-harvest interval, PHI, underline)
- (e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Note: All entries to be filled in as appropriate

Table B.7.6-2 Residue trials grapes – Southern Europe

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Boscalid
Crop / crop group : Grapes

Federal Institute for Risk Assessment, Thielallee 88 - 92
D-14195 Berlin
Federal Republic of Germany

Content of as (g/kg or g/l) : 500 g/kg
Formulation (e.g. WP) : WG
Commercial product (name) : Cantus (submitted to WN1 **005116-00**)
Applicant : BASF Aktiengesellschaft

Indoors / outdoors : Outdoors (Southern Europe)
Other as in formulation (common name and content) : --
Residues calculated as : Boscalid

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity / Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg as / ha	Water l / ha	kg as / hL						
	(a)	(b)				(c)		(a)		(d)	(e)
2003/1001357 ALO/25/02 ES-41710 Utera Seville 13.05.2004	Cardenal	1) 15.02.87 2) 25.04-10.05.02 3) 15.-25.07.02	0.6	800	0.075	10.06.02	BBCH 79	grapes	0.53 0.19 0.23 0.12	0 21 28 35	RIP2004-901
2003/1001357 AYE/18/02 ES-11471 Jerez de la Frontera, Cadiz 13.05.2004	Palomino	1) 22.01.86 2) 25.04.-12.05.02 3) 10.08.-10.09.02	0.6	800	0.075	22.07.02	BBCH 81	grapes	0.23 0.24 0.20 0.21	0 21 28 35	RIP2004-901

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity / Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg as / ha	Water l / ha	kg as / hL						
	(a)	(b)				(c)		(a)		(d)	(e)
2003/1001357 ITA/22/02 IT-15058 Viguzzolo Piemonte 13.05.2004	Barbera	1) -- 2) 01-15.06.02 3) 10.-18.09.02	0.6	800	0.075	12.08.02	BBCH 83	grapes	1.96 1.26 1.35 1.47	0 22 28 35	RIP2004-901
O2/S/02 ES-41053 Lebrija, Cadiz 13.05.2004	Palomino	1) Jan. 1968 2) 20.04.-10.05.02 3) 20.08.02	0.6	785	0.075	23.07.02	BBCH 79-81	grapes	0.18 0.12 0.19 0.11	0 20 27 34	RIP2004-902
2003/1001357 FTL/18/02 FR-31620 Fronton FR-South	Negrette	1) 15.03.72 2) 12.-22.06.02 3)	0.6	800	0.075	14.08.02	BBCH 81	grapes	1.14 0.34 0.32 0.30	0 21 28 35	RIP2004-901
2004/1015915 FBD/01/03 FR- 26600 Pont de I‘Isére FR-South 05.01.2006	Syrah	1) 01.02.82 2) 04.05.-21.05.03 3) 01.09.-03.09.03	0.6	800	0.075	06.08.03	BBCH 85	grapes	0.69 0.78 0.58 0.34	0 21 28 35	RIP2005-2259
2004/1015915 ITA/02/03 IT- 15058 Viguzzolo 05.01.2006	Barbera	1) -- 2) 01.06.-15.06.03 3) 05.09.-15.09.03	0.6	800	0.075	07.08.03	BBCH 83	grapes	0.98 0.76 0.88 0.42	0 21 28 35	RIP2005-2259

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity / Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg as / ha	Water l / ha	kg as / hL						
	(a)	(b)				(c)		(a)		(d)	(e)
2004/1015915 ALO/02/03 ES- 41710 Utrera (Sevilla) 05.01.2006	Cardenal	1) 15.02.87 2) 05.05.-17.05.03 3) 17.07.-21.07.03	0.6	800	0.075	16.06.03	BBCH 79	grapes	0.40 0.47 <u>0.50</u> 0.34	0 21 28 35	RIP2005-2259
2004/1015915 ALO/13/03 ES- 41720 Los Palacios (Sevilla) 05.01.2006	Airen	1) 15.02.96 2) 30.04.-10.05.03 3) 11.08.-12.08.03	0.6	800	0.075	07.07.03	BBCH 81	grapes	0.22 0.16 <u>0.28</u> 0.09	0 21 28 35	RIP2005-2259

Remarks:
(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Note: All entries to be filled in as appropriate

MRL calculation grapes
In the tables all results which are used for MRL calculation are underlined.
PHI:28 d (if at later PHIs higher residues were found this values were chosen for calculation).

Northern Europe
Supporting residue data according critical GAP:

0.23, 0.26, 0.39, 0.41, 0.48, 0.51, 0.78, 0.91 mg/kg

STMR: 0.45 mg/kg HR: 0.91 mg/kg
Rmax = 1.26 mg/kg Rber = 1.43 mg/kg

Southern Europe
Supporting residue data according critical GAP:

0.19, 0.21, 0.23, 0.28, 0.32, 0.50, 0.58, 0.88, 1.47 mg/kg

STMR: 0.32 mg/kg HR: 1.47 mg/kg
Rmax = 1.80 mg/kg Rber = 1.46 mg/kg

Rmax and Rber are calculated according EU-document7039/VI/95 EN of 22/07/97

A MRL of 2 mg/kg grapes is proposed.

B.7.8 Livestock feeding studies (Annex IIA 6.4; Annex IIIA 8.3)

Report:	Stewart J. 2002(RIP2006-46) A meat and egg magnitude of the residue study with BAS 510 F in laying hens BASF Corporation Agro Research; Princeton NJ 08543-0400; United States of America unpublished BASF DocID 2002/5002466
GLP:	Yes (laboratory certified by United States Environmental Protection Agency)

Material and methods

Test System
56 white Leghorn hens (Gallus gallus), in the age of about 42 weeks old, in the weight range from 1311 g to 1953 g were used in the study. The average total egg production data were considered normal and during the quarantine and test periods, no statistically significant differences in egg production or egg quality were noted

Feeding and husbandry
All birds were individually housed in 18’ x 12’ x 16' metabolism cages. Feed consumption was recorded for each bird daily.

Selection of dose levels
This feeding study was designed and performed in the US and was based on the calculation of the feed burden due to the US situation, taking into account canola, peas, sunflower, and peanuts and estimated tolerance levels.

Based on these calculations, nominal dose levels were 1.0 mg/kg (1x dose level), 5.0 mg/kg (5x dose level) and 20 mg/kg (20x dose level).

Dose preparation
Animals were dosed via capsules. The bottom-half of the gelatin capsules were loosely packed with corn starch. The appropriate amount of a solution of the test substance was transferred into the capsule and the capsules were allowed to air-dry prior to sealing the capsules by moistening the rim of top half of the capsule with a wet cotton swab and placing the two halves together. The control capsules each contained corn starch only. The capsules were prepared weekly and were stored frozen prior to use. To confirm the concentration of the dose solutions, aliquots from the two dosing solutions were diluted with acetonitrile and analyzed by LC/MS/MS.

Dose administration
The animals were orally dosed via gelatin capsule once daily. The achieved daily intake is calculated in terms of mg/kg feed and absolute intake in mg/day and animal. Residue concentration in the diet [mg/kg] are listed in Table B.7.8-1:

Table B.7.8-1: Summary of Boscalid Dose Levels

Group Number	Dose Level	Nominal Residue Concentration in the Diet [mg/kg]
I	Control (12 hens)	NA
II	1x (12 hens)	1.0
III	5x (12 hens)	5.0
IV	20x (20 hens)	20.0

The dosing period was of 29 days duration. Beginning on test day -1, samples of eggs were collected twice daily. Overall, the birds appeared normal and active throughout the study. The hens were sacrificed within 24 hours after administration of the last dose. For each hen, representative samples of liver, fat and muscle were collected for analysis.

Sampling:
Beginning on test day -1, samples of eggs were collected on Study Days –1, 1, 3, 5, 7, 10, 14, 17, 21, 24, 28, 31, 35 and 38. The eggs were pooled within each subgroup. Egg yields were recorded; no treatment related effects upon egg production were observed.

Terminal procedures
The birds were humanely sacrificed via decapitation followed immediately by exanguination within 24 hours after the last dose. For each bird, the liver and samples of muscle and fat were collected. All samples were frozen immediately and were shipped frozen to BASF for analysis.

Findings:

Body weight
Many animals lost weight over the course of the treatment period. However, this occurred in all dose groups including the controls.

Residue analysis
Analysis of egg and tissue samples was carried out according to BASF Analytical Method No. 471/0 to determine residues of boscalid and its metabolite M510F01 (including its conjugates). These analytes were determined to be the relevant residue in eggs and tissues in the hen metabolism study. BASF Analytical Method No. 471/0 is based on several liquid/liquid partitions, a SPE-purification on C_{18} material and quantification by LC/MS/MS. The limit of quantitation for parent and the metabolite M510F01 is 0.01 mg/kg in egg and 0.025 mg/kg in tissues. During the study, procedural recovery data were analyzed for each matrix. The overall recovery at the LOQ for the analyses of parent averaged 69 ± 5 % (n = 5) for the egg sample recoveries, 66 % (65 %, 66 %, n = 2) for the muscle sample recoveries, 66 % (66 %, 66 %, n = 2) for liver sample recoveries and 74 % (64 %, 83 %, n = 2) for fat sample recoveries. The overall recovery at the LOQ for the analyses of M510F01 averaged 81 ± 12 % (n = 5) for the egg sample recoveries, 87 % (94 %, 79 %, n = 2) for the muscle sample recoveries, 86 % (98 %, 74 %, n = 2) for liver sample recoveries and 96 % (96 %, 95 %, n = 2) for fat sample recoveries. Fortifications ranged from 0.01 to 0.1 mg/kg for the egg matrices, and from 0.025 to 0.5 mg/kg for liver. Muscle, and fat matrices were fortified with 0.025 mg/kg. Samples from control test chickens were fortified with boscalid for these experiments.

Residues in eggs and tissues
As shown in Table B.7.8-2 and Table B.7.8-3 at the 1.0 mg/kg (1x) and 5.0 mg/kg (5x) dose levels, all egg samples resulted in residues < 0.02 mg/kg, Only the 20x treatment demonstrated enough residue to show a time dependence of the residue levels, egg residues were < 0.02 mg/kg through test Day 3, then increased at Day 5 to 7, and reached a plateau within the first two weeks of dosing. At the 20.0 mg/kg dose level (20x) the highest residue was 0.06 mg/kg. The remaining residues from this group ranged from < 0.02 mg/kg (six days depuration) to 0.03 mg/kg (2 days depuration. Chicken liver, fat and muscle tissues were analyzed for residues of BAS 510 F

and M510F01. There were no detectable residues > LOQ in any muscle samples from the three treatment groups. In liver, residues were < 0.05 mg/kg for the 1x dose group. Residues ranged from 0.11 to 0.18 mg/kg and from 0.32 to 0.47 mg/kg for the 5x and the 20x dose group, respectively. In fat, residues were < 0.05 mg/kg for the 1x dose group. In this matrix, residues ranged from 0.05 to 0.12 mg/kg and from 0.14 to 0.20 mg/kg for the 5x and the 20x dose group, respectively. The residues in all matrices were < LOQ after a depuration period of three days. All residue data for egg and tissue samples are summarized in Table B.7.8-2 and Table B.7.8-3.

Table B.7.8-2: Summary of Group Mean Egg Results (Residues of Boscalid and the Metabolite M510F01 (including its Conjugates) Determined by BASF Analytical Method No. 471/0)

Day of Study	**Group Mean Boscalid Residues in Eggs (mg/kg)**			
	Control	**Group II 1 x**	**Group III 5 x**	**Group IV 20 x**
-1	< 0.02	< 0.02	< 0.02	< 0.02
1	< 0.02	< 0.02	< 0.02	< 0.02
3	< 0.02	< 0.02	< 0.02	< 0.02
5	< 0.02	< 0.02	< 0.02	0.283
7	< 0.02	< 0.02	< 0.02	0.046
10	< 0.02	< 0.02	< 0.02	0.046
14	< 0.02	< 0.02	< 0.02	0.05
17	< 0.02	< 0.02	< 0.02	0.044
21	< 0.02	< 0.02	< 0.02	0.054
24	< 0.02	< 0.02	< 0.02	0.036
28	< 0.02	< 0.02	< 0.02	0.054
Depuration phase				
31	n.a.	n.a.	n.a.	0.03
35	n.a..	n.a.	n.a.	<0.02
38	n.a.	n.a.	n.a.	<0.02

If residue levels were below the level of quantitation then the LOQ value (0.02 mg/kg) was used in averaging
n.a. not analysed

Table B.7.8-3: Summary of Residue Levels in Tissues (Boscalid and its Metabolite M510F01 (including its conjugatees) Determined by BASF Analytical Method No. 476/0)

	Group Mean Boscalid Residue (mg/kg)		
	Muscle	**Liver**	**Fat**
Control (Group I)	< 0.05	< 0.05	< 0.05
Group II (1 x)	< 0.05	< 0.05	< 0.05
Group III (5 x)	< 0.05	0.14	0.08
Group IV (20 x)	< 0.05	0.41	0.18

The deep freeze stability of residues of boscalid in hen matrices was demonstrated.

Conclusion:
A residue transfer study with boscalid was conducted in hens. The animals were dosed with 1.0, 5.0 and 20 mg/kg feed (dry matter) for a period of 28 days. At the 1.0 mg/kg (1 x) and 5.0 mg/kg (5 x) dose levels, all egg samples resulted in residues < 0.02 mg/kg. At the 20 x dose level, the residues reached a plateau of about 0.05 mg/kg within 2 weeks of dosing. After a depuration of 7 days, all residues in eggs are < 0.02 mg/kg. Chicken liver, fat and muscle tissues were analyzed for boscalid residues. No residues accumulated in any of those matrices at a dose level of 1.0 mg/kg (1x). At the 5x and 20x dose level, all residues of boscalid were < 0.05 mg/kg in muscle. At the 5x dose level, the highest amounts of detected residues were 0.18 mg/kg and 0.12 mg/kg for liver and fat, respectively. At the 20x dose level, the highest residues were 0.47 mg/kg and 0.20 mg/kg for liver and fat, respectively. In all investigated matrices, the residue levels were under the limit of quantitation after the depuration phase of 3 days.

Calculation of residues to be expected in livestock

Livestock feeding studies are very expensive experiments which involves the consumption of animals. It is as well from the economical as from the ethical point of view unjustifiable to repeat such studies without strong necessity.
Therefore it is not only acceptable but also advisable to consider foreseeable developments in the near future when calculating the dietary burden and the dose level for feeding studies. Taking only into account the limited number of crops included in the DAR (”one safe use” concept) the dietary burden would be unrealistic and the results of an adequate feeding study would not cover the use of the active substance already registered in Europe. Therefore the following calculation of the dietary burden (Table B.7.8-4) was done on basis of all available information including knowledge from the German national registration process.

Estimation of exposure of livestock

The estimation of the dose of boscalid which may be fed to animals is done on basis of relevant residue data in potential feeding stuff. Possible additional residues in crops grown in rotation are included. (see footnote).

Table B.7.8-4: Maximum intake of boscalid for cows, cattle, hens and pigs

	% DM (Dry matter)	Hen	Cow	Cattle	Pig	Residue mg/kg	Intake (mg/kg feed (DM))			
							Hen	Cow	Cattle	Pig
Body weight		1,9 kg	550 kg	350 kg	75 kg					
Maximum daily feed intake (mg/kg DM)		120 g	20 kg	15 kg	3 kg					
Maximum Percentage		% DM	% DM	% DM	% DM					
I. Gree forage (inkl. Hay)										
Hay	85,000		30,000			1,680 [1]		0,593		
II. Cereals										
Cereals, except Maize	86,000	35,000				0,500 [2]	0,203			
Bran (Wheat and Rye)	89,000	15,000				0,560 [3]	0,094			
III. Straw	86,000		20,000	50,000		34,89 [4]		8,114	20,285	
IV. Pulses	86,000	30,000	20,000		40,000	2,000 [5]	0,698	0,465		0,930
V. Roots and Tubers (e.g. Potatoes)	15,000	20,000	30,000	50,000	60,000	0,500 [6]	0,667	1,000	1,667	2,000
Maximum Intake (mg/kg Feed-DM)							1,662	10,172	21,952	2,930
Maximum Intake (mg/kg KG)							0,105	0,370	0,941	0,117
Maximum Intake (mg per animal)							0,199	203,440	329,273	8,791

[1] Maximum residue in hay grown in rotation. [2] MRL proposed for wheat, rye, barley [3] MRLs for cereals in consideration of processing studies. [4] maximum residue to be expected cereal straw. Sum of maximum residues in residue trials (HR: 26.9 mg/kg) and in crop rotation trials (HR: 7.99 mg/kg). [5] MRL proposed for beans with pods [6] MRL proposed for other commodities of plant origin in consideration of crop rotation.

The maximum dietary burden of 10.2 and 22 mg/kg in cow and cattle which represents a worst case (use of cereal straw as feeding stuff with highest residues and additional residues from crop rotation) is below / in the magnitude of the highest dosage applied to cows in the feeding study. Therefore it is reasonable to derive MRLs for food of animal origin from this dosage group (highest residues):

Table B.7.8-5: Residues in cow matrices

Matrix	Dosage II (5.91 mg/kg DM)	Dosage III (20.16 mg/kg DM)
Milk	< 0.05 mg/kg	0.05 mg/kg
Cream	0.12 mg/kg	0.34 mg/kg
Muscle	< 0.05 mg/kg	< 0.05 mg/kg
Fat	0.11 mg/kg	0.27 mg/kg
Liver	0.06 mg/kg	0.18 mg/kg
Kidney	0.07 mg/kg	0.24 mg/kg

Since there is no significant difference in the metabolism of boscalid in rats and ruminants (goat) no additional feeding study with pig is necessary. The maximum dietary burden calculated for pigs is in the magnitude of approximately half of the second dosage group of the cow feeding study.

For poultry a feeding study was submitted recently:

Table B.7.8-6: Residues in hen matrices

Matrix	Dosage I (1.02 mg/kg DM)	Dosage II (5.31 mg/kg DM)	Dosage III (19.63 mg/kg DM)
Eggs	< 0.02 mg/kg	< 0.02 mg/kg (day 14)	0.07 mg/kg (day 21)
Liver	0.05 mg/kg	0.18 mg/kg	0.47 mg/kg
Muscle	< 0.05 mg/kg	< 0.05 mg/kg	< 0.05 mg/kg
Fat	< 0.05 mg/kg	0.12 mg/kg	0.20 mg/kg

The calculated maximum dietary burden for hens (1.66 mg/kg DM) is slightly higher than the minimum dosage in the feeding study (1.02 mg/kg DM). Therefore is can be concluded that there are no residues in meat and eggs to be expected above the LOQ of 0.05 mg/kg and 0.02 mg/kg respectively. In liver and fat residues are to be expected which are below 0.1 mg/kg.

Proposed MRLs for food of animal origin

0,3 mg/kg	kidney (cow), fat (cow)
0,2 mg/kg	liver (cow)
0,1 mg/kg	liver (poultry, pork), fat (poultry, pork), kidney (pork)
0,05 mg/kg	milk, beef
0,02 mg/kg	eggs

B.7.9 Residues in succeeding or rotational crops (Annex IIA 6.6; Annex IIIA 8.5)

The active substance boscalid is relatively stable (persistent) in plant and soil. Boscalid can be absorbed from soil by plants and there is readily systemic transport of the active substance itself within plants. The available studies on rotational crops clearly indicate that there is a potential for residues in crops grown in rotation. To avoid possible problems with residues in crops which are not treated with plant protection products containing boscalid as well in monitoring as in the dietary risk assessment special measures are proposed.
It is necessary to establish MRLs which are high enough to cover possible residues in most rotational crops. The following cases should be distinguished

- The residue level in known from direct foliar application either by residue trials or by extrapolation according EU-document 7525/VI/95-rev.7, 12/6/2001. It can be assumed that the resulting MRL will cover possible additional rotational effects.

⇒ MRL derived from normal residue trials

- The residue level is known from rotational crop studies (field trials).

  ⇒ MRL derived from rotational crop studies

- There are no informations about possible residues

  ⇒ MRL is set on a default value of 0.5 mg/kg.
  This value will cover possible residues in most rotational crops. Nevertheless the results in cereal straw show that there may be some commodities with even higher residues (assumedly crops with slow growth and low weight like some (dry) herbs). These crops should be excluded from crop rotation by label instructions which should lay in the responsibility of the notifier.

The notifier has announced that boscalid will be developed for applications in a wide range of crops. In many crops there are already national applications. Therefore the number of default MRLs will be reduced in future. The dietary risk assessment shows that even in consideration of the default value of 0.5 mg/kg for most crops no risks for consumers are to be expected.

B.7.15 Estimates of potential and actual dietary exposure through diet and other means (Annex IIA 6.9; Annex IIIA 8.8)

Cronic dietary risk assessment
The dietary risk assessment is based on an ADI value of 0.04 mg/kg bw/d.
Meanwhile the active substance boscalid is on the market for some years. Therefore it seems to be appropriate to calculate the potential dietary exposure not only on basis of the uses reported in this monograph but to use also information from the German national registration procedure.
Currently the following values are proposed as MRLs for boscalid:

plant origin:

10 mg/kg	lettuce
3 mg/kg	strawberries, leek
2 mg/kg	grapes, beans with pods (fresh)
1 mg/kg	cherries, peaches and nectarines, apricots, carrots
0.5 mg/kg	plums
0.2 mg/kg	cucurbits with edible peel
0.05 mg/kg	rape seed, asparagus

Where no MRL is proposed a value of 0.5 mg/kg other products of plant origin is used in the calculation to cover possible residues in rotational crops (see B.7.9)

animal origin (see B7-8):

0,3 mg/kg	kidney (cow), fat (cow)
0,2 mg/kg	liver (cow)
0,1 mg/kg	liver (poultry, pork), fat (poultry, pork), kidney (pork)
0,05 mg/kg	milk, beef
0,02 mg/kg	eggs

Where no MRL is proposed a value of 0.05 mg/kg other products of animal origin is used in the calculation.

Table B.7.15-1: TMDI calculation – German diet

Active substance:	Boscalid	Total intake (mg/kg bw):	0,0251
ADI (mg/kg bw):	0,04	Percent ADI:	**62,75**
ARfD (mg/kg bw):	no ARfD	Method of calculation:	TMDI
Mean bodyweight (kg):	16,15		

Commodity	Mean diet (g/d)	MRL (mg/kg)	Intake (mg/kg bw)	Commodity	Mean diet (g/d)	MRL (mg/kg)	Intake (mg/kg bw)
Milk	230,8	0,05	0,0007146	Lamb´s lettuce, raw	0,1	0,5	3,096E-06
Cheese	8,7	0,3	0,0001616	Cress, total*	0,1	0,5	3,096E-06
Ewe's cheese	0,4	0,3	7,43E-06	Dandelion, processed*	0,1	0,5	3,096E-06
Goats cheese	0,1	0,3	1,858E-06	Arugula, total*	0,1	0,5	3,096E-06
Butter	8,9	0,3	0,0001653	Other lettuce species, raw	1	10	0,0006192
Single Cream	7,4	0,3	0,0001375	Other lettuce species, processed*	0,1	10	6,192E-05
Curd cheese / cottage cheese	14,8	0,3	0,0002749	Spinach and related species	3,4	0,5	0,0001053
Milk protein*	0,1	0,05	3,096E-07	Watercress*	0,1	0,5	3,096E-06
Other milk products	37,3	0,05	0,0001155	Chicory leaves, raw*	0,1	0,5	3,096E-06
Eggs	18	0,02	2,229E-05	Fresh herbs	0,7	0,5	2,167E-05
Beef	4,7	0,05	1,455E-05	Beans (pods and succulent immature seeds), processed	1,1	2	0,0001362
Veal	0,4	0,05	1,238E-06	Beans, shelled, processed	0,4	0,5	1,238E-05
Pork	7	0,05	2,167E-05	Peas (pods and succulent immature seeds), total*	0,1	0,5	3,096E-06
Lamb/mutton	0,2	0,05	6,192E-07	Peas, shelled, processed	2,1	0,5	6,502E-05
Rabbit	0,1	0,05	3,096E-07	Soybean sprouts, total*	0,1	0,5	3,096E-06
Chicken	5,5	0,05	1,703E-05	Alfalfa sprouts, raw*	0,1	0,5	3,096E-06
Duck	0,1	0,05	3,096E-07	Mungo bean sprouts total*	0,1	0,5	3,096E-06
Goose	0,1	0,05	3,096E-07	Chick peas, processed*	0,1	0,5	3,096E-06
Turkey	3,8	0,05	1,176E-05	Lentils fresh, processed	0,7	0,5	2,167E-05
Ostrich*	0,1	0,05	3,096E-07	Artichokes, processed*	0,1	0,5	3,096E-06
Hare*	0,1	0,05	3,096E-07	Bamboo shoots, processed*	0,1	0,5	3,096E-06
Venison of roe deer *	0,1	0,05	3,096E-07	Fennel, total	0,2	0,5	6,192E-06
Venison of red deer *	0,1	0,05	3,096E-07	Leek, total	1	3	0,0001858
Wild boar*	0,1	0,05	3,096E-07	Rhubarb, total	0,2	0,5	6,192E-06
Mallard*	0,1	0,05	3,096E-07	Asparagus,	0,3	0,05	9,288E-07

				processed			
Offals	0,1	0,3	1,858E-06	Celery, total*	0,1	0,5	3,096E-06
Processed meat products	24,5	0,05	7,585E-05	Mushrooms	1,3	0,5	4,025E-05
Fish	5,6	0,05	1,734E-05	Pulses	0,1	0,5	3,096E-06
Honey	1,6	0,05	4,954E-06	Oilseeds	3,1	0,5	9,598E-05
Citrus fruit	74,2	0,5	0,0022972	Potatoes	41,4	0,5	0,0012817
Nuts	2,4	0,5	7,43E-05	Tea	0,1	0,5	3,096E-06
Pome fruit	205,3	0,5	0,006356	Tealike products	0,7	0,5	2,167E-05
Apricots, total	5,9	1	0,0003653	Buckwheat, total *	0,1	0,5	3,096E-06
Cherries, total	5,8	1	0,0003591	Barley, total	0,2	0,5	6,192E-06
Peaches and nectarines, total	4,3	1	0,0002663	Oat, total	3,3	0,5	0,0001022
Plums, total	1,5	0,5	4,644E-05	Sorghum, total	0,3	0,5	9,288E-06
Table grapes, total	20,5	2	0,0025387	Maize, total	2,4	0,5	7,43E-05
Strawberries, total	7,9	3	0,0014675	Rye, total	12,8	0,5	0,0003963
Blackberries, total	0,1	0,5	3,096E-06	Rice, total	4,3	0,5	0,0001331
Raspberries, total	0,9	0,5	2,786E-05	Wheat, total	66,4	0,5	0,0020557
Blueberries, total	0,2	0,5	6,192E-06	Spelt grain, total	0,2	0,5	6,192E-06
Currants, total	1,3	0,5	4,025E-05	Cereal products (without produce of milling and crushing)	0,2	0,5	6,192E-06
Cranberries, processed*	0,1	0,5	3,096E-06	Spices	0,6	0,5	1,858E-05
Gooseberries, total	0,1	0,5	3,096E-06	Cocoa mass	2,1	0,5	6,502E-05
Other small fruits, portion in juice*	0,1	0,5	3,096E-06	Cocoa butter	0,8	0,5	2,477E-05
Rose hips, processed*	0,1	0,5	3,096E-06	Cocoa powder	1,8	0,5	5,573E-05
Elderberries, total	0,6	0,5	1,858E-05	Raw coffee*, total	0,1	0,5	3,096E-06
Sloe, portion in juice	0,1	0,5	3,096E-06	Starch	1,6	0,5	4,954E-05
Sea buckthorn, portion in juice*	0,1	0,5	3,096E-06	Amaranth	0,1	0,5	3,096E-06
Miscellaneous fruit	40,8	0,5	0,0012632	Molasses	0,3	0,5	9,288E-06
Carrots, total	16,6	1	0,0010279	Wine	0,2	0,5	6,192E-06
Root celery, total	0,7	0,5	2,167E-05	Quinoa*	0,1	0,5	3,096E-06
Swede, processed*	0,1	0,5	3,096E-06	Coconut oil	0,9	0,5	2,786E-05
Horseradish, processed*	0,1	0,5	3,096E-06	Palm oil	0,2	0,5	6,192E-06
Parsnip, processed	0,1	0,5	3,096E-06	Corn oil*	0,1	0,5	3,096E-06
Parsley root, total	0,1	0,5	3,096E-06	Grape kernel oil*	0,1	0,5	3,096E-06
Red radish, raw	0,2	0,5	6,192E-06	Soya products	0,2	0,5	6,192E-06
White radish, total	0,1	0,5	3,096E-06	Maple syrup	0,1	0,5	3,096E-06
Beetroot, total	0,3	0,5	9,288E-06	Maple syrup, portion in cream*	0,1	0,5	3,096E-06
Black salsifies, processed*	0,1	0,5	3,096E-06	Corn syrup*	0,1	0,5	3,096E-06
Bulb vegetables	3,1	0,5	9,598E-05	Licorice juice concentrate*	0,1	0,5	3,096E-06
Solanacea	20,3	0,5	0,0006285	Fig syrup*	0,1	0,5	3,096E-06
Cucurbits with edible	10,5	0,2	0,00013	Elder berry	0,1	0,5	3,096E-06

peel				blossoms			
Cucurbits with in-edible peel	3,9	0,5	0,0001207	Water chestnut*	0,1	0,5	3,096E-06
Sweet corn, processed	1,1	0,5	3,406E-05	Vine leaf, processed*	0,1	0,5	3,096E-06
Brassica vegetables	7,9	0,5	0,0002446	Carob*	0,1	0,5	3,096E-06
Endive, raw	0,2	0,5	6,192E-06				

Table 7.15-2: TMDI calculation – WHO diet

TMDI-CALCULATION

Active substance: Boscalid
ADI (mg/kg bw): 0,04

Mean food consumption in g/d (WHO European diet (1998))

Food	Consumption (g/day)	MRL (mg/kg)	Intake (mg/kg bw)
FOOD OF PLANT ORIGIN	*1253,4*		
1. FRUITS AND TREE NUTS	*287,8*		
(i) Citrus fruit	*49,1*	0,50	0,00040917
(ii) Tree nuts	*4,1*	0,50	0,00003417
(iii) Pome fruit	*51,4*	0,50	0,00042833
(iv) Stone fruit	*23,3*		
Apricots	3,5	1,00	0,00005833
Cherries	3,0	1,00	0,00005000
Peaches (including nectarines and similar hybrids)	12,5	1,00	0,00020833
Plums	4,3	0,50	0,00003583
(v) Berries and small fruit[1]	*121,2*		
a) Table and wine grapes	*113,8*	2,00	0,00379333
b) Strawberries	5,3	3,00	0,00026500
c) Cane fruit	*0,5*	0,50	0,00000417
d) Other small fruit and berries	*1,6*	0,50	0,00001333
e) Wild berries and wild fruit		0,50	0,00000000
(vi) Miscellaneous fruit	*38,7*	0,50	0,00032250
2. VEGETABLES	*339,0*		
(i) Root and tuber vegetables	*36,3*		
Beetroot	2,0	0,50	0,00001667
Carrots	22,0	1,00	0,00036667
Celeriac[4]	2,0	0,50	0,00001667
Horseradish		0,50	0,00000000
Jerusalem artichokes		0,50	0,00000000
Parsnips	2,0	0,50	0,00001667
Parsley root		0,50	0,00000000
Radishes	2,0	0,50	0,00001667
Salsify		0,50	0,00000000
Sweet potatoes	1,3	0,50	0,00001083
Swedes	2,0	0,50	0,00001667
Turnips	2,0	0,50	0,00001667
Yams		0,50	0,00000000
Chicory roots	1,0	0,50	0,00000833

(ii) Bulb vegetables	*31,8*	0,50	0,00026500
(iii) Fruiting vegetables	*129,1*		
a) Solanacea	*78,7*	0,50	0,00065583
b) Cucurbits with edible peel	*12,5*	0,20	0,00004167
c) Cucurbits with inedible peel	*29,6*	0,50	0,00024667
d) Sweet corn	8,3	0,50	0,00006917
(iv) Brassica vegetables	*47,4*	0,50	0,00039500
(v) Leaf vegetables and fresh herbs	*51,3*		
a) Lettuce and similar	*47,0*		
Cress		0,50	0,00000000
Lambs lettuce		0,50	0,00000000
Head lettuce	22,5	10,00	0,00375000
Leaf lettuce	22,5	10,00	0,00375000
Scarole (broad-leaf endive)	2,0	0,50	0,00001667
b) Spinach and similar	*2,1*	0,50	0,00001750
c) Watercress	0,1	0,50	0,00000083
d) Chicory (Witloof)	2,0	0,50	0,00001667
e) Herbs	*0,1*	0,50	0,00000083
(vi) Legume vegetables (fresh)	*26,0*		
Beans	12,0	0,50	0,00010000
Peas	14,0	2,00	0,00046667
(vii) Stem vegetables	*13,1*		
Asparagus	1,5	0,05	0,00000125
Cardoons		0,50	0,00000000
Celery	2,0	0,50	0,00001667
Fennel	0,1	0,50	0,00000083
Globe artichokes	5,5	0,50	0,00004583
Leeks	2,0	3,00	0,00010000
Rhubarb	2,0	0,50	0,00001667
(viii) Fungi	*4,0*	0,50	0,00003333
3. PULSES	*9,4*	0,50	0,00007833
4. OIL SEEDS	*28,3*	0,50	0,00023583
5. POTATOES	240,8	0,50	0,00200667
6. TEA	2,3	0,50	0,00001917
7. HOPS[2]	4,9	0,50	0,00004083
8. CEREALS	*223,3*	0,50	0,00186083
9. SPICES (without ginger)	0,4	0,50	0,00000333
10. GINGER	0,1	0,50	0,00000083
11. TEA LIKE PRODUCTS		0,50	0,00000000
12. COCOA BEANS	3,1	0,50	0,00002583
13. SUGAR BEET	106,1	0,50	0,00088417
14. COFFEE BEANS	7,9		
FOOD OF ANIMAL ORIGIN	*610,0*		
(i) Eggs	*37,5*	0,02	0,00001250
(ii) Milk	*342,6*	0,05	0,00028550
(iii) Meat	*205,3*	0,05	0,00017108
(iv) Edible offals	*12,6*		
Edible offals of cattle	6,0	0,20	0,00002000
Edible offals of sheep	1,3	0,05	0,00000108
Edible offals of goat		0,05	0,00000000
Edible offals of pig	5,0	0,10	0,00000833
Edible offals of chicken	0,3	0,10	0,00000050
(v) Fat	*10,7*		
Chicken fat	0,3	0,10	0,00000050
Pig fat	7,3	0,10	0,00001217
Others	3,1		
(vi) Honey	1,3	0,05	0,00000108

Intake whole (mg/kg bw): 0,021784

Percent of ADI (%): 54,46

Explanations:

1. strawberries, cane fruit and other small fruit and berries without wild fruit and wild berries
2. value from German food consumption
3. 31st session of the CCPR
4. value from 1994 table

Conclusion:
The calculation of the TMDI on basis of residue data presented in the DAR and in the German national registration process leads to a utilisation of the ADI of 58 % (German diet, child with 16,15 kg bw, VELS) and 54 % (WHO diet). Therefore a refined risk assessment (NEDI, IEDI) is not necessary at the moment.
A chronic dietary risk for consumers is highly unlikely.

Acute dietary risk assessment
Since there is from the toxicological point of view no need to set an ARfD there is no need to conduct an acute dietary risk assessment.
An acute dietary risk for consumers is highly unlikely.

B.8 Environmental fate and behaviour

B.8.1 Route and rate of degradation in soil (Annex IIA 7.1.1; Annex IIIA 9.1.1)

B.8.1.3 Soil accumulation study

Annex Point:	IIA-7.1.1.2.2/1
Author:	Kellner, O. Grote, C. and Platz, K.
Title:	Accumulation behaviour of BAS 510 F under field conditions over a 5-year-period (1998-2003) after application onto grapes in a vineyard
Date:	07.09.2004
Doc ID:	2004/1003851; BOD 2005-906
Guidelines:	SETAC, BBA IV, 4-1, IVA-Leitlinie
GLP:	yes
Valid:	yes

The accumulation behaviour of BAS 510 F under field conditions was investigated over a 5- year-period from 1998 to 2003 after application onto grapes in a vineyard. The trial was conducted at a site in Germany in Rhineland Palatinate (Rheinland-Pfalz). The soil was a loamy sand/sandy loam with a pH value of 7.5, an organic carbon content of 1.2 %, a cation exchange capacity of 15 meq/100 g dry soil and a maximum water holding capacity of 40 g water/100 g dry soil.
The nominal application rates were 3 times 700 g active substance/ha sprayed onto grapes at BBCH growth stages 67, 77 and 81. The amounts of products actually applied were determined by measuring the volumes in the tank before and after application. The rates were always between 680 and 735 g as/ha and therefore very near to the nominal rates.
BAS 510 KA F (1998) or BAS 510 01 F were always applied onto grapes with a gasoline powered mistblower with nominal amounts of spray mixture of 600, 700 and 800 L/ha at the respective growth stages (Table B.8.1-1).

Table B. 8.1-1: Application parameters of BAS 510 F in grapes

Appl. No.	Date	DAFT	Formulation	BBCH	Spray mixture L/ha	Product L/ha or kg/ha	as nominal g/ha
1	19.06.1998	0	BAS 510 KA F	67	598	1.39	700
2	28.07.1998	39	BAS 510 KA F	77	694	1.39	695
3	18.08.1998	60	BAS 510 KA F	81	777	1.36	680
4	17.06.1999	363	BAS 510 01 F	67	584	1.36	680
5	27.07.1999	403	BAS 510 01 F	77	693	1.39	695
6	18.08.1999	425	BAS 510 01 F	81	841	1.47	735
7	16.06.2000	728	BAS 510 01 F	67	605	1.41	705
8	24.07.2000	766	BAS 510 01 F	77	723	1.45	725
9	16.08.2000	789	BAS 510 01 F	81	835	1.46	730
10	20.06.2001	1097	BAS 510 01 F	67	616	1.44	720
11	26.07.2001	1133	BAS 510 01 F	77	712	1.42	710
12	23.08.2001	1161	BAS 510 01 F	81	803	1.41	705
13	26.06.2002	1468	BAS 510 01 F	67	590	1.38	690
14	29.07.2002	1501	BAS 510 01 F	77	711	1.42	710
15	21.08.2002	1524	BAS 510 01 F	81	832	1.46	730
16	12.06.2003	1819	BAS 510 01 F	67	619	1.45	725
17	16.07.2003	1853	BAS 510 01 F	77	694	1.39	695
18	05.08.2003	1873	BAS 510 01 F	81	822	1.44	720

DAFT = days after first treatment

The precipitation and distribution of the spray broth on the plots at the time of application was determined at the first application with a method using Petri dishes filled with soil. It can be concluded from the results that the spray broth reaching the soil via application is uniformly distributed throughout the plots. Additionally, the volume of the spray broth was kept small to avoid the formation of droplets rinsing off the leaves. Therefore it was decided, to take the soil cores from 1998 to 2000 as 3 replicates within a subplot at random, but for practical reasons not closer than 45 cm to the vines. In April 2000 the distribution of the soil residues within the subplots was determined after 3 years of BAS 510 F application and cultivation according to good agricultural practice. The results revealed that the soil residue were lowest right in the middle between the grape vines rows. Therefore, from the season 2001 on, the sampling pattern within the subplots was modified. The core area between the rows of ca. 70 cm was not sampled. All samples were taken at a maximum distance of 60 cm from the trunk of the vine.

Soil samples (soil cores) were taken down to a depth of 25 cm routinely three times a year, once before the first application, once after the last application in August and once in October. Results up to sampling 16 in June 2003 are reported. The samples were separated in layers of 0 to 10 and 10 to 25 cm (until sampling 9) and in layers of 0 to 10, 10 to 20 and 20 to 25 cm from sampling 10 onwards. The leaves and the plant material that was cut off the vines due to agricultural management were left on the plots. The grapes were harvested.

Replicate samples were analysed for BAS 510 F by BASF method 408/1. No corrections, neither for recoveries nor blanks, have been made, but all results were corrected for moisture content of the soil. The recoveries from n = 42 measurements of fortified samples had a mean value of 98.9 % with a relative standard deviation of 14 %. This proves the quality and repeatability of the method.

Control samples from untreated plots were analysed from sampling before application. As expected, all the soil samples from replicates 1 and 3 were free of residues of BAS 510 F. However, the 2 samples from replicate 2 (also prior to the first application) contained BAS 510 F, especially in the 10 to 25 cm layer. This was explained by accidental contamination of the samples. Overall, the data demonstrate that no interferences of the sample material with the analytical procedure occurred and that the control plots were free of residues of BAS 510 F.

By far the highest amounts of residues of BAS 510 F were detected in the 0 – 10 cm soil layers. Up to sampling no. 4, only very minor quantities above the LOQ were found in the 10 - 25 cm soil layer. At later samplings, the residue level in the 10 - 25 cm layer increased slightly due to agricultural engineering of the plots. Therefore, it was decided to separate the soil cores into increments of 0 - 10, 10 - 20 and 20 – 25 cm starting with the season 2001 to get a clearer picture of the distribution of BAS 510 F with respect to soil depth.

The residues observed in the different soil layers were converted from mg/kg to kg/ha under consideration of the following equation. Residues lower than the determination limit (< 0.01 mg/kg) were treated as 0 mg/kg.

$$c_{kg/ha} = c_{mg/kg} * 10^{-6} * d * \sigma * A$$

where
d = depth of the considered soil layer (0.1 or 0.15 or 0.05) [m]
σ = soil bulk density (1500 kg/m^3) [kg/m^3]
A = considered area (1 ha) [m^2]

The residues of the associated soil layers of each soil core converted to kg/ha were summed up. The mean values of the different replicates of each sampling date were calculated and used for the estimation approach. The model data used for the estimation approach are given in Table B.8.1-2.

Table B. 8.1-2: Analytical results: BAS 510 F residues in soil (sum of the different layers of each soil core, given in kg as/ha)

Sampling date	DAFT	Replicate 1	DAFT	Replicate 2	DAFT	Replicate 3	mean of replicates used for estimation
20.08.1998	62	0.480	62	0.443	62	0.552	0.492
26.10.1998	129	0.386	129	0.498	129	0.497	0.460
09.06.1999	355	0.612	355	0.824	355	0.661	0.699
19.08.1999	426	1.884	426	1.993	426	1.799	1.892
27.10.1999	495	1.312	495	1.918	495	0.895	1.375
15.06.2000	727	1.457	727	1.932	727	0.977	1.455
29.08.2000	802	2.174	802	1.879	802	1.931	1.994
25.10.2000	859	2.231	859	2.430	8.59	1.518	2.060
07.06.2001	1084	2.017	1084	2.600	1084	1.683	2.100
24.08.2001	1162	2,848 1)	1162	3.478	1162	2.428 1)	2.918
22.10,2001	1221	3.167	1221	3.811	1221	1.916	2.964
12.06.2002	1454	2.834	1454	3.138	1454	2.267	2.746
22.08.2002	1525	6.317	1525	7.083	1525	4.445	5.948 2)
28.10.2002	1592	2.824	1592	2.822	1592	2.811	2.819
05.06.2003	1812	2.312	1812	3.218	1812	1.880	2.470

DAFT =day after first treatment

1) As no samples for the soil layers 10 cm - 20 cm and 20 cm - 25 cm were taken at replicates 1 and 3, the analysed residues of the comparable layers of replicate 2 are considered.

2) The residue observed at sampling time 22.08.2002 was assessed to be an outlier. Because of steady dissipation between the single applications and likely crop interception, the expected increase should be clearly less than the nominal annual application rate, whereas the measured increase was nearly the double of the nominal annual application rate. The measured residue was therefore not considered for the modelling approach.

A simple biphasic estimation model was established using of the software tool ModelMaker (v.3 patch 3.0.4), in order to investigate if the residue in soil has reached its steady state concentration (steady state level) within the study period.

As the field accumulation study was executed with a regular application procedure with similar application rates and similar application times each year, one can expect a steady increase of the soil concentration up to the maximum level. When the plateau concentration is reached, the annual dissipation rate corresponds to the annual application rate of the pesticide. The chosen biphasic estimation model describes this accumulation behaviour in principle. It reflects the initial concentration at the day of first application, a time period with a linear increase of the residue concentration and a hinge point were the maximum concentration is reached and remains at steady state. The initial concentration, a constant b that describes the linear increase and the hinge point a (time point at steady state) were estimated/optimised under consideration of the observed residues.

$$c(t) = \begin{cases} c_0 + b * t & \text{for } 0 \le t \le a \\ c_{plateau} = c_0 + b * a & \text{for } t > a \end{cases}$$

where
c(t) = concentration at time t [kg/ha]

c_0 = initial concentration after the first application [kg/ha]
b = linear slope constant [kg/ha/d]
a = time point of steady state (”hinge point”) [d]
$c_{plateau}$ = plateau concentration at steady state [kg/ha]
t = time [d]

The hinge point a (time to reach steady state) was estimated with 1220 days. The related standard deviation of 138 days and type-I error rate of < 0.001 are low and give evidence of a successful and significant estimation of the hinge point (see also Figure 8.1-1). The last sampling point was taken at day 1812 after first treatment (DAFT), whereas the estimated hinge point is calculated much lower with 1220 DAFT. It was thus concluded that the steady state level was reached within the study period.

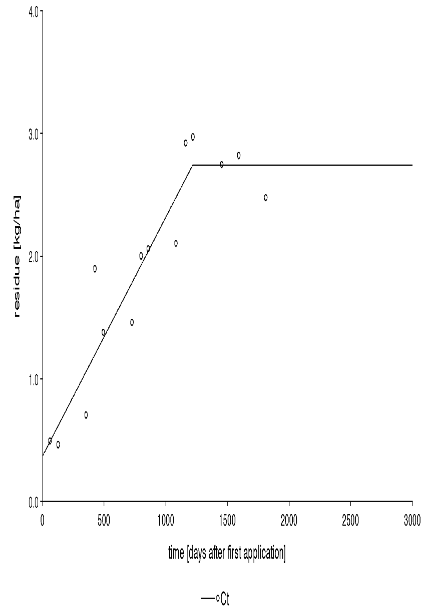


Figure B. 8.1- 1: Result of fitting a biphasic curve to the observed residue data

A second modelling approach was established to estimate the minimum and maximum soil concentrations of the field accumulation study. Those are mainly influenced by the application rates, interception of the cultivated crop (grapevine) and pesticide re-entry into the soil layer through residues in or on leaves. The dissipation behaviour in soil does also play a significant role for the accumulation behaviour of BAS 510 F. All those influences are considered in this modelling approach. To prevent an over-parameterisation of the estimation model, the dissipation rate was fixed to a realistic average amount deduced from a previous dissipation study. The model entry values that consider the different application rates and application times were deduced from the actual application procedure. As the amount and time point of pesticide re-entry due to leaf residues varies over the whole study period, an average value was estimated. The re-entry (fraction of intercepted amount) was estimated under consideration of the observed residues by use of the software tool ModelMaker (v.3 patch 3.0.4). As the input parameters of the model are based on mean values and as the actual daily climatic conditions were not considered, this modelling approach describes the average accumulation behaviour of BAS 510 F.

It was assumed that the whole pesticide entry occurs at the day of the application event. The interception amount depends on the different growth stages of the cultivated crop. The interception amounts considered for this estimation approach are based on recommendations of FOCUS. The resulting pesticide soil entry considered in this estimation approach is the sum of the nominal application rate minus the respective crop interception plus the estimated fraction of re-entry of the intercepted amount due to leaf residues.

$$c(t_1) = c(t_2) + A - (A * f_{\text{int}}) + (A * f_{\text{int}} * f_{re-entry})$$

where
$c(t_1)$ = concentration at time after application [kg/ha]
$c(t_2)$ = concentration at time before application [kg/ha]

A	=	nominal application rate (fixed)	[kg/ha]
f_{int}	=	FOCUS crop interception (fixed)	-
$f_{re\text{-}entry}$	=	fraction of re-entry of the intercepted amount (estimated)	-

The application rates and the application times considered for the modelling approach are given in Table B.8.1-1. The respective crop interception amounts for BBCH 67, 77 and 81 are set as 0.7, 0.7 and 0.85, respectively.

Dissipation according to single first order kinetics was considered for this modelling approach. The trial site of the field accumulation study was located in Grünstadt/Rhineland Palatinate. Therefore the dissipation behaviour investigated in a field dissipation study Schifferstadt/Rhineland Palatinate with comparable climatic conditions was considered for the modelling approach. As the respective half-life of 212 d was normalised to a standard temperature of 20° C, it had to be adapted to a realistic mean temperature of 10 °C of the accumulation study. The half-life was thus recalculated using the Arrhenius equation as recommended by FOCUS with a Q10 value of 2.2.

$$HL_{10°C} = HL_{20°C} * Q_{10}^{(20°C-10°C)/10}$$

The resulting half-life considered for the modelling approach was 466 d (degradation rate constant 0.0015 d^{-1}).

The second modelling approach yielded minimum and maximum plateaus of 2000 g as/ha and 3100 g as/ha, respectively (as graphically depicted in Figure B.8.1-2). However, these amounts cannot be used directly for the risk assessment, since the accumulation study was performed with a higher number of applications and dose rates for BAS 510 F in grapes (3 × 700 g as/ha) than relevant for the EU risk assessment now (1 × 600 g as/ha).

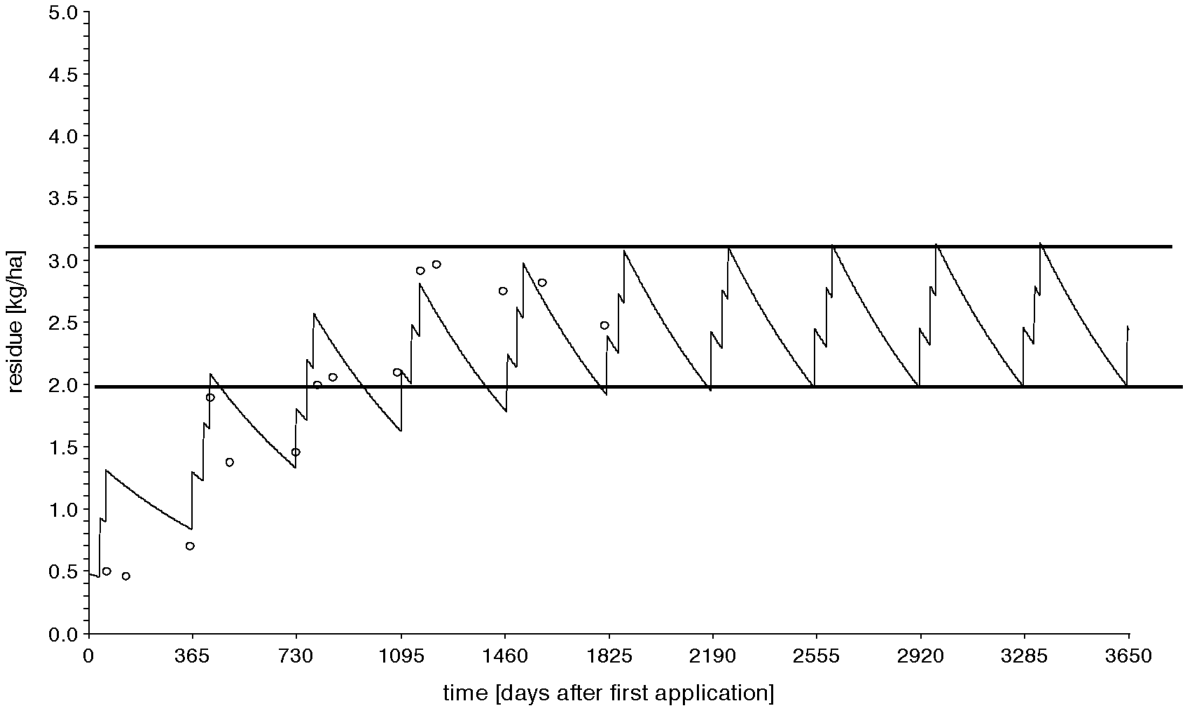


Figure B.8.1-2: **Result of fitting a soil residue dynamics curve to the observed residue data (vines)**

Conclusion:

A concentration plateau in soil was reached in an accumulation study in grapes over 5 years with annual application of 3 × 700 g as/ha. According to a simple biphasic model, this plateau was reached at about 1220 days (40 – 41 months) after the first treatment. A more sophisticated assessment of the data using ModelMaker yielded minimum and maximum plateaus of 2000 g as/ha and 3100 g as/ha, respectively. In relation to the tested annual application rate of 2100 g as/ha, this is equivalent to an accumulation factor of 95 % for the background areic concentration directly before the annual application and to an accumulation factor of 148 % for the expected maximum areic concentration after the application of the compound.

However, closer inspection of the modelled concentration curve and the individual measured data-points reveals some aspects that must be considered when applying the results of the study for PEC_{soil} calculations. First, the measured concentrations of boscalid directly before application of the compound in June 2002 (1454 DAFT) and June 2003 (1812 DAFT, i.e. after the plateau should have been reached) are both higher than the modelled level with 2746 and 2470 g as/ha, respectively (mean 2608 g as/ha, n = 2; i.e. 124 % of annual application rate). Second, the modelled maximum concentration levels exceed the modelled background concentration by more than 50 %, although for an average interception of 0.75 (mean of 0.7, 0.7 and 0.85 for the individual application events), only 25 % exceedance could have been expected. This indicates that the standard calculation approach for PEC_{soil} might not be fully appropriate in this context. There seems to be a significant impact on modelled results of compound reload into soil (most probably with falling leaves) or of other effects not considered in standard PEC_{soil} calculations.As regards the maxima reached within a year, the concentrations obtained two months after the 3rd annual application in October 2001(1221 DAFT) and October 2002(1592 DAFT) are virtually as high as the concentrations measured directly after that 3rd application in August 2002. The mean of those measured maximum concentrations is 2.900 g as/ha (n = 3; i.e. 138 % of annual application rate) and thus lower than the modelled level of 148 %. This might be seen as a confirmation for the maximum plateau as obtained from the ModelMaker evaluation.

Annex Point:	IIA-7.1.1.2.2/2
Author:	Grote, C. and Platz; K.
Title:	Accumulation behaviour of BAS 510 F under field conditions over a 7-year-period (1998-2004) after applications onto vegetables
Date:	31.05.2005
Doc ID:	2005/1013964; BOD 2005-907
Guidelines:	SETAC, BBA IV, 4-1, IVA-Leitlinie
GLP:	yes
Valid:	yes

The accumulation behaviour of BAS 510 F under field conditions in vegetables has been investigated over a six-year-period from 1998 to 2004. (The report title suggests that accumulation behaviour had been observed over a period of seven years. However, results are available for a period of six years only.) The trial was conducted at a site in Germany in Rhineland Palatinate (Rheinland-Pfalz). The soil was a loamy sand with an organic carbon content of 1.0 %, a pH value of 7.8, cation exchange capacity of 13 mVal/100 g dry soil and a maximum water holding capacity of 43 g water/100 g dry soil.

BAS 510 F was applied in 1998 onto lettuce (nominal 2 × 300 g as/ha) and green beans (nominal 3 × 500 g as/ha) and in 1999 onto carrots (nominal 3 × 300 g as/ha) and cauliflower (nominal 2 × 400 g as/ha). The total amounts of BAS 510 F applied were nominally 2100 g in 1998 and 1700 g in 1999. In the year 2000, spring wheat was grown on the plots and no product containing BAS 510 F was applied to these plots. In general, cultivation of vegetables in two consecutive years with cultivation of cereals in the third year stands for a rather common crop rotation in agricultural practice in Germany. It also represents a reasonable worst case for the application of BAS 510 F in a crop rotation.

The three-year crop rotation with its crops and applications of BAS 510 F as previously described in detail was repeated. In 2001, BAS 510 F was applied onto lettuce (nominal 2 × 300 g as/ha) and green beans (nominal 3 × 500 g as/ha) and in 2002 onto carrots (nominal 3 × 300 g as/ha) and cauliflower (nominal 2 × 400 g as/ha). In 2004, the cycle was started again with application onto lettuce (nominal 2 × 300 g as/ha) and green beans (nominal 3 × 500 g as/ha). The total amounts of BAS 510 F nominally applied per ha were 2100 g as in 2001, 1700 g as in 2002, none in 2003 and again 2100 g as in 2004.

The actual amounts of BAS 510 F applied onto the field as determined by spray broth calculation differ only slightly. A summary of the application parameters including dates of applications, formulation, crops, growth stages and product and spray mixture applied is given in Table B.8.1-3.

Table B.8.1-3.: Application parameters of BAS 510 F in vegetables

Application No.	Date	DAFT	Formulation	Crop	Growth stage [BBCH]	Spray mixture [L/ha]	Product [L/ha or kg/ha]	as nominal [g/ha]
1	14.05.98	0	BAS 510 KA F	Lettuce	17	595	0.595	298
2	03.06.98	20	BAS 510 KA F	Lettuce	43	811	0.608	304
3	25.08.98	103	BAS 510 KA F	Green bean	61	589	0.982	491
4	07.09.98	116	BAS 510 KA F	Green bean	65	799	0.999	500

5	17.09.98	126	BAS 510 KA F	Green bean	67	823	1.029	515
6	20.05.99	371	BAS 510 01 F	Carrot	14	395	0.593	297
7	07.06.99	389	BAS 510 01 F	Carrot	41	575	0.575	288
8	22.06.99	404	BAS 510 01 F	Carrot	47	756	0.567	284
9	02.09.99	476	BAS 510 01 F	Cauliflower	19	617	0.822	411
10	17.09.99	491	BAS 510 01 F	Cauliflower	41	781	0.781	391
11	04.05.01	1086	BAS 510 01 F	Lettuce	17	600	0.60	300
12	23.05.01	1105	BAS 510 01 F	Lettuce	43	814	0.61	305
13	23.07.01	1166	BAS 510 01 F	Green bean	61	593	0.99	495
14	02.08.01	1176	BAS 510 01 F	Green bean	65	767	0.96	480
15	21.08.01	1195	BAS 510 01 F	Green bean	67	774	0.97	485
16	15.05.02	1462	BAS 510 01 F	Carrot	16	419	0.63	315
17	27.05.02	1474	BAS 510 01 F	Carrot	41	586	0.59	295
18	17.06.02	1495	BAS 510 01 F	Carrot	45	806	0.60	300
19	02.09.02	1572	BAS 510 01 F	Cauliflower	19	608	0.81	405
20	13.09.02	1583	BAS 510 01 F	Cauliflower	41	784	0.78	390
21	26.05.04	2204	BAS 510 01 F	Lettuce	17	618	0.62	310
22	08.06.04	2217	BAS 510 01 F	Lettuce	42	800	0.60	300
23	23.08.04	2293	BAS 510 01 F	Green bean	61	605	1.01	505
24	03.09.04	2304	BAS 510 01 F	Green bean	65	806	1.01	505
25	17.09.04	2318	BAS 510 01 F	Green bean	67	794	0.99	495

DAFT = days after first treatment

Soil samples were taken twice a year in 3 replicates, once before application and once after harvest. Initially, the soil cores were divided into 0 - 10, 10 - 25 and 25 – 50 cm segments. From 2001 onwards, the increments for analysis were changed to 0 - 10, 10 - 20, 20 - 30, 30 - 40 and 40 – 50 cm to give a more detailed overview of the distribution of the residues within the soil layers. Results up to sampling no. 13 in spring 2004 are reported.

Replicate samples were analysed for BAS 510 F by BASF method 408/1. No correction, neither for recoveries nor blanks, has been made, but all results were corrected for moisture content of the soil. The recoveries from n = 55 measurements of fortified samples had a mean value of 95.9 % with a relative standard deviation of 11.7 %. This proves the quality and repeatability of the method.

Control samples from untreated plots were analysed from sampling before application. They were free of residues. These data demonstrate that no interferences of the sample material with the analytical procedure occurred and that the control plots were free of residues of BAS 510 F.

The results of the first six years of the vegetable accumulation study confirm the results that were found after application of BAS 510 F on bare soil. After application in the growth season, significant residues of BAS 510 F can be detected in soil in the spring of the following year. In contrast to the field soil dissipation studies, BAS 510 F was found in this study also in deeper layers of the soil horizon. This was caused by the tillage of the soil including ploughing once a year down to 35 cm depth. However, the highest amounts of residues were detected from 0 to 30 cm depth.

The residues observed in the different soil layers were converted from mg/kg to kg/ha as described above for the soil accumulation study in vines. These areic concentrations were then summed up per soil core and the mean of the three replicates calculated. The model data used for the estimation approach are given in Table B.8.1-4.

Table B.8.1.4: Residue data of the accumulation study of BAS 510 F in vegetable

DAFT	Date	BAS 510 F [kg/ha]			
		Replicate 1	Replicate 2	Replicate 3	mean
-14	30.04.98	0	0	0	
151	12.10.98	0.619	1.006	2.483	1.369
298	08.03.99	0.604	1.01	0.491	0.701
538	03.11.99	1.602	1.871	1.077	1.516
669	13.03.00	1.088	0.93	0.802	0.940
830	21.08.00	1.219	1.084	0.941	1.081
1056	04.04.01	0.470	0.620	0.546	0.545
1272	06.11.01	1.515	1.886	1.631	1.677

1386	28.02.02	1.185	1.344	1.286	1.265
1650	19.11.02	2.696	2.421	2.519	2.545
1768	17.03.03	0.815	1.001	0.764	0.860
1925	21.08.03	1.685	2.285	1.694	1.888
2132	15.03.04	1.025	1.140	1.124	1.096

DAFT days after first application

The analytical results were further investigated by modelling. The dates of the different application events, the respective application rates of BAS 510 F to the cultivated crops, the growth stages of the crops, and crop interception as given by FOCUS were taken into account for estimating the minimum and maximum residue levels in soil after repeated application. The FOCUS crop interception values at the different application events vary between 25 % and 80 %. The nominal application rates were 2100 g as/ha in the first year, 1700 g as/ha in the second year and no application in the third year and so on. This application pattern results in an average annual application rate of BAS 510 F of 1270 g as/ha.

The effective soil loads of BAS 510 F at the respective application events were deduced from the nominal application rates, the crop interception and the fraction of crop residues of BAS 510 F that finally reaches the soil after harvest or with falling leaves. As suitable information of this reload fraction is not available, the amount was estimated under consideration of the residue data of the accumulation study. To prevent an over-parameterisation of the estimation model the modelling approach is based on the simple assumption that the reload entry of BAS 510 F takes place at the time of the application event.

The dissipation behaviour of BAS 510 F in the accumulation study could not be estimated independently from the fraction of BAS 510 F that finally reaches the soil with crop residues after harvest or with falling leaves. For that reason the dissipation time of BAS 510 F in the accumulation study was not estimated but fixed to a realistic value. In doing so, the average dissipation behaviour of BAS 510 F in soil as observed in different field dissipation studies of BAS 510 F was considered. The respective half-lives at these trial sites when standardised to a reference temperature of 20 °C are in a very close range. The mean half-lives of the different trial sites vary between 98 d and 212 d. The vegetables were irrigated according to GAP. Thus, fair dissipation behaviour of BAS 510 F can be expected and the arithmetic mean half-life of 139 d was considered as a realistic input parameter for the estimation approach. The mean half-life of 139 d valid for a reference temperature of 20 °C was converted to the average annual temperature of the accumulation study of about 10 °C. The conversion was made with a derivation of the Arrhenius equation as recommended by FOCUS. The mean field half-life in soil of BAS 510 F standardised (converted) to the experimental average annual temperature of 10 °C is 305.8 d.

The observed residues of the accumulation study were fitted under consideration of the varying application pattern and dissipation according to first order kinetics. As explained above, the modelling approach is based on simple assumptions with respect to reload of previously intercepted amounts of BAS 510 F into soil (at the time of the application event) and temperature dependence of dissipation (described by the annual mean temperature instead of actual daily temperatures of the field experiment). For that reason the fitted curve (see Figure B.8.1-3) does only reflect the formation of the soil residues in general, but not the individual observed values.

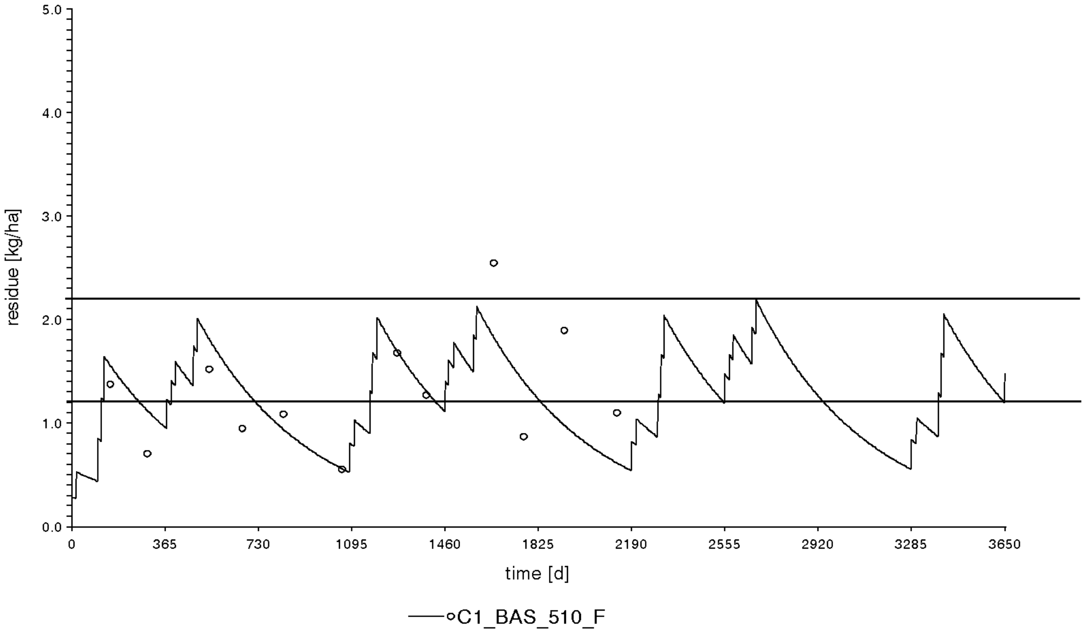


Figure B.8.1-1: **Result of fitting a soil residue dynamics curve to the observed residue data (vegetables)**

Because of the varying annual application rates of BAS 510 F (as is true for a realistic crop rotation scenario), the minimum and maximum plateau concentrations at steady state vary, too. The reported minimum plateau amount of BAS 510 F is the maximum estimated concentration in springtime before the first annual application event in the second of two consecutive years with application of BAS 510 F. In order to reflect worst-case conditions, the minimum value in springtime following the year without application of BAS 510 F was not considered. The reported maximum plateau concentration is the estimated maximum value (peak amount) at steady state. The minimum and maximum estimated plateau concentration of BAS 510 F following multiple applications onto vegetables are 1200 g as/ha and 2200 g as/ha, respectively. However, these amounts cannot be used directly for the risk assessment, since the accumulation study was performed with a higher number of applications and dose rates for BAS 510 F in vegetables than relevant for the EU risk assessment now. The current supported use for carrots treated with BAS 510 F is 2 × 267 g as/ha instead of 3 × 300 g as/ha as in the accumulation study. For lettuce, the current supported use consists of 2 × 400 g as/ha (instead of 2 × 300 g as/ha), for beans 2 × 500 g as/ha (instead of 3 × 500 g as/ha) and for cauliflower 3 × 267 g as/ha (instead of 2 × 400 g as/ha).

Conclusion:

The RMS has noticed that the study report is actually an interim report. It was confirmed by the notifier that the study is on-going for at least one further crop rotation cycle to allow a more reliable fitting of the soil residue dynamics curve to the experimental data.

The minimum plateau concentration of 1200 g as/ha according to the current fitted curve would represent an accumulation of 95 % in relation to the average treatment rate over three years of 1270 g as/ha (i.e mean of 2100, 1700 and 0 g as/ha). Likewise, the maximum plateau concentration of 2200 g as/ha would represent an accumulation of 174 %.

It is obvious from the modelled concentration curve and the individual measured data-points that three out of the four last measured concentrations in soil are significantly higher than predicted. In contrast, the fit appears to be quite satisfactory for the first four years of the study. No final conclusion on the actual plateau levels is possible as long as no measured data for a third crop rotation cycle are available. It is in principle agreed that the risk assessment should consider the measured/modelled accumulation within the 2-year period of actual treatments, rather than the concentration levels obtained after a year without any treatment. However, measured values for that time-point are only available one year (plateau definitely not reached) and four years after the first treatment. Furthermore, like in the soil accumulation study in vines, it is obvious from the modelling results that other effects not considered in standard PEC_{soil} calculations (e.g. reload of initially intercepted residues of the active substance) significantly contribute to the actual concentrations in soil.

Nevertheless, an evaluation based on selected measured concentrations in the study is considered to provide a reliable value for a preliminary risk assessment. Due to regular ploughing as a part of soil treatment in vegetable and cereal cultivation, it can be assumed that the background concentration level, as soon as it is reached, will be evenly distributed over the 0 - 30 cm soil horizon. It can further be assumed that this level is well represented by the measured concentrations in the 10 - 20 cm soil layer in samples taken before ploughing. Those concentrations reflect the input through application and reload from previous, but not from the current year. The 10 - 20 cm soil layer is preferred over the 20 - 30 cm soil layer, because the mixing effect of ploughing is considered to be highest in that medium layer and because the results from the deeper 20 - 30 cm soil layer may be biased by edge/border effects. For the selection of sampling dates, the following considerations were made: In samples taken between the start of the study in April 1998 and March 2000, definitely no plateau could have been reached. The sampling dates August 2000 (830 DAFT) and April 2001 (1056 DAFT) follow a year without application of boscalid (cultivation of cereals). In November 2001 (1272 DAFT), the first application after the break had not yet been incorporated into the soil. The samples numbered 9 to 11 from February 2002 (1386 DAFT), November 2002 (1650 DAFT) and March 2003 (1768 DAFT) appear suitable. The concentrations remain fairly constant over the year, indicating that some plateau (i.e. equilibrium between input and degradation) could have already been reached. The subsequent sampling dates (August 2003 , 1925 DAFT, and March 2004, 2132 DAFT) again follow a year without application of boscalid and thus cannot be considered. The individual results for sampling dates 9 to 11 are summarised in Table B.8.1-5. The overall mean of the concentrations amounts to 0.345 mg/kg.

Table B.8.1-5: Measured concentrations of boscalid in the 10 – 20 cm soil layer

Sample No.	soil depth [cm]	sampling date	BAS 510 F [mg/kg]	mean [mg/kg]
9	10 - 20	28.02.2002	0,440	0,439
			0,438	
			0,439	
10	10 - 20	19.11.2002	0,429	0,413
			0,335	
			0,474	
11	10 - 20	17.03.2003	0,168	0,185
			0,217	
			0,169	
Overall				0,345

As a preliminary surrogate for a maximum plateau, the concentration at 1650 DAFT (November 2002) can be taken. As shown above for the vineyard study, this value will also cover other effects not considered in standard PEC_{soil} calculations which significantly contribute to the actual concentrations in soil. The areic concentration at 1650 DAFT is 2545 g as/ha. In relation to the corresponding application rate of 1700 g as/ha (i.e. the maximum is considered to reflect the last application before sampling), this would represent an accumulation of 150 %. This accumulation percentage can be used in the calculation of PEC_{soil} values resulting from application of boscalid on a soil that already contains a background plateau concentration of the active substance.

B.8.2 Adsorption, desorption and mobility in soil (Annex IIA 7.1.2, 7.1.3; Annex IIIA 9.1.2)

B.8.2.1 Adsorption and desorption

It was stated in the monograph that on the basis of the findings of the adsorption/desorption study, BAS 510 F could be classified as ‘non-mobile’ in soil. However, with a K_{OC} in the range 500 – 1000, the compound must in fact be classified as ‘slightly mobile’.

B.8.3 Predicted environmental concentrations in soil (PEC_S) (Annex IIIA 9.1.3)

Annex Point:	IIIA-9.1.3/6
Author:	Platz, K.
Title:	Predicted environmental concentrations in soil after long-term use of BAS 5100 F

(Boscalid) under consideration of a bean and grapevine crop scenario
Date: 21.05.2005
Doc ID: BASF DocID 2005/11014172; BOD 2005-908
Guidelines: FOCUS (2000)
GLP: No, not subject to GLP regulations
Valid: n.a. (modelling exercise)

This modelling calculation estimates the overall predicted environmental concentrations in soil ($PEC_{lt,overall}$) of BAS 510 F after long-term application onto beans and grapevine. In a first step the soil concentrations at steady state after long-term use ($PEC_{plateau,min}$) of BAS 510 F were estimated by using a percentage rate deduced from two accumulation field studies and by using the following parameters:

	grapevine scenario	bean scenario
total annual application rate	600 g as/ha	1000 g as/ha
minimum accumulation factor in soil as derived from a field accumulation study	95 %	95 %
depth of the considered soil cultivation layer	10 cm	30 cm
considered density of the soil layer	1.5 g/cm^3	1.5 g/cm^3
$PEC_{plateau,min}$	0.38 mg/kg (570 g/ha)	0.21 mg/kg (950 g/ha)

In a second step, the short-term soil load (PEC_{ini}) of BAS 510 F was estimated for the upper soil layer before the next soil cultivation procedure using the following parameters:

	grapevine scenario	bean scenario
total annual application rate	600 g as/ha	1000 g as/ha
fraction of crop interception	85 %	80 %
mixing depth	5 cm	5 cm
considered density of the soil layer	1.5 g/cm^3	1.5 g/cm^3
PEC_{ini}	0.12 mg/kg (90 g/ha)	0.27 mg/kg (200 g/ha)

The overall (maximum) PEC values in soil after long-term application of BAS 510 F are estimated as:

	grapevine scenario	bean scenario
$PEC_{lt,overall}$ (= $PEC_{plateau,min}$ + PEC_{ini})	0.50 mg/kg	0.48 mg/kg

Conclusion:

As argued before in the assessment of the two accumulation field studies, the RMS has reservations against using the ”minimum plateau accumulation factor” of 95 % from those studies in a standard PEC_{soil} calculation for two reasons. First, there is some degree of uncertainty in the vineyard study and even more in the vegetables study whether the level of 95 % actually represents the long-term plateau concentration in soil. Second, the PEC_{ini} from the standard PEC_{soil} calculation does not account for the amount of boscalid that is initially intercepted, but then ‘reloaded’ in the soil most probably via falling leaves or of other effects not considered in standard PEC_{soil} calculations.. However, it has become clear from the descriptive modelling of the soil accumulation study that this entry path will contribute significantly to the actual concentrations of boscalid in soil. Consequently, the $PEC_{lt,overall}$ values above cannot be used for the risk assessment.

Annex Point: IIIA-9.2.1/3, also relevant for IIIA-9.1.3
Author: Jene, B.
Title: Predicted environmental concentrations of BAS 510 F in groundwater (PEC_{gw}) and soil accumulation ($PEC_{soilaccu}$) under worst case degradation conditions for France
Date: July 2003
Doc ID: BASF DocID 2003/11009266; BOD 2005-909
Guidelines: -/-
GLP: No, not subject to GLP regulations
Valid: n.a. (modelling exercise)

This study consists of two parts, calculating PEC_{soil} and $PEC_{groundwater}$ separately. Here, only the PEC_{soil} calculation is summarised. This new modelling study was performed, because it was concluded with RMS to use the maximum field DT_{50} of 212 d as worst case scenario. Simulations were carried out for the two scenarios Hamburg and Châteaudun with the modelling tool FOCUS-PEARL 1.1.1. For PEC_{soil} calculation the following parameters have been used:

	grapevine scenario	vegetable scenario (cabbage, beans)
scenarios	Châteaudun, Hamburg	Châteaudun, Hamburg
application rate	600 g as/ha	2 × 500 g as/ha
application date	28 days before harvest	7, 14 days before harvest
crop interception	50 %	70 %
amount reaching soil	0.3 kg/ha/a	2 × 0.15 kg/ha/a
DT_{50}	212 d	212 d
Moisture Dependency	switched off	switched off

The $PEC_{soil,Accu}$ plateau values for the grapevine and the vegetables scenario are as follows:

Grapevine	Châteaudun		Hamburg	
	Areic mass kg/ha	Concentration mg/kg	Areic mass kg/ha	Concentration mg/kg
Average min	0.29	0.39	0.39	0.52
Average max	0.59	**0.79**	0.68	**0.91**
TWA	0.45	0.60	0.55	0.73

Vegetables	Châteaudun		Hamburg	
	Areic mass kg/ha	Concentration mg/kg	Areic mass kg/ha	Concentration mg/kg
Average min	0.30	0.40	0.39	0.52
Average max	0.59	**0.78**	0.68	**0.90**
TWA	0.44	0.58	0.53	0.71

These concentrations are calculated on basis of a minimum worst case soil depth of 5 cm. If tillage is carried out, the residues in the soil will be mixed within the tillage layer. For a representative mixing depth of 20 or 30 cm, the calculated concentrations would be reduced a by factor of 4 or 6, respectively.

For the assessment of the $PEC_{groundwater}$ calculation, please see B.8.6.4.

Conclusion:

This modelling study is a modification of the study by Hauck (2001) (IIIA-9.1.3/3, already assessed in the monograph). Modified parameters include the maximum field DT_{50} value of 212 d (instead of the mean field DT_{50}), an interception of 50 % for grapevines and 70 % for beans (instead of 0 %) and deactivation of moisture correction in modelling. The latter was justified by the fact that the also the relevant DT_{50} had been calculated without considering moisture correction factors. These modifications are considered acceptable for a higher-tier modelling approach.

It was argued by the notifier that actual concentrations in the upper 5 cm soil layer would be reduced by tillage. This is true from a long-term perspective. However, tillage would not reduce the concentration peak in the upper soil layer directly after application of the plant protection product. It should also be considered that the FOCUS scenarios were defined to represent a worst case with respect to leaching. Downward movement of the modelled compound in the soil column will thus be more prominent than under worst-case conditions for accumulation in soil.

Annex Point:	IIIA-9.1.3
Author:	Calculation by RMS

The notifier had proposed to calculate $PEC_{lt,overall}$ values by adding a $PEC_{plateau,min}$ as derived by modelling from the two soil accumulation studies and a PEC_{ini} considering FOCUS interception values. As explained above, the RMS cannot accept those values for a risk assessment, since the reload of initially intercepted boscalid to soil (most probably due to falling leaves) or other effects which are not included in standard PEC_{soil} calculations are not considered. Instead, an alternative approach is proposed that directly makes use of the measured or modelled minimum and maximum concentrations from the soil accumulation studies.

For the vineyard study, the approach relies on the following assumptions: The background plateau concentration over the whole soil column of 30 cm can be represented either by the modelled minimum plateau concentration of 2000 g as/ha (95 % of the annual application rate in the study) or by the measured concentration levels in June 2002 and 2003 directly before the respective annual application (mean 2608 g as/ha, i.e. 124 % of the annual application rate in the study). The annual input is reflected in either the modelled maximum plateau concentration of 3100 g as/ha (148 % of the annual application rate in the study) or by the measured concentration levels in October 2001, August, 2002 and October 2002 (mean 2900 g as/ha, i.e. 138 % of the annual application rate in the study). For the purpose of PEC_{soil} calculation, it is assumed that the difference between background and maximum of 53 % (ModelMaker evaluation) or 14 % (measured concentrations) is completely located in the upper 5 cm soil layer. The relevant PEC_{soil} for the risk assessment is the sum of the background concentration in mg/kg for 30 cm soil depth and the annual input in mg/kg for 5 cm soil depth (Table B.8.1-6).

Table B.8.1-6: PEC_{soil} in the upper 5 cm soil layer resulting from accumulated background concentration and annual application in vineyards

Vineyard 1 × 600 g as/ha		Areic concentration [g as/ha]	Mass-related concentration for 30 cm soil depth [mg/kg]	Mass-related concentration for 5 cm soil depth [mg/kg]
Modelled minima and maxima				
Background	95 %	570	0.127	
Maximum	148 %	888		
Annual input (maximum – background)		318		0.424
PEC_{soil} (0-5 cm)		**413**		**0.551**
Measured minima and maxima				
Background	124 %	744	0.165	
Maximum	138 %	828		
Annual input (maximum – background)		84		0.112
PEC_{soil} (0-5 cm)		**208**		**0.277**

For beans, no reliable maximum plateau concentration can be derived from the ModelMaker evaluation of the currently available data. Consequently, the maximum is derived from the highest measured concentration in the study (2545 g as/ha, equivalent to 150 % accumulation as related to the corresponding application rate of 1700 g as/ha). The background plateau concentration over the whole soil column of 30 cm can be represented either by the modelled minimum plateau concentration of 1200 g as/ha (95 % of the mean annual application rate over three years in the study) or by the mean of the measured concentration levels in the 10 - 20 cm soil layer in February 2002, November 2002 and March 2003 of 0.345 mg/kg (for the average treatment rate over three years of 1270 g as/ha). If that concentration is normalised to the intended treatment rate of 1000 g as/ha in beans, a value of 0.272 mg/kg is achieved. The principle of the PEC_{soil} calculation is the same as explained for the vineyard study. The results are given in Table B.8.1-7.

Table B.8.1-7: PEC_{soil} in the upper 5 cm soil layer resulting from accumulated background concentration and annual application in beans

Beans 2 × 500 g as/ha		Areic concentration [g as/ha]	Mass-related concentration for 30 cm soil depth [mg/kg]	Mass-related concentration for 5 cm soil depth [mg/kg]
Modelled minimum and measured maximum				
Background	95 %	950	0.165	
Maximum	150 %	1500		

Annual input (maximum – background)		550		0.733
PEC_{soil} (0-5 cm)		**708**		**0.944**
Measured minima and maxima				
Background		1224	0.272	
Maximum	150 %	1500		
Annual input (maximum – background)		276		0.368
PEC_{soil} (0-5 cm)		**480**		**0.640**

The chosen approach accounts for the fact that the minimum plateau concentration might have been underestimated by the model, particularly in the case of the vegetables study. The annual input is calculated from the difference between the minimum plateau concentration and maximum measured or modelled concentration in the respective studies. Provided the measured maximum concentrations will not exceed the maximum plateau (which is considered confirmed for the vineyard study and preliminary assumed for the vegetables study), any underestimation of the minimum plateau concentration would result in an overestimation of the annual input and thus also an overestimation of the resulting PEC_{soil} for the upper 5 cm layer.

Overall conclusion on PEC_{soil} calculation:

Concentrations of boscalid in soil reflecting accumulation as well as the annual application on top of that background concentration were calculated by means of $FOCUS_{gw}$ modelling and by using measured and modelled minimum and maximum plateau concentrations from two soil accumulation studies. For an annual application of 600 g as/ha to vines, the calculated concentrations for the upper 5 cm soil layer range from 0.277 to 0.910 mg/kg (208 to 683 g as/ha). For an application of 2 × 500 g as in beans as a part of a three year crop rotation including cereals, the respective concentrations are 0.640 to 0.944 mg/kg (480 to 708 g as/ha).

B.8.6 Predicted environmental concentrations in surface water and in ground water (PEC_{SW}, PEC_{GW}) (Annex IIIA 9.2.1, 9.2.3)

B.8.6.2 PEC in surface water

Annex Point: IIIA-9.2.3
Author: Calculation by RMS

The concentrations in surface water resulting from spray drift after application of 1 × 600 g as/ha in vines and 2 × 500 g as/ha in beans were recalculated by the RMS considering the 90th percentile and 82nd percentile drift values according to Ganzelmeier, respectively. The recalculated PEC_{act} and PEC_{twa} values from 1 to 100 days after the final application consider the DT50 of 9 d in water from the non-irradiated laboratory water/sediment study.

The risk assessment is based on the long-term effects on the rainbow trout, *Oncorhynchus mykiss* in a 93-day flow-through test. In that study, effects became manifest over a period of 11 d after hatch. Thus a $PEC_{twa,11\,d}$ is the relevant endpoint from this section. For vines, the respective values range from 10.82 µg/L (3 m buffer) to 1.66 µg/L (10 m buffer). For beans, the $PEC_{twa,11\,d}$ with the averaging period starting directly after the second application (7 – 18 d) is 4.24 µg/L (1 m buffer). This value is higher than the $PEC_{twa,11\,d}$ of 3.92 µg/L for the averaging period 0 – 11 d and thus relevant for the risk assessment. All calculated values are provided in Tables B.8.6-1 and B.8.6-2 with the $PEC_{twa,11\,d}$ relevant for the risk assessment printed in bold.

Table B.8.6-1: **PEC$_{sw}$ calculation for application of 1 × 600 g as/ha boscalid to vines, spray drift exposure (90th percentile; scenario grapevine, late)**

Time/integration period [d]	3 m buffer		5 m buffer		10 m buffer	
	PEC$_{act}$ [µg/L]	PEC$_{twa}$ [µg/L]	PEC$_{act}$ [µg/L]	PEC$_{twa}$ [µg/L]	PEC$_{act}$ [µg/L]	PEC$_{twa}$ [µg/L]
0	16.04	16.04	7.24	7.24	2.46	2.46
1	14.85	15.44	6.70	6.97	2.28	2.37
2	13.75	14.87	6.21	6.71	2.11	2.28
3	12.73	14.32	5.75	6.46	1.95	2.20
4	11.79	13.81	5.32	6.23	1.81	2.12
7	9.36	12.40	4.22	5.60	1.43	1.90
11	6.88	**10.82**	3,10	4,88	1,05	1,66
14	5.46	9.82	2.46	4.43	0.84	1.51
21	3.18	7.95	1.44	3.59	0.49	1.22
28	1.86	6.58	0.84	2.97	0.28	1.01
42	0.63	4.76	0.29	2.15	0.10	0.73
100	0.01	2.08	0.00	0.94	0.00	0.32

Table B.8.6-2: **PEC$_{sw}$ calculation for application of 2 × 500 g as/ha boscalid to beans, spray drift exposure (82nd percentile, scenario arable crops)**

Time/integration period [d]	1 m buffer	
	PEC$_{act}$ [µg/L]	PEC$_{twa}$ [µg/L]
0	6.28	6.28
1	5.81	6.05
2	5.38	5.82
3	4.98	5.61
4	4.61	5.41
7	3.66	4.86
11	2.69	**4.24**[1] / 3.92[2]
14	2.14	3.84
21	1.25	3.11
28	0.73	2.58
42	0.25	1.87
100	0.00	0.82

[1] twa-interval 7-18 d (averaging starts after 2nd application)
[2] twa-interval 0-11 d (averaging starts after 1st application)

B.8.6.3 PEC in sediment

Annex Point:	IIIA-9.2.4/4
Author:	Platz, K.
Title:	Kinetic evaluation of the accumulation behaviour in sediment after long-term application of BAS 510 F (Boscalid) under consideration of different water sediment studies
Date:	21.10.2004
Doc ID:	BASF DocID 2004/1022502; WAS 2005-367
Guidelines:	-/-
GLP:	No, not subject to GLP regulations
Valid:	n.a. (modelling exercise)

The kinetic evaluation was performed in order to estimate the accumulation behaviour in sediment after long-term application of BAS 510 F (boscalid). The accumulation behaviour was estimated on the basis of a standard laboratory study conducted in the dark and on the basis of an outdoor water sediment study performed under natural sunlight.

The standard water sediment study was conducted in the laboratory at 20 °C in the dark. The study includes two aquatic test systems from different origins, one representing a pond (Kellmetschweiher) and the other a river (Berghauser Altrhein). In both test systems, no significant amounts of metabolites were found in the water phases or in the sediments. Only bound residues could be detected in sediment. The highest amounts in sediment of BAS 510 F were observed in test system B (Berghauser Altrhein). To consider worst-case conditions system B was therefore used for the modelling approach of the standard laboratory water sediment study.

The higher-tier outdoor water sediment study was initiated to investigate the degradation and transformation of BAS 510 F in a water/sediment system under more realistic outdoor conditions. Since in natural water/sediment systems (rivers, lakes), photolysis and sediment sorption may influence the degradation of BAS 510 F simultaneously, this supplementary outdoor study was carried out, where both factors were combined. The outdoor study uses a pond (Kellmetschweiher) water/sediment system. In this outdoor water sediment study an additional metabolite M510E64 was observed in the water phase.

In the present evaluation, two different compartment models were chosen for the standard laboratory and the outdoor water sediment study to achieve a successful fit of the observed residues.

As a principle of these approaches, compartments are defined which represent the compounds and different matrices. Experimental data are allocated to the individual compartments and transitions between these compartments are then postulated and described mathematically based upon scientific considerations. The mathematical model consists of a system of differential equations and involves several free parameters that shall be adjusted to the specific degradation data by non-linear parameter estimation procedures. The initial concentrations of BAS 510 F in the water compartment were estimated as well.

The quality of the estimations was checked with statistical items like the standard deviation and the type I-error rates of the estimated parameters. The modelled curves to the observed residues in water and sediment were evaluated visually and the determination coefficients were given.

The development of the amounts of BAS 510 F in sediment was extrapolated under consideration of one seasonal treatment (application period 365 days) with identical application rates. The extrapolated amounts of active substance in sediment are expressed in percent of the seasonal applied application rate.

Laboratory study

As no metabolite could be observed in the standard laboratory study conducted in the dark, the loss of BAS 510 F in the water phase was attributed to the sorption processes onto the sediment. That means the dissipation flow rate of BAS 510 F in the water phase (F12) corresponds to the formation rate to sediment. As the sorption and desorption processes of BAS 510 F in the water sediment system couldn't be satisfactorily described by single first-order kinetic flow-rates, a bi-phasic kinetic model according to Gustafson Holden was used to describe the dissipation behaviour in the water phase of BAS 510 F. The formation of the bound residues was attributed to the degradation flow of BAS 510 F in sediment (F23). The degradation of BAS 510 F in sediment could be explained by single first-order kinetics. A graphical description of the 3-compartment model is shown in Figure B.8.6-1.

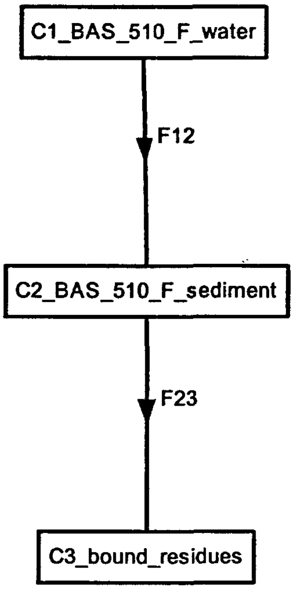


Figure B. 8.6-1: **3-compartment model for the fate and behaviour of boscalid in a non-irradiated laboratory water/sediment study**

The observed residues of BAS 510 F in water and sediment were fitted as described above. Low standard deviations, low type-I error rates and a high coefficient of determination confirmed the correctness of estimation model and estimated parameters. It is concluded that an extrapolation of the amount of BAS 510 F in sediment after long-term application is thus based on reliable assumptions. The comparison of the fitted curves to the observed residues in water and sediment are given in Figure B.8.6.-2. The visual check shows an excellent fit of the observed residues in water and sediment.

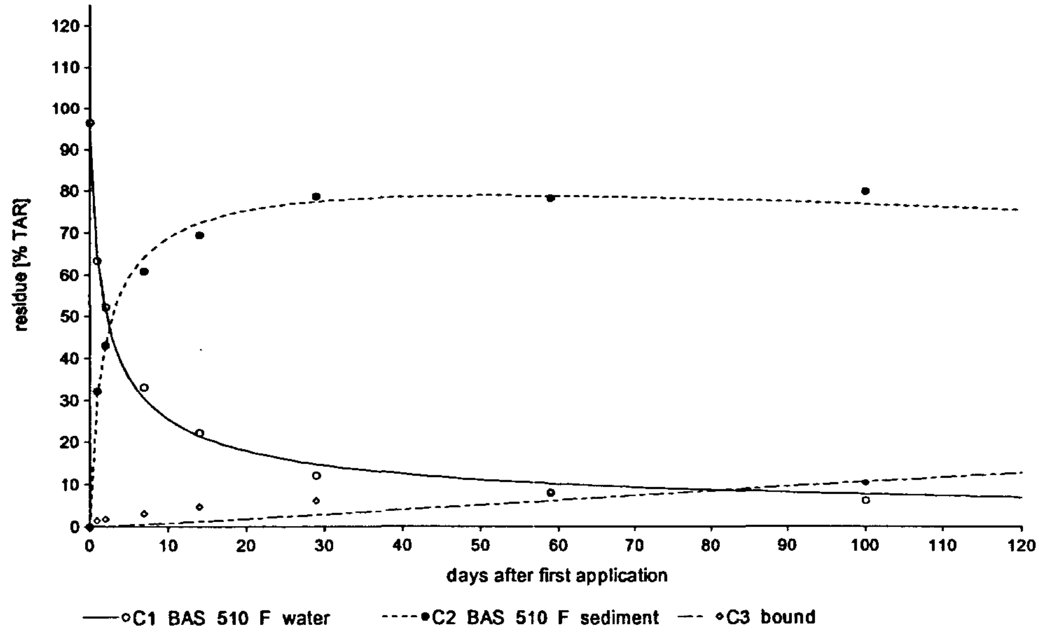


Figure B. 8.6-2: **Fitted curves to the observed residues in water and sediment of the non-irradiated laboratory water/sediment study**

The maximum amount of BAS 510 F in sediment after long-term application estimated on the basis of the standard laboratory study is reached at about 8 years after first application. The estimated maximum plateau amount of BAS 510 F in sediment at steady state is 217 % of the seasonal applied application rate. The extrapolated residues of BAS 510 F after long-term application in sediment under consideration of the standard laboratory study and the resulting maximum plateau amount of BAS 510 F at steady state are illustrated in Figure B.8.6-3.

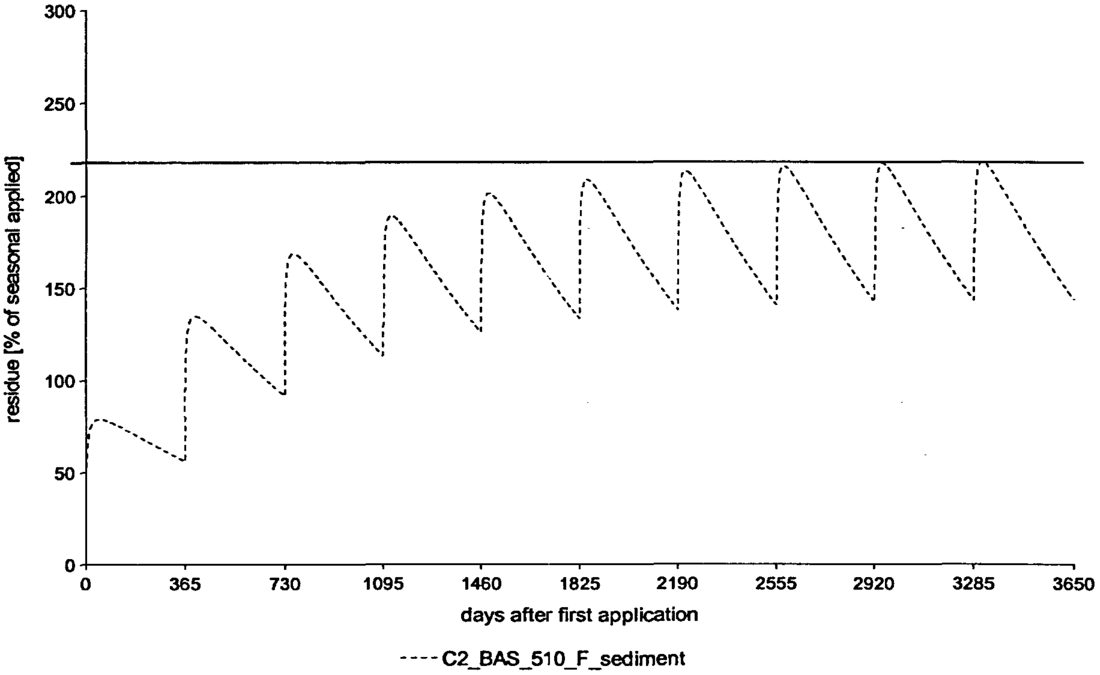
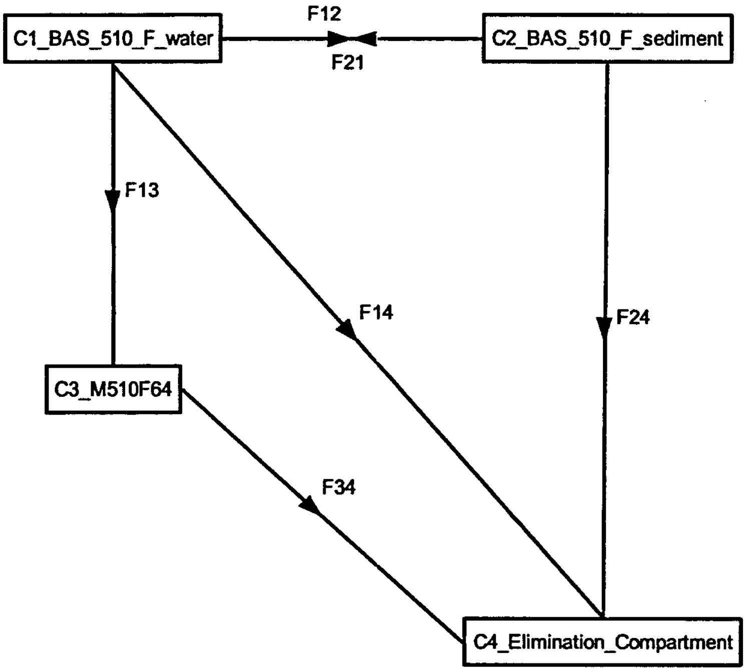


Figure B. 8.6-3: **Modelled concentration curve for boscalid in the sediment of a non-irradiated laboratory water/sediment study**

Outdoor study

The observed residues in the water and in the sediment phase are fitted with help of a compartment model that considers the dissipation of BAS 510 F in water as well as the sorption and desorption processes of BAS 510 F in the sediment phase and formation and degradation of M510F64 in the water phase. The observed residues in water and sediment could be well described by single first-order kinetics. The compartment model as implemented in ModelMaker is given in Figure B.8.6-4.

Figure B. 8.6-4: **multi-compartment model for the fate and behaviour of boscalid in an outdoor water/sediment study**



The observed residues of BAS 510 F in water and sediment were fitted as described above. During optimisation, the degradation rate constant k24 (degradation in sediment) became < 10^{-10} 1/d and was set to 0. A high type-I error rate of k14 (degradation in water) was considered negligible for the overall result, because the value of k14 is relatively small as compared to the other rate constants. The coefficient of determination gives evidence of a successful fit. It is concluded that the extrapolation of the amount of BAS 510 F in sediment under consideration of similar seasonal treatments is thus based on reliable assumptions. The comparison of the fitted curves to the observed residues in water and sediment are given in Figure B.8.6-5. The visual check shows an excellent fit of the observed residues in water and sediment.

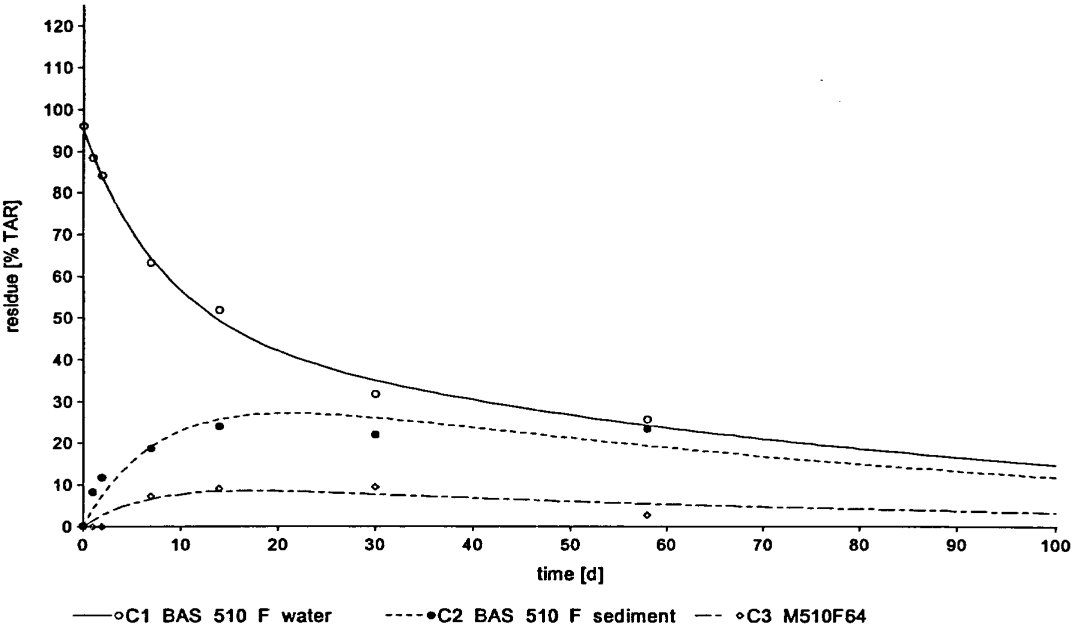


Figure B. 8.6-5: **Fitted curves to the observed residues in water and sediment of the outdoor water/sediment study**

The modelled concentration curve of BAS 510 F after long-term application estimated on the basis of the higher tier outdoor water sediment study shows that there is no accumulation risk of the parent compound in sediment. The maximum amount in sediment after long-term application of BAS 510 F was estimated with 27.2 % of the seasonal application rate. The extrapolated residues of BAS 510 F after long-term application in sediment under consideration of the standard laboratory study and the resulting maximum plateau amount of BAS 510 F at steady state are illustrated in Figure B.8.6-6

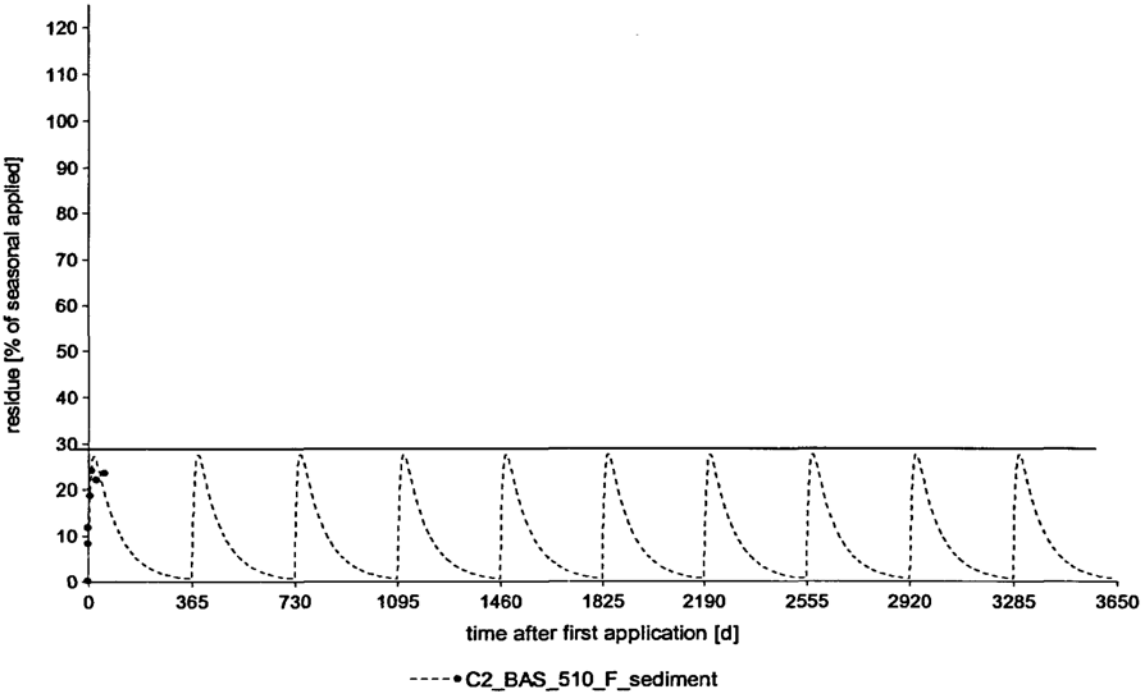


Figure B. 8.6-6: **Modelled concentration curve for boscalid in the sediment of a non-irradiated laboratory water/sediment study**

Conclusion:

Residue dynamics and distribution of boscalid in a water/sediment system could be modelled with sufficient accuracy for a non-irradiated standard laboratory study as well as for an outdoor study. The results are considered a reliable basis for assessing the potential of boscalid to accumulate in sediment and of the corresponding accumulation plateaus. These are 217 % for the laboratory study and 27.2 % for the outdoor study. No agreed guidance exists as yet for the inclusion of results from outdoor water/sediment studies in a risk assessment; therefore the value obtained for the laboratory study is used.

Annex Point:	IIIA-9.2.4/5
Author:	Platz, K.
Title:	Predicted environmental concentrations in sediment after long-term application of BAS 510 F (Boscalid)
Date:	21.05.2005
Doc ID:	BASF DocID 2005/1014173; WAS 2005-368
Guidelines:	-/-
GLP:	No, not subject to GLP regulations
Valid:	n.a. (modelling exercise)

This study predicts the environmental concentration in sediment after long term application of boscalid. The calculation study uses the maximum accumulation value of 217 % in sediment as calculated by Platz (2004), see above.

As drift entry is the main entry route into surface water it was taken into account for the PEC_{sed} calculation. The PEC in sediment was calculated for a 1 cm and a 5 cm sediment layer depth. In available guidance, a sediment layer depth of 1 cm is recommended as conservative approach for a PEC_{sed} calculation. Since a sediment layer depth of 5 cm seemed to be more realistic for a long-term assessment, this was additionally considered. The considered density of the sediment layer was 1.3 kg/L.

The drift values used for the grapevine scenario at buffer zones of 3 m (standard FOCUS buffer zone), 5 m and 10 m (overall 90th percentile valid for single application) were 8.02 %, 3.62 % and 1.23 % of the application rate, respectively. Application of BAS 510 F at a late growth stage of grapevine was taken into account (worst-case). The drift values used for the beans scenario at buffer zones of 1 m (standard FOCUS buffer zone), 5 m and 10 m (82nd percentile valid for double applications, equivalent to overall 90th percentile) were 2.38 %, 0.47 % and 0.24 % of the application rate, respectively.

The maximum predicted environmental concentrations in sediment at steady state of BAS 510 F after long-term application was calculated as described in the following equation. The results are listed in Table B.8.6-3.

$$PEC_{sed,accu,\max} = \frac{A \cdot f_{drift} \cdot f_{plateau}}{depth * bd}$$

where

$PEC_{sed,accu,max}$ = maximum PEC in sediment of BAS 510 F (boscalid) after long-term application [mg/kg]
A = total annual application rate [mg/m^2]
f_{drift} = drift fraction [-]
$f_{plateau}$ = estimated maximum plateau amount at steady state (217 % of yearly application rate) [-]
depth depth of the considered sediment layer (0.01 m and 0.05 m) [m]
bd density of the considered sediment layer ($1.3\ g/cm^3 = 1300\ kg/m^3$) [$kg/m^3$]

Table B.8.6-3: Predicted environmental maximum plateau concentrations in sediment at steady state ($PEC_{sed,accu,max}$) after long-term application of boscalid

	sediment layer depth: 1 cm		sediment layer depth: 5 cm	
	grapevines (1 × 600 g as/ha) [mg/kg]	beans (2 × 500 g as/ha) [mg/kg]	grapevines (1 × 600 g as/ha) [mg/kg]	beans (2 × 500 g as/ha) [mg/kg]
0 m	-	-	-	-
1 m	-	0.397	-	0.079
3 m	0.803	-	0.161	-
5 m	0.363	0.078	0.073	0.016
10 m	0.123	0.040	0.025	0.008

B.8.6.4 PEC in groundwater

Annex Point: IIIA-9.2.1/3
Author: Jene, B.
Title: Predicted environmental concentrations of BAS 510 F in groundwater (PECgw) and soil accumulation (PECsoilaccu) under worst case degradation conditions for France
Date: July 2003
Doc ID: BASF DocID 2003/1009266; WAS 2005-366
Guidelines: -/-
GLP: No, not subject to GLP regulations
Valid: n.a. (modelling exercise)

The following predictions are an extension of the PEC_{gw} calculations as described in the monograph. These additional PEC_{gw} calculations were made upon the request to use the worst-case field half-life as a high end benchmark reflecting an extreme leaching scenario.

The degradation behaviour of BAS 510 F had been investigated in five field soils as shown in Table B.8.6-4. Standardisation of the field values was performed for temperature but not for soil moisture. Standardisation was only possible for three out of the five studies, but not for the Spanish sites Huelva and Sevilla due to scattering of the data and high uncertainty of the estimated degradation rate. Nevertheless, the 'best fit' DT_{50} values indicate that the half-lives in the Huelva and Sevilla trials are in the lower range of the observed field half-lives. The longest field half-life of the Schifferstadt study is larger by a factor of 2 than the second longest half-life (Stetten). This DT_{50} of 212 d was used to assess leaching in the two sensitive scenarios Piacenza and Châteaudun as to model a worst-case situation.

Table B.8.6-4: DT_{50} of BAS 510 F in the field and half-lives standardised to reference temperature of 20°C

Code	Location	DT_{50} (best fit) [d]	DT_{50} (1st order, standardised to 20 °C) [d]
DU2/15/97	Stetten DE	55.7	106
DU3/06/97	Schifferstadt DE	176.7	212
D05/03/98	Grossharrie DE	144	98
ALO/05/98	Huelva ES	78	n.c.*
ALO/06/98	Sevilla ES	27	n.c.*
Arithmetic mean		96.3	139

* not calculated due to experimental conditions – a reasonable half life cannot be derived, because of the high standard deviation of the degradation rate

Calculations were carried out for the scenario Piacenza using the model FOCUS-PEARL 1.1.1 as well as for the macropore scenario Châteaudun using the model FOCUS-MACRO 3.3.1. The parameterisation of the scenarios Piacenza and Châteaudun was taken according to the implementation in the models and shown in the FOCUS groundwater report. For the Piacenza scenario, only natural precipitation was simulated and no additional irrigation for vine was considered, because irrigation is mostly not allowed in viticulture in France (the study was initially prepared for the purpose of a national authorisation in France) and the inclusion of irrigation would result in unrealistically high groundwater recharge.

Except the half-life in soil, the parameters used for the calculations are identical with the earlier calculations described in the monograph (B.8.6.1, Table B.8.6-3). The worst-case half-life of 212 days was taken from the Schifferstadt field study. To be consistent with the evaluation method of the study that considered temperature but not moisture dependency of the degradation rate, the moisture dependency in the model was switched off (moisture exponent = 0).

Application scenario

The simulations are carried out for grapevine. The application rate is 1 × 600 g as/ha and crop interception was set to 50 % (relevant for grapevine during flowering, will increase during later growth stages). In order to consider a worst-case application date, 1st October as the latest possible application time in the year was simulated.

Piacenza scenario with FOCUS-PEARL 1.1.1

Despite the very high groundwater recharge rates between 150 and 935 mm/year (mean = 470 mm/year), the 80th percentile as well as the maximum annual leachate concentration is clearly below the groundwater threshold of 0.1 µg/L. The average concentration of boscalid closest to the 80th percentile is 0.031 µg/L This value occurs in period from 01-Jan-1918 to 31-Dec-1918.

Chateaudun scenario with FOCUS-MACRO 3.3.1

Despite the consideration of macroporosity, the 80th percentile of 0.0012 µg/L as well as the maximum annual leachate concentration of 0.0015 µg/L is clearly below the groundwater threshold of 0.1 µg/L.

Conclusion:

Using the worst-case field half-life of 212 days, the simulations with FOCUS-PEARL 1.1.1 for the most vulnerable Piacenza scenario as well as calculations with FOCUS-MACRO 3.3.1 for the Châteaudun scenario with macropores show that the groundwater threshold of 0.1 µg/L is not exceeded.

As compared to the earlier study reported in the monograph, the calculated 80th percentile concentrations are lower in the Piacenza (0.031 µg/L in new vs. 0.042 µg/L in old study) as well as in the Châteaudun scenario (0.0012 µg/L in new vs. 0.005 µg/L in old study). This is most likely due to the impact of 50 % crop interception in the new study, whereas the earlier study considered no crop interception and thus had reflected an absolute worst case in that respect. Switching off moisture correction in FOCUS modelling when using the Schifferstadt degradation data was justified by the notifier with uncommonly dry conditions in that trial. According to Table B.8.1-18 in the monograph, the accumulated rainfall for Schifferstadt amounted to 194 mm 0-90 d after treatment and to 712 mm 0-545 d after treatment. This indicates that the annual rainfall most probably was below 600 mm. Thus, underestimation of degradation in the $FOCUS_{gw}$ scenarios Piacenza (750 mm annual rainfall) and Châteaudun (600 mm annual rainfall) is not to be expected.

The new results are in accordance with the results from the previous calculations as reported in the monograph. The potential of boscalid to reach groundwater under vulnerable conditions is low. The risk of unacceptable groundwater concentrations after use in vines according to good agricultural practice is negligible.

B.8.10 References relied on

Annex point/ reference number	**Author(s)**	**Year**	**Title** **source (where different from company)** **report no.** **GLP or GEP status (where relevant), published or not** **BVL registration number**	**Data protection claimed** **Y/N**	**Owner**
IIA-7.1.1.2.2/1	Kellner, O. et al.	2004	Accumulation behaviour of BAS 510 F under field conditions over a 5-year-period (1998 – 2003) after application onto grapes in a vineyard BOD 2005-906	Y	BASF
IIA-7.1.1.2.2/2	Grote, C. Platz, K.	2005	Accumulation behaviour of BAS 510 F under field conditions over a 7-year-period (1998 – 2004) after application onto vegetables BOD 2005-907	Y	BASF
IIIA-9.1.3/6	Jene. B.	2003	Predicted environmental concentrations of BAS 510 F in groundwater (PECgw) and soil accumulation (PECsoilaccu) under worst case degradation conditions for France BOD 2005-909	Y	BASF
IIIA-9.2.1/3	Jene, B.	2003	Predicted environmental concentrations of BAS 510 F in groundwater (PECgw) and soil accumulation (PECsoilaccu) under worst case degradation conditions for France WAS 2005-366	Y	BASF
IIIA-9.2.4/4	Platz, K.	2004	Kinetic evaluation of the accumulation behaviour in sediment after long-term application of BAS 510 F (Boscalid) under consideration of different water sediment studies WAS 2005-367	Y	BASF
IIIA-9.2.4/5	Platz, K.	2005	Predicted environmental concentrations in sediment after long-term application of BAS 510 F (Boscalid) WAS 2005-368	Y	BASF

B.9 Ecotoxicology

B.9.1 Effects on birds (Annex IIA 8.1; Annex IIIA 10.1)

B.9.1.3 Summary of effects on birds

Data are listed in Table B.9.1-1 in the context of the additionally submitted risk assessment according to SANCO/4145/2000. The respective studies have already been assessed in the monograph.

Table B.9.1-1: Summary of effects of BAS 510 F on birds

Test species	Test system	Results
Colinus virginianus	Acute oral toxicity	LD_{50} > 2000 mg as/kg bw NOED = 2000 mg as/kg bw
Colinus virginianus	short-term dietary toxicity	LC_{50} > 5000 mg as/kg diet NOAEC = 5000 mg as/kg diet LDD_{50} > 1094.3 mg as/kg bw/d *)
Anas platyrhynchos	short-term dietary toxicity	LC_{50} > 5000 mg as/kg diet NOAEC = 625 mg as/kg diet LDD_{50} > 1413.2 mg as/kg bw/d *)
Colinus virginianus	sub-chronic toxicity and reproduction	NOAEL = 300 mg a.s./kg diet NOAEDD = 24.1 mg as/kg bw/d *)
Anas platyrhynchos	sub-chronic toxicity and reproduction	NOAEL = 1000 mg a.s./kg diet NOAEL = 128.6 mg as/kg bw/d *)

*) Daily Dose (mg/kg bw/d) calculated based on mean food consumption and body weight data.

B.9.1.6 Risk assessment

B.9.1.6.1 Risk assessment for the active substance

Annex Point:	IIIA-10.1
Author:	Welter, K.
Title:	Formulation Cantus (BAS 510 01 F) – use in oilseed rape, bush beans and vines in Germany. Assessment of the potential risk to birds (M-III, 10.1)
Date:	November 2005
Doc ID:	BASF DocID 2005/1029947; -/-
Guidelines:	-/-
GLP:	n.a.
Valid:	n.a.

An extensive risk assessment for birds according to SANCO/4145/2000 was submitted by the notifier in the context of a national application for registration of a plant protection product. For the EU assessment, such assessment had not been required in the Peer Review. In formal terms, with respect to a decision on Annex I inclusion of boscalid, the risk assessment for birds as described in the monograph is still considered valid. Nevertheless, the RMS has decided to include the additionally submitted risk assessment in this addendum to make the underlying data and assumptions available to all Member States and to provide an aid for national evaluations of plant protection products containing boscalid after an inclusion of the compound in Annex I of Directive 91/414/EEC.

Exposure assessment for the active substances

According to SANCO/4145/2000, the estimated daily uptake of a compound is given by the following equation:

ETE = (FIR / bw) × C × AV × PT × PD (mg/kg bw/d)

where
ETE = Estimated daily uptake of compound (= estimated theoretical exposure)
FIR = Food intake rate of indicator species (gram fresh weight per day)
bw = Body weight (g)
AV = Avoidance factor (1 = no avoidance, 0 = complete avoidance)
PT = Fraction of diet obtained in treated area (number between 0 and 1)
PD = Fraction of food type in diet (number between 0 and 1; one type or more types)

In case of multiple applications and/or long-term considerations, the concentration C may be expressed as
$C = C_0 \times MAF \times f_{twa} \times DF$

where
C_0 = Initial concentration after a single application calculated from RUD (= Residue Unit Dose) multiplied by the application rate (kg a.s./ha)
MAF = Multiple application factor (concentration immediately after the last application compared to a single application)
f_{twa} = Time-weighted-average factor (average concentration during a certain time interval compared to the initial concentration after single resp. last application)
DF = Deposition factor (1 - Interception)

Both equations can be combined and converted to the following form, which will be used in this assessment.

ETE = (FIR / bw) × RUD × AV × PT × PD × MAF × f_{twa} × DF × Appl. Rate (mg/kg bw/d)

Tier 1 risk assessment (calculation of TER values)

An assessment is conducted for the application of 1 × 600 g as/ha in vines (Table B.9.1-3) and 2 × 500 g as/ha in beans (Table B.9.1-4). The assessment of the application in winter rape (named in the title of the study) is not documented, since it is not relevant for the EU assessment.

Table B.9.1-2: Exposure assessment for BAS 510 F in vines (Tier 1)

Crop stage	Indicator species	FIR (fresh) / body weight	Food type	RUD [mg as/kg]	PT	PD	DF	f_{twa}	MAF	Use Rate [kg as/ha]	ETE [mg as/kg]
Acute											
Early / late	Insectiv. bird	1.04	Small insects	52	1	1	1	-/-	n.a.	0.6	32.45
Short-term											
Early / late	Insectiv. bird	1.04	Small insects	29	1	1	1	-/-	n.a.	0.6	18.10
Long-term											
Early / late	Insectiv. bird	1.04	Small insects	29	1	1	1	n.a.	n.a.	0.6	18.10

Table B.9.1-3: Exposure assessment for BAS 510 F in beans (Tier 1)

Crop stage	Indicator species	FIR (fresh) / body weight	Food type	RUD [mg as/kg]	PT	PD	DF	f_{twa}	MAF	Use Rate [kg as/ha]	ETE [mg as/kg]
Acute											

Early / late	Medium herbiv bird	0.76	Leafy crops	87	1	1	1	-/-	1.4	0.5	46.28
Early / late	Insectiv. bird	1.04	Small insects	52	1	1	1	-/-	n.a.	0.5	27.04
Short-term											
Early / late	Medium herbiv bird	0.76	Leafy crops	40	1	1	1	-/-	1.6	0.5	24.32
Early / late	Insectiv. bird	1.04	Small insects	29	1	1	1	-/-	n.a.	0.5	15.08
Long-term											
Early / late	Medium herbiv bird	0.76	Leafy crops	40	1	1	1	0.53	1.6	0.5	12.89
Early / late	Insectiv. bird	1.04	Small insects	29	1	1	1	n.a.	n.a.	0.5	15.08

The resulting TER values (shown in Table B.9.1-4 and Table B.9.1-5) indicate an acceptable risk on the acute and short-term time-scale for both applications and all indicator species. For the long-term time scale, the TER values are below the Annex VI acceptability criterion of 5. A refined risk assessment is required.

Table B.9.1-4: Toxicity/exposure ratios for BAS 510 F in vines (Tier 1)

Crop stage	Indicator species	Food type	TER
Acute			
Early / late	Insectiv. bird	Small insects	$TER_a > 2000 / 32.45 > 61.63$
Short-term			
Early / late	Insectiv. bird	Small insects	$TER_{st} = 1094.3 / 18.10 = 60.46$
Long-term			
Early / late	Insectiv. bird	Small insects	$TER_{lt} = 24.07 / 18.10 = 1.33$

Table B.9.1-5: Toxicity/exposure ratios for BAS 510 F in beans (Tier 1)

Crop stage	Indicator species	Food type	TER
Acute			
Early / late	Medium herbiv. bird	Leafy crops	$TER_a > 2000 / 46.28 > 43.22$
Early / late	Insectiv. bird	Small insects	$TER_a > 2000 / 27.04 > 73.96$
Short-term			
Early / late	Medium herbiv. bird	Leafy crops	$TER_{st} = 1094.3 / 24.32 = 45.00$
Early / late	Insectiv. bird	Small insects	$TER_{st} = 1094.3 / 15.08 = 72.57$
Long-term			
Early / late	Medium herbiv. bird	Leafy crops	$TER_{lt} = 24.07 / 12.89 = 1.86$
Early / late	Insectiv. bird	Small insects	$TER_{lt} = 24.07 / 15.08 = 1.60$

B.9.1.6.2 Refined risk assessment

Application in vines – insectivorous bird scenario

Focal species: A survey on the birds inhabiting vineyards has been conducted at four study sites in south-western Germany from April to August 2003 by territory mapping (Pedall, I. et al. 2003). The study sites differed in structure from richly structured small-scale vineyards to large scale monotonous vineyards. Among the insectivorous guild, the yellowhammer and the blackbird were those species identified as characteristic, i.e. they were encountered regularly feeding in the vineyards by Pedall, I. et al. (2003). The representative status of the yellowhammer for Central European vineyards was corroborated by a comprehensive study in southern Germany on birds of vineyards (Seitz, B.J. 1989). The yellowhammer was considered to be the most common bird species in vineyards in southern Germany (Braun, M. 1985; Seiler,W. 1986). Therefore, the yellowhammer (*Emberiza citrinella*) is chosen as focal species for the insectivorous scenario in grapevine. The FIR/bw ratios for arthropod and seed food were calculated according to Crocker, D.R. et al. (2002) to be 0.77 and 0.26, respectively.

PT (Proportion of diet obtained from the treated area): Due to their mobility, birds are capable of extending their foraging habitat beyond the borders of a single treated field. It was shown for the skylark (Green, R.E. 1978), the starling (Tinbergen, J.M. 1976) and the redshank (Goss-Custard, J.D. 1970) that foraging birds make use of suboptimal areas to a considerable extent as well. This might be due to the reason that such behaviour would allow the birds to gain information on new potential food sources. This might be especially important on farmland where, as a result of mechanised agriculture, abundant food sources can appear or disappear within few hours (Green, R.E. 1978). This underlines that exclusive foraging on one single treated field is highly unlikely.

This is corroborated by data from CSL Report PN0915 (Crocker, D.R. et al., 2001). In this radio-telemetry study, the habitat use of different bird species (blackbird, linnet, skylark, yellowhammer) was evaluated in summer and winter on mixed arable land. The mean active tracking time, which is the relevant number for refining a long-term exposure assessment, was found to be highest in off-crop habitat elements (set-asides/hedges). For single arable habitat elements (oil seed rape, beets, potatoes, cereals), the vast majority of mean active tracking times were clearly below 30 %. The only exception is the active time for blackbirds in oil seed rape, which was found to be 60 % in summer.

To conclude, literature and recent telemetry data indicate that the mean active time spent in arable crops would be clearly below the default value of 1.0. Hence, for scenarios which cannot be justified by specific PT data, it is still considered conservative to apply a factor PT = 0.5 for refinement.

PD (Proportion of diet): The yellowhammer is known to feed on seeds, especially of grasses, while invertebrates are preyed in the breeding season and casually throughout remainder of the year (Perrins, C.M. 1998).

A field study on the diet of the yellowhammer was conducted in an intensively managed and richly structured agricultural area in Schleswig-Holstein, Germany between 6th June and 8th August 1987-90 (Lille, R. 1996). The prey items of adult yellowhammers (12 pairs) were studied (1416 foraging flights of the adults) by means of photographical documentation (1691 photos) and direct observations. The prey items consisted of almost 84 % animal and 16 % vegetable items. Main components of the diet were 47 % dipteran larvae (particularly Syrphid larvae), 16 % cereal grains (especially oats), 12 % lepidopteran larvae. Further items were arachnids (8 %), coleopterans (6 %), dipteran imagines (4 %), lepidopteran adults (2 %). Approximately 4 % of the items could not be determined (Lille, 1996).

This study also revealed data on the size of the prey items of yellowhammers. According to the results, the prey size and prey weight ranged from 3 mm/5 mg in case of harvestmen (*Opiliones*) to 30 mm/380 mg for craneflies (*Tipulidae*).

The majority of the nestling diet of yellowhammers (42 % of 4764 prey items) consists of small prey items with an average weight between 5 and 20 mg. This prey size class was dominated by small syrphid larvae (8 mm/20 mg) (Lille, R. 1996). The next prey size class included objects of 20-40 mg fresh weight (such as cereal grains) and of 40-60 mg fresh weight. 82 % of the analysed food items had a fresh weight between 5 mg and 60 mg. 58 % of the prey weight was above 20 mg. The fresh weight per load delivered to the nestlings was found to range between 5 mg and 1150 mg, but 95 % of the loads had a weight below 580 mg (average weight 194 mg ± 187 mg, n = 1416) (Lille, R. 1996).

In the guidance document SANCO/4145/2000, the residue estimate for 'small' insects is derived from Kenaga, E.E. (1973) on the basis of residues in weed seeds, which would typically measure 1-2 mm. The residue estimate for 'large' insects comes from Kenaga, E.E. (1973) as well. This value was based on residues on wheat seeds, which are typically 4-5 mm in length. Hence, it is proposed to include a working definition of 'large' insects being ≥ 5 mm and 'small' insects being < 5 mm. From the results of the comprehensive study by Lille, R. (1996) on diet of yellowhammers, it is obvious that the bulk of the food items of yellowhammer nestlings (which represent the worst case scenario for such risk assessments) is equivalent to or exceeds the size of cereal grains (5 mm). Thus, as a realistic approach in a tier 2 assessment, the use of default residues of large insects (size of cereal grain or larger) would be justified for the bulk of arthropod prey species.

As a conclusion and synopsis of the results obtained by Lille, R. (1996) and presented above, a realistic diet composition of the yellowhammer is estimated to comprise 15 % weed seeds (cereal grains are not expected to be available in vineyards), 75 % large insects and 10 % small insects. In fact, the amount of typical small insects such as aphids and collembolans reported to be eaten was rather small (Bösenberg, K. 1958 refers to "few individuals of aphids"; Moreby, S.J. and Stoate, C. , 2000) give a figure of 1.2 % percentage in diet for aphids and collembolan, respectively; Lille, R. 1996 does not mention this size-class at all). Thus, the suggested composition of diet is considered to be a realistic but still conservative estimate of the diet of yellowhammers foraging in vineyards.

DF (Deposition factor): The yellowhammer almost exclusively forages on the ground (Snow & Perrins, 1998). Thus, the inclusion of a deposition factor of 0.3 (according to FOCUS interception factor of 0.7 for vines at the stage of flowering) is deemed valid.

The refined long-term exposure assessment, accounting for aforementioned refinement options for the yellowhammer in vineyards is summarised in Table B.9.1-6.

Table B.9.1-6: Refined long-term exposure assessment (insectivorous birds) for BAS 510 F in vines (Tier 2)

Crop stage	FIR (fresh) / body weight	Food type	RUD [mg as/kg]	PT	PD	DF	f_{twa}	MAF	Use Rate [kg as/ha]	ETE per diet fraction [mg as/kg]	ETE Sum [mg as/kg]
Yellowhammer – vines											
Early / late	0.77	Arthropods (small)	29	0.5	0.1	0.3	n.a	n.a	0.6	0.20	0.61
	0.77	Arthropods (large)	5.1	0.5	0.75	0.3	n.a.	n.a.	0.6	0.27	
	0.26	Weed seeds	4	0.5	0.15	0.3	n.a	n.a	0.6	0.14	

Application in beans – insectivorous bird scenario

Focal species: In an evaluation paper in 2004, the PPR Panel chose the yellow wagtail as focal species for the insectivorous scenario in potatoes and tomatoes. It is assumed that, due to structural similarities, the yellow wagtail would also be the relevant species in bush beans. This is corroborated by data published by Schümperlin (1994). In a study on the breeding population of the yellow wagtail in north-eastern Switzerland, yellow wagtail territories were found in beans, though other leafy crops (potatoes, sugar beet) were preferred. Based on that, the yellow wagtail (*Motacilla flava*) is considered as key focal species for the insectivorous scenario in bush beans. The FIR/bw ratio for arthropod and food was calculated according to Crocker et al. (2002) to be 0.88.

PT (Proportion of diet obtained from the treated area): PT is set to 0.5, based on the same rationale as for the insectivorous bird scenario in vines.

PD (Proportion of diet): In a study on the foraging behaviour of yellow wagtails in the UK, the diet of solitary foraging yellow wagtails was examined on non-flooded areas of a meadow (Davies, N.B. 1977). The predominant prey types of foraging yellow wagtails were flies, which were caught around dung pats. The availability of the individual prey types was estimated by counting the number of prey individuals per 100 dung pat transects. The size distribution of available insects and ingested insects (from assessment of faecal material) was ascertained (see Table B.9.1-7). The insects are presented in a range of sizes, from which the prey size preference of yellow wagtails is determined. This research result can be used for the risk assessment.

Table B.9.1-7: The prey types eaten by solitary foraging yellow wagtails (adopted from Davies, N.B. 1977)

Prey type	Body length [mm]	Availability [%]	Remains in droppings [%]
Scatophagidae	5-10	77.1	35.1
Sphaeroceridae	1-2	6.9	2.3
Sphaeroceridae	3-4	10.1	41.3
Sepsidae	3-4	0.7	0.0
Coleoptera	2-3	5.1	6.4
Others	--	0.1	14.9

Scatophagidae vary from 5 mm to 10 mm in body length with females being smaller. On the dung pats, males outnumbered females by 3.7 to 1.0. Yellow wagtails preferred flies having about 7 mm in length. Prey up to this size is swallowed immediately in a very short period of time (< 1 sec). Larger prey, 10 mm in length, is bashed against a perch, sometimes dropped and took 5 – 10 sec to handle (Davies, N.B. 1977). From caloric specific values and the handling times for each size of prey, the energy intake per unit handling time was calculated. It became obvious that the size of the prey selected by wild wagtails corresponds to the optimum prey size they can

handle. Thus, small prey items (1 – 2 mm) were ignored, because although quick to handle, the ratio between energy used for foraging and energy gained from successful prey was too unfavourable for the bird. On the other end of the scale, the largest *Scatophagidae* were rejected, because although worth very much energy, they took too long to handle (Davies, N.B. 1977).
Based on the data presented by Davies, N.B. (1977), which is the most comprehensive study on the yellow wagtail diet currently available, the majority of prey items collected by yellow wagtails are 3 - 4 mm and greater. As argued above for the yellowhammer in vines, it is proposed to include a working definition of 'large' insects being ≥ 5 mm and 'small' insects being < 5 mm. Employing the results from Table B.9.1-7, the proportion of large insects (5-10 mm category) in the diet of yellow wagtails is 35 % ($PD_{large\ insects} = 0.35$), and the PD for small insects is set as to represent the remaining proportion of the diet ($PD_{small\ insects} = 0.65$).

Foraging technique: The foraging technique of nine yellow wagtails in an agricultural landscape was subject of a comprehensive study in the German state of Brandenburg, eastern Germany. According to the results of this study, the most common foraging technique was picking from the soil while running on the ground. Capturing prey from a perch or collecting arthropods from vegetation were of minor importance only (Stiebel, 1996). This was corroborated by the already mentioned study on prey selection and foraging behaviour of pied and yellow wagtails in Britain (Davies, N.B. 1977). That author distinguished three types of foraging techniques:

1. Picking (84%): The birds walk and pick up prey items from the ground surface.
2. Run-picking (9%): The wagtails make quick darting runs at a prey item and pick it up either from the ground or as it takes off.
3. Fly-catching (7%): The birds make a short sally up off the ground and catch prey mid-air.

Based on that information, the notifier proposes a subdivision of yellow wagtails' prey items into two groups: the first group comprises soil-dwelling insects ($PD_{soil\text{-}dwelling} = 0.93$), the second group consists of insects obtained by fly-catching, which clearly cannot be attributed to soil-dwelling insects ($PD_{flying} = 0.07$). The RMS agrees that differentiation between soil-dwellers and other arthropods constitutes in principle a suitable approach for a refined risk assessment. However, not all prey items picked up directly from the ground are necessarily 'soil dwellers' in the narrower sense. The article of Davies, N.B. (1977) describes the technique used for catching dung flies as follows: a wagtail will perform a darting attack on flies on a dung pat causing the insects to escape and will then pick up from the soil surface those flies returning to the dung pat. However, dung flies should certainly not be seen as 'soil dwellers'. Since no information is currently available on the distribution of prey items between actual soil dwellers and other arthropods temporarily resting or feeding on the soil surface, the RMS proposes not to include such differentiation quantitatively in the risk assessment.

DF (Deposition factor): In SANCO/4145/2000, the effect of crop interception on residues on soil-dwelling invertebrates is only considered in tall-growing crops (orchards, vines, hops). However, it is deemed appropriate to account for that exposure-mitigating effect also for other cultures. Deposition rates for beans corresponding to the interception factors according to focus are as follows,

100 %	BBCH 00-09 (Bare - emergence)
75 %	BBCH 10-19 (Leaf development)
60 %	BBCH 20-39 (Stem elongation)
30 %	BBCH 40-89 (Flowering)
20 %	BBCH 90-99 (Senescence, Ripening)

BAS 510 F will be applied twice in beans between growth stage BBCH 60 and 69 with an application interval of 7-10 d. This use pattern correlates with a deposition rate of 30 % of the applied amount on the ground. Based on that, a DF of 0.3 is proposed by the notifier. However, as mentioned above, the RMS does not agree with the assumption that the proportion of actual soil dwellers in a yellow wagtail's diet can be directly deduced from the bird's foraging technique. Consequently, no setting of a DF for a certain fraction of the arthropod diet is possible.

The refined long-term exposure assessment, accounting for aforementioned refinement options for the yellow wagtail in beans is summarised in Table B.9.1-8.

Table B.9.1-8: Refined long-term exposure assessment (insectivorous birds) for BAS 510 F in beans (Tier 2)

Crop stage	FIR (fresh) / body weight	Food type	RUD [mg as/kg]	PT	PD	DF	f_{twa}	MAF	Use Rate [kg as/ha]	ETE per diet fraction [mg as/kg]	ETE Sum [mg as/kg]
Yellow wagtail – beans											
Early / late	0.88	Arthropods (small)	29	0.65	0.5	1	n.a.	n.a.	0.5	4.15	4.54
	0.88	Arthropods (large)	5.1	0.35	0.5	1	n.a.	n.a.	0.5	0.39	

Application in beans – herbivorous bird scenario

PT (Proportion of diet obtained from the treated area): PT is set to 0.5, based on the same rationale as for the insectivorous bird scenario in vines.

DF (Deposition factor): BAS 510 F is intended to be applied in beans at BBCH 60-69 (flowering). In general, herbivorous birds prefer young leaves and plant shoots, disregarding older green plant material. Based on that, it is assumed that herbivorous birds will not eat bean plants at this stage. Furthermore, the canopy of the crop is very broad at this stage, and it is therefore unlikely that weeds may grow within the crop. However, to take a conservative approach, it is assumed that in some fields the crop will grow sparser, thereupon allowing the growth of some weeds which might be consumed by birds.
Under these conditions the deposition of the product on the weeds will be relatively low because of the interception by the crop. According to the prescriptions of FOCUS$_{gw}$, the inclusion of a Deposition Factor (DF) of 0.3 is valid for BBCH growth stages between 40 and 89 of beans.

The refined long-term exposure assessment for herbivorous birds in beans is summarised in Table B.9.1-9.

Table B.9.1-9: Refined long-term exposure assessment (herbivorous birds) for BAS 510 F in beans (Tier 2)

Crop stage	FIR (fresh) / body weight	Food type	RUD [mg as/kg]	PT	PD	DF	f_{twa}	MAF	Use Rate [kg as/ha]	ETE per diet fraction [mg as/kg]	ETE Sum [mg as/kg]
Herbivorous default bird species											
BBCH 60-69	0.76	Weed plants	40	0.5	1	0.3	0.53	1.6	0.5	1.93	1.93

Tier 2 risk assessment (calculation of refined TER values)

The TER$_{lt}$ values resulting from a refined risk assessment (shown in Table B.9.1-10) show an acceptable risk on the long-term time-scale for all applications and indicator species.

Table B.9.1-10: Refined long-term toxicity/exposure ratios for BAS 510 F in vines and beans (Tier 2)

Crop	Focal species	Food type	TER$_{lt}$
Vines	Yellowhammer	Insects / weed seeds	24.07 / 0.61 = 39.45
Beans	Yellow wagtail	Insects	24.07 / 4.54 = 5.30
Beans	Herbivorous bird	Weed plants	24.07 / 1.93 = 12.47

Conclusion:

The risk to birds resulting from uptake of boscalid through diet after application of the active substance in vines or beans can be considered acceptable in the acute scenario as well as on the short-term and the long-term time-scale.

B.9.1.6.3 Bioaccumulation and food chain behaviour

The log P_{OW} of the active substance BAS 510 F was determined to be 2.96, hence roughly 3.0, which triggers an assessment as to the potential risk of secondary poisoning.
The risk assessment for earthworm-eating birds (…) and fish-eating birds (…) is depicted below in short tabular form.

Table B.9.1-11: Risk to earthworm-eating birds

Parameter	Boscalid (BAS 510 F)	Comment
PEC_{soil} (twa, 21 days) [mg/kg soil]	0.912	derived from maximum plateau in vegetable soil accumulation study, recalculated to application of 2 × 500 g as/ha to beans, $PEC_{soil,max}$ = 0.944 mg/kg, $DT_{5ß}$ = 212 d
K_{OW}	915	-/-
K_{oc}	507	minimum (lowest binding to soil – worst case for accumulation in earthworms)
f_{oc}	0.02	default
BCF_{worm}	0.985	$BCF_{worm} = (PEC_{worm} / PEC_{soil}) = (0.84 + 0.01 \times K_{OW}) / f_{oc} \times K_{oc}$
PEC_{worm}	0.899	$PEC_{worm} = PEC_{soil} \times BCF$
Daily dose [mg/kg bw]	0.988	$ETE = PEC_{worm} \times 1.1$
NOEDD [mg/kg bw]	24.07	See 9.1.3
TER_{lt}	24.35	> 5

Table B.9.1-12: Risk to fish-eating birds

Parameter	Boscalid (BAS 510 F)	Comment
PEC_{sw} (twa, 21 days) [mg/L]	0.00318	
BCF_{fish}	125	whole fish, maximum of unchanged boscalid (normalised to 6 % lipid content)
PEC_{fish}	0.398	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dose [mg/kg bw]	0.083	$ETE = PEC_{fish} \times 0.21$
NOEDD [mg/kg bw]	24.07	See 9.1.3
TER_{lt}	288.35	> 5

Conclusion:

The risk to birds resulting from secondary poisoning through accumulation of boscalid in possible prey items can be considered acceptable.

B.9.2Effects on aquatic organisms (Annex IIA 8.2; Annex IIIA 10.2)

B.9.2.1 Toxicity data

B.9.2.1.1 Long-term toxicity to fish

Annex Point: IIA-8.2.2.1
Author: Zok, S.

Title: BAS 510 F - Early life-stage toxicity test on the rainbow trout (*Oncorhynchus mykiss* Walbaum 1792)
Date: 1999
Doc ID: 1999/11847
BBA-Ref.-No.: WAT2001-366
Guidelines: OECD 210, adopted July 17, 1992 and (U.S.) EPA-FIFRA 72-4 (a), 1982
GLP: Yes
Valid: Yes (already assessed in monograph)

In the light of recent discussions, the ELS test under flow through conditions was re-assessed with respect to the time to onset of the effects. Since the NOEC of 125 µg/L was derived for mortality and behavioural changes of larvae/fish, it is deemed more appropriate to calculate this relevant period under exclusion of the egg phase (considered as a kind of protected life stage). At the LOEC of 250 µg/L, time of hatching and hatch success were not affected. 50 % hatch were reached on day 32. Mortality started to occur on day 43 (7 dead out of 87 larvae/fish) and was pronounced until day 48 (26 dead out of 87 larvae/fish). Thereafter, only few deaths occurred sporadically until study termination at day 97 (29 dead out of 87 larvae/fish). Control values were 10 dead out of 90 larvae/fish at day 0 and 15 dead out of 90 larvae/fish at day 97. From that information, a probably more appropriate twa-interval of 11 d is deduced.

B.9.2.1.2 Sediment-dwelling organisms

Annex Point: IIA-8.2.7/1
Author: Dohmen, P.
Title: Effects of BAS 510 F on the development of sediment dwelling larvae of *Chironomus riparius* in a water-sediment system.
Date: 2001
Doc ID: 2000/1018538; WAT 2001-381
Guidelines: -/-
GLP: Yes
Valid: Yes

The study had already been validated and assessed in the monograph. Following a re-evaluation requested in the WG Evaluation on 15.07.2004, the NOEC from this study was set to 1 mg as/L (nominal) instead of the initially proposed value of 2 mg/L.
The reduction of the emergence rate at 2 mg/L amounts to 20 %. Although this value has not been found statistically significant, the variation coefficient at this concentration is high. Therefore, the effect should not be neglected.

Annex Point: IIA-8.2.7/2
Author: Weltje L.
Title: Chronic toxicity of Boscalid (BAS 510 F) to the non-biting midge *Chironomus riparius* exposed via spiked-sediment
Date: 31.08.2005
Doc ID: Study No. 232363; BASF DocID 2005/1022464; WAT 2005-733
Guidelines: OECD 218: Sediment-water chironomid toxicity test using spiked sediment (Feb. 2004)
GLP: Yes
Valid: Yes

Material and methods:

Test substance: BAS 510 F (Reg. No. 300 355), batch no. 81/1 (= BB81/1); purity: 98.4 %; specification (Document J).
Test species: *Chironomus riparius*, egg masses obtained from in-house cultures, larvae less than 3 days old at test initiation.
Test design: Static system containing spiked artificial sediment and water (Elendt, M4-medium); test duration 28 days; 6 test concentrations, each with

	4 replicates plus a control and solvent control with 6 replicates; 20 larvae per vessel; assessment of emergence ratio (number of emerged insects divided by the number of introduced larvae), development rate (proportion of larval development per day).
Test concentrations:	Solvent control, solvent free control, 1.87, 3.75, 7.50, 15.0, 30.0 and 60.0 mg/kg dry sediment (nominal).
Test conditions:	Glass vessels with ca. 100 g wet spiked artificial sediment and ca. 400 mL M4 water (Elendt medium), pH 7.89 - 8.63, oxygen content 7.30 - 9.36 mg/L, total hardness 2.40 - 2.79 mmol/L, ammonium 0.156 - 38.395 mg/L, conductivity 693 µS/cm (bulk M4 water), feeding with TetraMin, gentle aeration, water temperature 19.0 - 20.1 °C, photoperiod: 16 h light : 8 h dark; light intensity 511 – 963 lux.
Analytics:	Analytical measurements of test substance concentrations in overlaying water, pore water and sediment were conducted during the course of the study using GC/MS.
Statistics:	Standard procedures, analysis of variance, Bonferroni’s test, Dunnett's test, Williams’-test ($\alpha = 0.05$).

Findings:

Analytical measurements: Analysis of sediment by GC/MS at DAT 2 yielded recovery of 77.6 to 136.6 %. Overlaying water concentrations, measured on DAT 2, showed a linear relation with those in sediment and ranged from 0.0196 to 0.5672 mg/L. The pore water concentrations measured in the nominal 15 and 60 mg/kg treatments on DAT 2 were somewhat higher than those in overlaying water. At DAT 30, sediment concentrations in the nominal 15 and 60 mg/kg treatments had decreased to ca. 52 % of the nominal values, while the corresponding overlaying water concentrations slightly increased. The results are based on initially (= DAT 2) measured sediment concentrations.

Biological results: On day 15 after insertion of the larvae (= DAT 17), the first emerged midges were observed, which is normal under the conditions of our test system. Males always emerge earlier than females, which is a natural phenomenon in *C. riparius*. There was no indication for different effects on males and females, therefore male and female data were pooled for the calculations. In the nominal 3.75 mg/kg treatment, one replicate was excluded from further consideration, since a female midge, which had escaped from the breeding stock, laid an egg mass in this vessel.
No significant effects of BAS 510 F were detected on emergence ratio (ANOVA, followed by Bonferroni’s, Williams’ or Dunnett's test, $p > 0.05$). The development rate was significantly affected by BAS 510 F in the highest treatment (ANOVA, followed by Bonferroni’s, Williams’ or Dunnett's test, $p < 0.05$).

Table B.9.2-1: Effect of BAS 510 F on emergence and development rates of the non-biting midge *Chironomus riparius*

Concentration (nominal) [mg a.s./kg]	Solvent control	Solvent free contr.	1.87	3.75	7.5	15.0	30.0	60.0
Concentration (initially measured) [mg a.s./kg dry weight]	< LoQ	< LoQ	1.69	3.13	10.25	13.124	23.26	47.75
Emergence rate	0.9756	0.9333	0.9375	0.9000	0.9424	0.9625	0.9750	0.9750
Development rate	0.0591	0.0603	0.0586	0.0596	0.0595	0.0592	0.0592	0.0575*
	Endpoints [mg/kg dry sediment (initially measured)]							
EC_{50}	> 47.75							
$NOEC_{\text{development rate}}$	23.26							
$LOEC_{\text{development rate}}$	47.75							

* significantly different from the pooled controls ($p < 0.05$)

Conclusion:

The NOEC for the development rate was 23.26 mg/kg dry sediment (based on initially measured concentrations). Consequently, the LOEC for the development rate was

47.75 mg/kg dry sediment (initially measured). For both endpoints, the EC_{50} is > 47.75 mg/kg dry sediment (initially measured).

B.9.2.2 Summary of aquatic toxicity data

Data are listed in Table B.9.2-2 in the context of the revised risk assessment due to recalculated PEC values. Except for *Chironomus riparius*, the respective studies have already been assessed in the monograph.

Table B.9.2-2: Laboratory toxicity data for aquatic species (most sensitive species of each group)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L)
O. mykiss	boscalid	static – 96 h	LC_{50}	2.7
O. mykiss		flow-through – 97 d (ELS)	NOEC	0.125
D. magna		static – 48 h	EC_{50}	5.33
D. magna		semi-static – 21 d	NOEC	1.31
P. subcapitata		static – 96 h	E_rC_{50}	3.75
			E_bC_{50}	1.34
C. riparius		static – 28 d spiked water	NOEC	1.0
C. riparius		static – 28 d spiked sediment	NOEC	23.26 mg/kg
Activated slugde		static – 0.5 h	Respiration rate	> 1000

B.9.2.3 Risk assessment

Due to recalculation of the PEC_{sw} values and due to the revised database for *Chironomus riparius*, a revision of the risk assessment for aquatic organisms became necessary. Except for the long-term effects on fish and on sediment organisms (with respect to accumulation of boscalid in the sediment), the risk assessment is based on initial PEC_{sw} values resulting from drift. The TER values for long-term effects on fish are calculated on the basis of a $PEC_{twa,11\,d}$ (see explanation above under B.8.6.1 and B.9.2.1.1). The TER values reflecting the risk to sediment dwellers from accumulation of boscalid in the sediment are based on a calculated $PEC_{sed,plateau}$ value. All relevant figures are compiled in Table B. 9.2-3.

Table B.9.2-3: Relevant PEC values for aquatic systems

Scenario	Distance			
	1 m	3 m	5 m	10 m
vines, 1 × 600 g as/ha				
PEC_{ini} [µg/L]	-/-	16.04	7.24	2.46
$PEC_{twa,11\,d}$ [µg/L]	-/-	10.82	4,88	1,66
$PEC_{sed,plateau}$ [mg/kg]	-/-	0.803[1] / 0.161[2]	0.363[1] / 0.073[2]	0.123[1] / 0.025[2]
beans, 2 × 500 g as/ha, 7 d interval				
PEC_{ini} [µg/L]	6.28	-/-	-/-	-/-
$PEC_{twa,11\,d}$ [µg/L]	**4.24**[3] / 3.92[4]	-/-	-/-	-/-
$PEC_{sed,plateau}$ [mg/kg]	0.397[1] / 0.079[2]	-/-	0.078[1] / 0.016[2]	0.040[1] / 0.008[2]

[1] sediment depth 1 cm
[2] sediment depth 5 cm
[3] twa-interval 7-18 d (averaging starts after 2nd application)
[4] twa-interval 0-11 d (averaging starts after 1st application)

The TER values compiled in Table B.9.2-4 relate to the respective highest PEC values, i.e. distance 3 m and 1 m for grapes and beans, respectively, twa-interval 0-42 d for $PEC_{twa,42\,d}$ in beans and sediment depth 1 cm for $PEC_{sed,plateau}$ in both cultures.

Table B.9.2-4: Toxicity/exposure ratios for the most sensitive aquatic organisms

Application rate (kg as/ha)	Crop	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger
1 × 0.600	grapevines	*O. mykiss*	acute	3	168	100
		O. mykiss	long-term	3	12	10
		D. magna	acute	3	332	100
		D. magna	long-term	3	82	10
		P. subcapitata	short-term	3	84	10
		C. riparius spiked water	long-term	3	62	10
		C. riparius spiked sediment	long-term	3	29	10
2 × 0.500	beans	*O. mykiss*	acute	1	430	100
		O. mykiss	long-term	1	29	10
		D. magna	acute	1	849	100
		D. magna	long-term	1	209	10
		P. subcapitata	short-term	1	213	10
		C. riparius, spiked water	long-term	1	159	10
		C. riparius, spiked sediment	long-term	1	59	10

Conclusion:

All calculated TER values are all well above the respective Annex VI acceptability criteria alreeady at the lowest distance (vines 3 m, beans 1 m) of treated area to surface water body. Thus, no unacceptable effects are expected for aquatic organisms as a result of the proposed uses of boscalid.

B.9.3 Effects on other terrestrial vertebrates (Annex IIIA 10.3)

B.9.3.1 Summary of terrestrial vertebrate toxicity data

The selection of the appropriate endpoint for assessing the long-term effects on mammals was discussed in the Peer Review Process (point 5(3) in Reporting Table, resulting in Open point 3.1 in the Evaluation Table). After reassessment of the data, the RMS now agrees with the proposal to use the endpoint of 1000 ppm (67 mg/kg bw/d) as derived from the reproduction study in rat in the risk assessment.

The overall database shows that changes in liver and thyroid were observed after two years in rat and after one year in dogs as well as after 28 days in rats. Such effects on thyroid are potentially population relevant and should be considered in the risk assessment. However, the effects observed at a concentration level of 100 ppm after two generations in the reproduction study in rat were not pronounced.

The earlier RMS argumentation for using the 100 ppm (6.7 mg/kg bw/d) endpoint from the reproductive study in rat was based on the reasoning that effects on body weight are usually population relevant. At 1000 ppm in the two generation rat study, reductions of body weight (up to 8.7 %) as well as body weight gain (up to 19%) were observed. Taking into account that exposure in the toxicity test is far from being representative for the actual exposure under field conditions, it had been agreed to set the NOEC at 1000 ppm.
The argumentation of the notifier to use 10000 ppm (1183 mg/kg bw/d) from the two generation rat study is not accepted. Potentially relevant effects were already observed in other studies at this concentration level.

B.9.3.2 Risk assessment

B.9.3.2.1 Risk assessment for the active substance

As a consequence of the revised endpoint for long-term effects to mammals, i.e. NOEAEC = 1000 ppm instead of NOEC = 100 ppm from the two-generation study in the rat, the corresponding TER values (Table B.9.3-1) are increased by a factor of 10.

Table B.9.3- 1: Revised long-term TER values for mammals based on a NOEAEC of 1000 ppm from the two-generation study in the rat

Application rate (kg as/ha)	Crop	Category (*e.g.* insectivorous bird)	Time-scale	TER	Annex VI Trigger
0.6	Grapes	Insectivorous mammal	long-term	80	5
0.5	Field crops	Herbivorous mammal	long-term	120	5

B.9.6 Effects on earthworms (Annex IIA 8.4; Annex IIIA 10.6.1)

B.9.6.1 Risk assessment

Considering the results from the submitted accumulation studies in soil and the correspondding PEC_{soil} values, the risk assessment for earthworms was revised. For the assessment of the chronic risk to earthworms following an use of boscalid over many consecutive years, the long-term PEC_{soil} values (see B.8.3 above) are compared to the biological threshold rate of 1000 g as/ha (equivalent to 1.333 mg/kg soil according to standard parameters 5 cm soil layer and soil density of 1.5 g/cm^3), which is considered to be the NOEAEC (No Observed Environmentally Adverse Effect Concentration).

Two different sets of PEC_{soil} data are available: either directly deduced from measured and/or modelled concentrations in the soil accumulation studies or modelled with the groundwater leaching model FOCUS-PEARL 1.1.1 for the two intended uses in the scenarios Hamburg and Châteaudun. The respective data and the resulting TER values are compiled in Table B.9.6.1.

Table B.9.6-1: TER-values for long-term exposure of earthworms to Boscalid

	PEC_{soil}		TER_{lt}
	mg as/kg	kg as/ha	
vines (1 × 600 g as/ha)			
modelled concns.	0.551	413	2.42
measured concns.	0.277	208	4.81
FOCUS-PEARL 1.1.1 Hamburg	0.91	680	1.47
FOCUS-PEARL 1.1.1 Châteaudun	0.79	590	1.69
beans (2 × 500 g as/ha)			
meas. + mod. concns.	0.944	708	1.41
measured concns.	0.640	480	1.56
FOCUS-PEARL 1.1.1 Hamburg	0.90	680	1.47
FOCUS-PEARL 1.1.1 Châteaudun	0.78	590	1.69

Conclusion:

The calculated TER values are higher than 1 for all crop scenarios and all plateau estimations considered. Since the ecotoxicological endpoint was deduced as a NOEAEC from two field studies, i.e. under conditions highly relevant for actual use, no additional assessment factor (margin of safety) is considered necessary in this case. It is thus concluded that the risk to earthworm communities is acceptable for the two assessed crop scenarios vines and beans treated with boscalid (BAS 510 F) according to the label instructions.

B.9.11 References relied on

Annex point/ reference number	Author(s)	Year	Title source (where different from company) report no. GLP or GEP status (where relevant), published or not BVL registration number	Data protection claimed Y/N	Owner
AIIA-8.2.2.1	Zok, S.	1999	BAS 510 F - Early life-stage toxicity test on the rainbow trout (Oncorhynchus mykiss Walbaum 1792). 1999/11847 ! 52F0179/975051 GLP, unpublished WAT2001-366	Y	BAS
IIA-8.2.7/1	Dohmen, P.	2001	Efects of BAS 510 F on the development of sediment dwelling larve of *Chironomus riparius* in a water-sediment system BASF DocID 2000/1018538 WAT 2001-381	Y	BASF
IIA-8.2.7/2	Weltje, L.	2005	Chronic toxicity of Boscalid (BAS 510 F) to the non-biting midge *Chironomus riparius* exposed via spiked-sediment BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. Study code 232363; BASF DocID 2005/1022464 WAT 2005-733	Y	BASF
IIIA-10.1	Bösenberg, K.	1958	Zur Nestlingsnahrung der Goldammer. Der Falke 5:58-61. AVS 2006-43	N	-/-
IIIA-10.1	Braun, M.	1985	Die Veränderung der Vogelwelt in einem ehemaligen Weinbaugebiet (1975/1985). Naturschutz und Ornithologie in Rheinland-Pfalz 4:38-46 AVS 2006-39	N	-/-
IIIA-10.1	Crocker, D.R., Hart, A., Gurney, J., McCoy, C.	2002	Methods for estimating daily food intake of wild birds and mammals. Central Science Laboratory, Project PN0908. Final Report. AVS 2006-29	N	-/-
IIIA-10.1	Crocker, D.R., Prosser, P., Bone, P., Irving & K. Brookes	2001	Project PN0915: Improving estimates of wildlife exposure to pesticides in arable crops. Milestone 03/03 - Radio-tracking progress report AVS 2006-33	N	-/-
IIIA-10.1	Davies, N.B.	1977	Prey selection and social behaviour in wagtails. Journal of Animal Ecology 46: 37-57	N	-/-

Annex point/ reference number	**Author(s)**	**Year**	**Title source (where different from company) report no. GLP or GEP status (where relevant), published or not BVL registration number**	**Data protection claimed Y/N**	**Owner**
			AVS 2006-35		
IIIA-10.1	Goss-Custard, J.D.	1970	Responses of redshank (*Tringa totanus* L.) to spatial variations in the density of their prey. Journal of Animal Ecology 39: 91-113 AVS 2006-32	N	-/-
IIIA-10.1	Green, R.E.	1978	Factors affecting the diet of farmland skylarks, *Alauda arvensis*. Journal of Applied Ecology 47: 913-928 AVS 2006-30	N	-/-
IIIA-10.1	Kenaga, E.E.	1973	Factors to be considered in the evaluation of toxicity of pesticides to birds in their environment. Environmental Quality and Safety. Academic Press, New York, II: 166-181 AVS 2006-36	N	-/-
IIIA-10.1	Lille, R.	1996	Zur Bedeutung von Brachef lächen für die Avifauna der Agrarlandschaft: Eine nährungs-ökologische Studie an der Goldammer *Emberiza citrinella*. Verlag Paul Haupt, Bern Stuttgart Wien. AVS 2006-42	N	-/-
IIIA-10.1	Moreby, S. J., Stoate, C.	2000	A quantitative comparison of neck-collar and faecal analysis to determine passerine nestling diet. Bird Study 47:320-331 AVS 2006-44	N	-/-
IIIA-10.1	Pedall, I.., Storch, V., Riffel, M.	2003	Vogelcoenosen südwestdeutscher Weinberge. Pollichia 90:353-367 AVS 2006-37	N	-/-
IIIA-10.1	Perrins, C.M.	1998	Cramp's the complete book of the western Palearctic. in Optimedia. AVS 2006-41	N	-/-
IIIA-10.1	Schümperlin, W.	1994	Die Brutpopulation der Schafstelze Motacilla flava im unteren Thurgau und im angrenzenden Zürcher Weinland. In: Ornithol. Beob., Bd. 91, Nr. 1, S. 52-56.	N	-/-
IIIA-10.1	Seiler, W.	1986	Sommervogelgemeinschaften von flurbereinigten und nicht bereinigten Weinbergen im württembergischen Unterland. Ökologie der Vögel 8:95-107. AVS 2006-40	N	-/-
IIIA-10.1	Seitz, B.-J.	1989	Beziehungen zwischen Vogelwelt und Vegetation im Kulturland - Untersuchungen im südwestdeutschen Hügelland. Beihefte zu den Veröffentlichungen für	N	-/-

Annex point/ reference number	**Author(s)**	**Year**	**Title source (where different from company) report no. GLP or GEP status (where relevant), published or not BVL registration number**	**Data protection claimed Y/N**	**Owner**
			Naturschutz und Landschaftspflege in Baden-Württemberg 54:1-236 AVS 2006-38		
IIIA-10.1	Snow, D. W., Perrins, C. M.	1998	The birds of the western Palearctic, vol. 2. Passerines. Oxford University Press, Oxford, UK	N	-/-
IIIA-10.1	Stiebel, H.	1996	Untersuchungen zur Habitatwahl und Habitatnutzung der Schafstelze (Motacilla flava L. 1758) in einer Agrarlandschaft. Diplomarbeit, Univ. Göttingen.	N	-/-
IIIA-10.1	Tinbergen, J.M.	1976	How starlings (*Sturnus vulgaris* L.) apportion their foraging time in a virtual single prey situation on a meadow. Ardea 64: 155-170 AVS 2006-31	N	-/-

Addendum 4

to the Draft Assessment Report

of 08 November 2002

(relating to Volume 3)

Boscalid

14 May 2007

Rapporteur Member State: Germany

Contents

To Volume 3:

B.8 Fate and behaviour

B.8.4 Fate and behaviour in water (Annex IIA 7.2.1; Annex IIIA 9.2.1, 9.2.3)

B.8.4.1 Rate and route of degradation in aquatic systems

B.8.4.1.2 Water/sediment study

In connection with the recalculation of PEC_{sw} and PEC_{sed} values (see below), the existing outdoor water/sediment study was re-assessed according to the principles of FOCUS kinetics.

Annex Point: AIIA-7.2.1.3.2
Author: Kellner, O.
Title: Degradation and distribution of BAS 510 F in a water-sediment system under outdoor condi-tions
Date: 2001
Doc ID: BASF DocID 2000/1017038
WAS2001-149
Guidelines: based on BBA IV 5-1
GLP: yes
Validity: yes

Annex Point: AIIIA-9.2.3
Author: J. Bangert
Title: Predicted environmental concentrations in surface water and sediment of BAS 510 F (boscalid) following application of BAS 510 01 F (CANTUS) to beans, peas, spring oilseed rape, winter oilseed rape and vine according to FOCUS considering soil accumulation of boscalid
Date: March 2007
Doc ID: BASF DocID 2007/1017347
Guidelines: n.a.
GLP: n.a.
Validity: n.a.

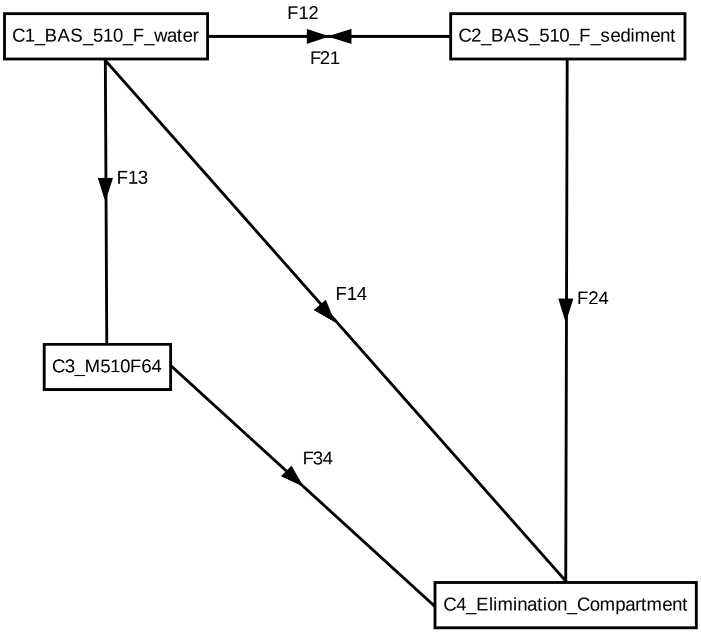
The conditions of the water/sediment study under outdoor conditions represent a more realistic environmental scenario than the classic water/sediment study in the dark. Since, in natural water/sediment systems (rivers, lakes), photolysis and sorption to the sediment may influence the degradation of BAS 510 F simultaneously, a supplementary outdoor study, where both factors were combined, was carried out. The outdoor study used a pond (Kellmetschweiher) water/sediment system. The relevant information on that study can be found in the DAR. Also the dissipation times in water and sediment were already calculated in the DAR. Because of varying temperatures during the test period, only the observations up to day 58 with fairly constant temperatures of about 20 °C were considered.

To achieve appropriate modeling input parameter for FOCUS surface water calculations, the water/sediment study was reassessed according to the principles of FOCUS kinetics. Also for that assessment, the number of 7 observations can be seen as sufficient for the estimation of appropriate kinetic endpoints.

Description of the fitting approach

The observed residues of BAS 510 F and its metabolite M510F64 in the water phase and of the parent in the sediment phase are fitted with the help of a compartment model that considers the dissipation of BAS 510 F in water and in sediment, the sorption and desorption processes of BAS 510 F in the sediment phase and the formation and degradation of M510F64 in the water phase. Only the observed residues up to day 58 with fairly constant experimental temperature conditions of about 20 °C are considered for estimation. The compartment model is described in B.8.4-2.

Figure B.8.4-2 **Compartment model used for the determination of the degradation rates of BAS 510 F and its metabolite M510F64 in an irradiated water/sediment system**



The flowrates F12 and F21 describe the sorption and desorption of boscalid to and from sediment. The flowrates F13 and F14 reflect the degradation processes of the parent compound in the water phase. F24 stands for the degradation of BAS 510 F in sediment. F13 represents also the formation rate of the acidic metabolite M510F64 that can be exclusively assigned to the water phase. The differential equations that describe the compartment model are shown below.

$$\frac{dC1}{dt} = -F12 + F21 - F13 - F14 = -k12 \times C1 + k21 \times C2 - (k13 + k14) \times C1$$
$$\frac{dC2}{dt} = +F12 - F21 - F24 = +k12 \times C1 - (k21 + k24) \times C2$$
$$\frac{dC3}{dt} = +F13 - F34 = +k13 \times C1 - k34 \times C3$$

The rate constants that were estimated during the optimisation procedure are given in Table B.8.4-11.

Table B.8.4-11: Calculated initial concentrations, first order degradation parameters and statistical results of the fitting procedure

Fitted parameter	Parameter value	Standard deviation	t-Value	Type-I error rate
C1initial [%]	95.3	1.8	53.1	<0.001
k12 [1/d]	0.0455	0.0063	7.2	<0.001
k13 [1/d]	0.0165	0.0074	2.2	0.041
k14 [1/d]	0.0051	0.0078	0.6	0.529
k21 [1/d]	0.0697	0.0147	4.8	<0.001
k24 [1/d]	$<10^{-10}$	-	-	-
k34 [1/d]	0.0871	0.0515	1.7	0.112
k13 + k14 [1/d] (= degradation of boscalid in the water phase)	0.0216	0.0023¹⁾	9.4¹⁾	<0.001¹⁾

1) The standard deviation, the t-value and the type-I error rate of the total degradation rate of the parent in the water phase (k13+k14) were achieved by variation of the estimation model used for the first assessment of the water/sediment study in the DAR.

During the optimisation process, the degradation rate constant of boscalid in sediment (k24) became < 10^{-10} 1/d and was set to zero. The estimation result is reliable as no significant correlation to other estimated parameters was observed. The total degradation rate constant of the parent in the water phase (k13 + k14 = 0.0216 1/d) was estimated with an excellent reliability as indicated by its type-I error rate. The resulting DT_{50} values from the estimation approach are given in Table B.8.4-12.

Table B.8.4-12: Dissipation times and half-lives of BAS 510 F in water and sediment

Compound	Best fit DT_{50}/ Half-life	Phase	Results 2nd approach [d]
BAS 510 F	Best fit DT_{50} derived graphically; describing the total decay of boscalid in water	Water	16
BAS 510 F	**Half life used for modeling1) (biotic/abiotic degradation)**	**Water**	**32**
BAS 510 F	Best fit DT_{50} derived graphically; describing the total decay of boscalid in sediment	Sediment	66
M510F64	Half-life (biotic/abiotic degradation)	Water	8

1) biotic/abiotic degradation rate in water separated from partitioning required for models

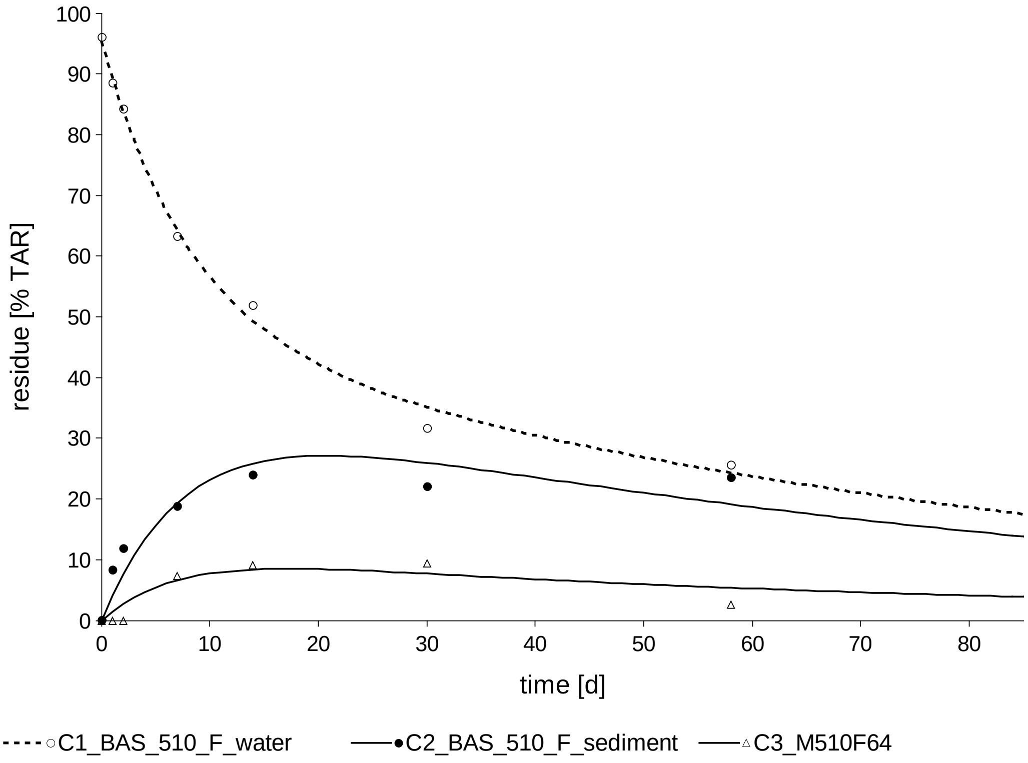
The DT_{50} value of BAS 510 F that describes the total decay in the water phase was determined graphically to be 16 days. The DT_{50} value of BAS 510 F in sediment that was derived graphically (time period from the maximum of the fitted curve to its half) is 66 days. The coefficient of determination for the fit of the total system and the error level chi^2 test value for the fit of the boscalid residues in water and sediment are given in Table B.8.4-13.

Table B.8.4-13: Coefficient of determination and the error level chi^2 test of the boscalid residues

	Coefficient of determination r^2	**Error level chi^2 test [%]**
Water	-	2.7
Sediment	-	16.7
Total	0.99	-

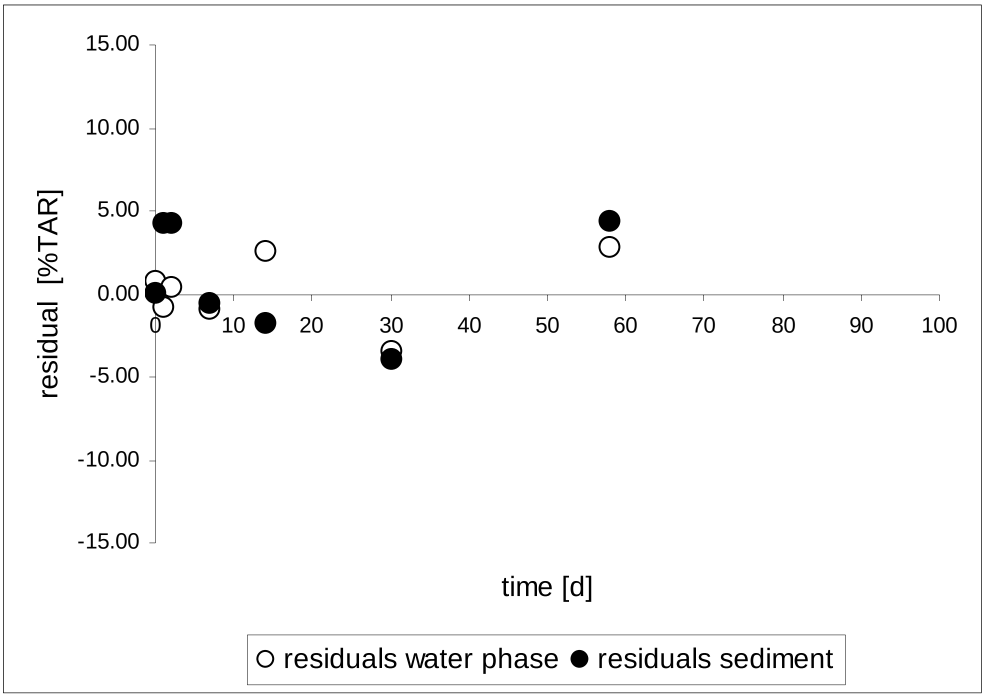
The coefficient of determination for the fit of the total system of 0.99 and the error level chi^2-test values of 2.7 % and 16.7 % for the fit of the residue in water and sediment give evidence of a successful fit approach. Figure B.8.4-2 shows the simulated residue curves of boscalid and its metabolite M510F64 fitted to the measured residues in the water/sediment study.

Figure B.8.4-3: Simulated residue curves fitted to the measured residues of boscalid and the metabolite M510F64 in water and sediment



The residual plots of boscalid in the water and sediment phases are given in Figure B.8.4-4. The residuals of the parent in water and sediment are randomly scattered around the zero line.

Figure B.8.4-4: **Residual plot of simulated and measured concentrations of boscalid in water and sediment**



The half-life of boscalid in the water phase (only degradation processes considered) calculated for the higher tier outdoor water/sediment study was 32 days. The type-I error rate, the coefficient of determination and the results of the chi²-test show that the estimated half-life is appropriate for use in the present modeling study.
The degradation rate constant of the parent in sediment (k24 in Figure B.8.4-2) was estimated to be < 10^{-10} 1/d (see Table B.8.4-12). Therefore, a half-life of 1000 days in sediment that can be seen as a conservative assumption according to the FOCUS kinetics report was considered for the simulations.

Conclusion

The half-life of BAS 510 F in the water phase based on the biotic/abiotic degradation rate (SFO kinetics) is 32 days. It can be used as input parameter for the FOCUS surface water modeling approach.

B.8.6 Predicted environmental concentrations in surface water and in ground water (PEC_{SW}, PEC_{GW}) (Annex IIIA 9.2.1, 9.2.3)

B.8.6.2 PEC in surface water and sediment

Data requirement 2.3b

A comment was made on the possible impact of accumulation in soil on PECsw. A respective statement was requested from the RMS in the Joint EFSA/COM Evaluation Meeting, 04.-06.12.2006

Two soil accumulation studies were submitted and assessed by the RMS in the Addendum 2 (May 2006). The first of them was made in grapes over 5 years with annual application of 3 × 700 g as/ha. The plateau was reached at about 1220 days (40 – 41 months) after the first treatment. This is equivalent to an accumulation factor of 95 % for the background areic concentration directly before the annual application and to an accumulation factor of 148 % for the expected maximum areic concentration after the application of the compound. The second one was made under field conditions in vegetables have been investigated over a six-year-period from 1998 to 2004, results showed that the minimum plateau concentration of 1200 g as/ha according to the current fitted curve would represent an accumulation of 95 % in relation to the average treatment rate over three years of 1270 g as/ha (i.e mean of 2100, 1700 and 0 g as/ha). Likewise, the maximum plateau concentration of 2200 g as/ha would represent an accumulation of 174 %. Therefore is clear that boscalid is a persistent substance for which an accumulation in soil is expected. How this accumulation can contribute to the PECsw must be assessed.

PECsw calculation performed by RMS that was used for risk assessment only includes the contribution due to drift during application, run-off/erosion was consider minor routes of entry. The details of the calculation due to run-off/erosion and drainage was not included in the addendum and should be included. In this case run-off/erosion is one of the main routes of entry in surface water due to the potential accumulation of the substance in soil and the worst case for run-off/soil erosion contribution is when the plateau in soil was reached.

RMS should consider the plateau concentrations in soil for the PECsw calculation due to run-off/erosion, and all possible routes of entry (drift; run-off/erosion; drainage) must be considered together for the PECsw calculation.

Based on the above comments risk assessment for aquatic organism should be re-calculated based on the new PECsw calculation.

Annex Point:	AIIIA-9.2.3
Author:	J. Bangert
Title:	Predicted environmental concentrations in surface water and sediment of BAS 510 F (boscalid) following application of BAS 510 01 F (CANTUS) to beans, peas, spring oilseed rape, winter oilseed rape and vine according to FOCUS considering soil accumulation of boscalid
Date:	March 2007
Doc ID:	BASF DocID 2007/1017347
Guidelines:	n.a.
GLP:	n.a.
Validity:	n.a.

Material and methods

FOCUSsw Simulation models

For the calculation of exposure concentrations at Step 3, a software tool has been developed: SWASH, acronym for Surface WAter Scenarios Help serving as an overall graphical user interface (GUI). Within SWASH, the models PRZM and MACRO calculate the water and substance fluxes that enter the water body via runoff/erosion and drainage, respectively. The model TOXSWA simulates the fate of the pesticide in the water body following loading caused by spray drift deposition and either runoff/erosion or drainage. The concentrations calculated with TOXSWA include actual and time-weighted average PEC values in the water layer and the sediment, which are needed for subsequent aquatic risk assessments.

Agricultural use pattern of CANTUS

The product BAS 510 01 F (CANTUS) is a formulation with the active ingredient BAS 510 F – boscalid. According to the Good Agricultural Practice (GAP), BAS 510 01 F is applied to beans, peas, spring oilseed rape, winter oilseed rape and vine. The maximum application rate of the active ingredient to beans and peas is 500 g as/ha in a twofold application with an application interval of 7-10 days. The maximum application rate to spring and winter oilseed rape is 250 g as/ha in a twofold application with an application interval of 4-6 weeks. The maximum application rate to vine is 600 g as/ha in a single application.
Depending on the crop, BAS 510 01 F can be applied at different growth stages. For the PEC_{sw} and PEC_{sed} calculations, it was assumed that the application window starts 7 days after crop emergence, leading to low interception and maximum soil load, which is considered as a conservative assumption. A summary of the application scenarios is given in Table B.8.6-23.

Table B.8.6-23: Application scenarios of BAS 510 01 F

Crop	Beans and peas	Spring and winter oilseed rape	Vine
FOCUS crop	Legumes	Spring and winter oilseed rape	Vine
Growth stage [BBCH]	60-69	30, 63-65	68-81
Number of applications	2	2	1
Interval	7-10 days	4-6 weeks	-
Application rate BAS 510 F [g as/ha]	500	250	600

PEC_{sw} and PEC_{sed} calculations for the intended use pattern, which is given in Table B.8.6-23, were carried out according to the FOCUS recommendations. Additionally, single application scenarios for legumes and oilseed rape with 500 g as/ha and 250 g as/ha, respectively, were considered. This step is necessary to check, if a single application scenario leads to higher concentrations than multiple applications, since the absolute amounts of the overall 90th drift percentiles for single application are higher than for multiple applications.

Application timing at Step 3

To standardise the assessments, the actual dates of application are determined by the Pesticide Application Tool (PAT) implemented in the models PRZM and MACRO in the SWASH shell. The user is asked to enter the first possible date of application, the number of days in the application window, the number of applications and the minimum interval between applications. PAT then attempts to select appropriate application dates that meet two criteria: no more than 2 mm day^{-1} of precipitation should occur on any day within two days before or

after an application and at least 10 mm of precipitation (cumulative) should occur within 10 days of an application. For this purpose, a minimum application window is determined by assuming a minimum time span of thirty days plus the time period between the first and the last application. In order to meet the above-mentioned climate criteria, an application window of 30 days (single application to vine), of 37 days (twofold application to legumes) and 58 days (twofold application to oilseed rape) was chosen in this modeling study.
Appropriate application dates were selected in the way to ensure low crop interception and hence, a maximum soil load of BAS 510 F. Therefore, the first possible application event was set to an early time point. For all relevant scenarios, the emergence date for legumes, spring oilseed rape, winter oilseed rape and vine plus a time span of 7 days was assumed as the earliest possible date for applications as a conservative worst-case estimation.
For the winter oilseed rape scenario, the method to determine the application date was modified due to the dormant phase of the crop in winter, which is longer than the intended application interval. The first application date was assumed in autumn just before the drainage period. Therefore, the application window of 30 days for the first application starts 7 days after emergence. The second application was assumed in the following year after the drainage period. Therefore, the application window of 30 days starts at 1 April. The detailed application timing as used for the calculations is shown in Table B.8.6-24 below.

Table B.8.6-24: Application timing for BAS 510 F in legumes, spring and winter soilseed rape and vine in the relevant scenarios

Scenario	Water body	Application window	Application dates according to PAT*	Crop emergence
Legumes, BBCH 60-69 (2 × 500 g as/ha)				
D3	ditch	22 April - 29 May	21 April, 4 May 1992**	15 April
D4	pond, stream	30 April - 6 June	14 May, 21 May 1985**	23 April
D5	pond, stream	22 March - 28 April	8 April, 22 April 1978**	15 March
D6	ditch	27 April - 3 June	3 May, 14 May 1986**	20 April
R1	pond, stream	22 April - 29 May	26 April, 3 May 1984**	15 April
R2	stream	27 April - 3 June	27 April, 7 May 1977**	20 April
R3	stream	28 April - 4 June	18 May, 1 June 1980**	21 April
R4	stream	28 April - 4 June	28 April, 8 May 1984**	21 April
Spring oilseed rape, BBCH 30, 63-65 (2 × 250 g as/ha)				
D1	ditch, stream	26 May - 23 July	17 June, 15 July 1982**	19 May
D3	ditch	17 April - 14 June	20 April, 22 May 1992**	10 April
D4	pond, stream	8 May - 5 July	30 May, 4 July 1985**	1 May
D5	pond, stream	22 March - 19 May	8 April, 11 May 1978**	15 March
R1	pond, stream	17 April -14 June	26 April, 13 June 1984**	10 April
Winter oilseed rape, BBCH 30, 63-65 (2 × 250 g as/ha)*****				
D2	ditch, stream	1 November - 1 December	1 April 1986, 3 November 1986, 1 April 1987***	25 October
D3	ditch	9 September - 9 October	4 April 1992, 26 September 1992, 1 April 1993***	2 September
D4	pond, stream	10 September - 10 October	18 April 1985, 10 September 1985, 1 April 1986***	3 September
D5	pond, stream	27 September - 27 October	8 April 1978, 26 October 1978, 1 April 1979****	20 September
R1	pond, stream	11 September - 11 October	17 September 1978, 5 April 1979**	4 September
R3	stream	12 October - 11 November	27 October 1980, 13 April 1981**	5 October

Vine, BBCH 68-81 (1 × 600 g as/ha)				
D6	ditch	8 February - 10 March	27 February 1986	1 February
R1	pond, stream	22 April - 22 May	26 April 1984	15 April
R2	stream	22 March - 21 April	22 March 1977	15 March
R3	stream	8 April - 8 May	11 April 1980	1 April
R4	stream	17 March - 16 April	21 March 1984	10 March

* Automatic calculation of application dates by PAT can lead to deviations from proposed intervals as application dates must match the climate criteria for an appropriate accordance to FOCUS guidance.

** The first date is relevant for the single application.

*** Three applications are relevant for the simulation period in TOXSWA for the drainage scenarios which starts at 1 January and ends at 30 April the following year. The second date is relevant for the single application.

**** Three applications are relevant for the simulation period in TOXSWA for the drainage scenarios which starts at 1 January and ends at 30 April the following year. The date of the single application is 27 September.

***** The application window for the first application in autumn is given. The application window for the second application in spring is from 1 April to 1 May.

Environmental fate parameters of boscalid

Degradation of BAS 510 F in soil

The degradation behavior of BAS 510 F was investigated in five field soils (data shown in the DAR). Standardisation of the field values was performed for temperature but not for soil moisture. Standardisation was only possible for three out of the five studies due to the scattering of the data and a high uncertainty of the estimated degradation rate from the Spanish sites Huelva and Sevilla.

However, the results of the non-standardised ‘best fit’ DT_{50} resulting from the original field studies show that the half-lives measured in Huelva and Sevilla are in the lower range of the field half-lives. The DT_{50} values in Huelva with 27 days and in Sevilla with 78 days are the lowest and third to lowest value. It can therefore be concluded that the geometric mean value of 130 days, which is used for the calculations, already represents a worst case.

Sorption parameters of BAS 510 F

The sorption onto soil was investigated by batch-equilibrium sorption studies for the compound BAS 510 F (see DAR). Adsorption and desorption in different soils was measured and Freundlich isotherms were calculated. For BAS 510 F the adsorption K_{foc} values ranged from 507 to 1 110 mL/g with corresponding Freundlich exponents 1/n between 0.839 and 0.887. The respective mean values were a K_{foc} of 771 mL/g and a Freundlich exponent of 1/n = 0.864. They were used for the calculations.

Fate and behavior in aquatic systems

The dissipation behavior of BAS 510 F – boscalid in water has been studied in two water/sediment studies under different test conditions. The first study was performed under standard laboratory conditions in the dark. To reflect a more realistic environmental scenario, the second water/sediment study was conducted under outdoor conditions with the influence of natural sunlight.

Standard water/sediment study

The standard water/sediment study was conducted in the laboratory at 20 °C in the dark. The study includes two aquatic test systems from different origins, one representing a pond (Kellmetschweiher) and the other a river (Berghäuser Altrhein). The residues of system A (Kellmetschweiher) and system B (Berghäuser Altrhein) observed by HPLC analysis (mean of diphenyl and pyridine labeled samples) are given in the DAR.

The dissipation of boscalid in the water phase of system A and B was mainly based on sorption processes. Low amounts of bound residues could be observed in the sediment with a maximum of 13 % at day 100 after treatment. The decay in the water phase was determined graphically (non SFO) with DT_{50} values of 9 days and 3 days for system A and B, respectively. Appropriate DT_{50} values (input parameters for FOCUSsw Step 3 calculations) that describe the degradation processes in water and sediment could not be deduced from the water/sediment study conducted in the dark. Therefore, DT_{50} values of 1000 days for water and sediment that can be seen as conservative assumptions according to the FOCUS kinetics report were taken into account.

Higher tier outdoor water/sediment study

The conditions of the water/sediment study under outdoor conditions represent a more realistic environmental scenario than the classic water/sediment study in the dark. Since, in natural water/sediment systems (rivers, lakes), photolysis and sorption to the sediment may influence the degradation of BAS 510 F simultaneously, a supplementary outdoor study, where both factors were combined, was carried out. The outdoor study used a pond (Kellmetschweiher) water/sediment system. The relevant information on that study can be found in the DAR.

To achieve appropriate modeling input parameter for FOCUS surface water calculations, the water/sediment study was reassessed according to the principles of FOCUS kinetics. The approach is described above under B.8.4.1.2. The half-life of BAS 510 F in the water phase based on the biotic/abiotic degradation rate (SFO kinetics) is 32 days. It is used as input parameter for the FOCUS surface water modeling approach.

Input parameter overview

Two sets of PEC values were simulated using two different degradation rates in the water phase which were derived from the standard water/sediment study in the dark (DT_{50} 1000 days, conservative assumption based on FOCUS) and the higher-tier irradiated water/sediment study (DT_{50} 32 days). For a summary of the environmental fate parameters of BAS 510 F used in model calculations, see Table B.8.6-25.

Table B.8.6-25: Summary of FOCUS Step 3 input parameters for BAS 510 F - boscalid

Parameter	Value	Remarks
Entry routes into surface water	Spray drift Runoff Drainage	
Molecular weight [g mol^{-1}]	343.2	Phys.-chem. Properties
Water solubility [mg L^{-1}]	5	Phys.-chem. Properties
Vapor pressure [Pa]	7.2×10^{-7}	Phys.-chem. Properties
DEGRADATION IN SOIL		
DT_{50} (soil) [d]	130	Geometric mean of field dissipation studies (n=3, standardised at 20 °C)
Temperature correction function Reference temperature [°C] MACRO: [K^{-1}] PRZM: Q_{10} [-]	 20 0.079 2.2	FOCUS recommendation
Moisture correction function Reference moisture [-] PRZM / MACRO: moisture exponent [-]	 pF 2 0.7	FOCUS recommendation
SORPTION TO SOIL		
$K_{f,oc}$ [mL g^{-1}]	771	Arithmetic mean
1/n [-]	0.864	Arithmetic mean

Parameter	**Value**	**Remarks**
DEGRADATION IN AQUATIC SYSTEMS		
DT_{50} water [d] derived from the higher tier outdoor water/sediment study	32	Estimated from data of irradiated water/sediment study
DT_{50} sediment [d] derived from the higher tier outdoor water/sediment study	1000	Due to the very low estimated k-rate, conservative default value
DT_{50} water [d] derived from the standard water/sediment study	1000	Conservative assumption for the degradation behavior in the total system
DT_{50} sediment [d] derived from the standard water/sediment study	1000	No measured value available, conservative default value
DT_{50} crop [d]	10	FOCUS recommendation
Temperature correction function Reference temperature [°C] TOXSWA: activation energy [J mol^{-1}]	20 54 000	FOCUS recommendation
MANAGEMENT RELATED PARAMETERS		
Crop uptake factor [-]	0.5	FOCUS recommendation
Wash off coefficient [cm^{-1}]	0.5	FOCUS recommendation

Modification of standard FOCUS Step 3 calculations considering the soil accumulation of boscalid

The average half-life of boscalid of 130 days and the results of two field studies (see DAR) indicate an accumulation potential of boscalid in the soil. The accumulated amounts of the substance in soil originating from applications in previous years can lead to higher PEC in surface water and sediment due to higher substance entries from drainage and runoff.
The models PRZM and MACRO that describe the water and substance fluxes entering the water body via runoff/erosion and drainage already includes application events in previous years and subsequent boscalid soil accumulation. These simulated soil concentrations were adapted to the accumulated soil concentrations that could be deduced from experimental soil accumulation studies as described in following section.

Accumulated soil concentrations of boscalid deduced from field studies

The concentrations in soil following long-term application of BAS 510 F were deduced from a vegetable and a grapevine accumulation study (see Addendum 2). The observed and fitted residue concentrations of BAS 510 F from these accumulation studies are shown in Figure B.8.6-3 and Figure B.8.6-4.

Figure B.8.6-3: Fitted curve for the residues of BAS 510 F observed in the vineyard accumulation study and the estimated minimum plateau amount

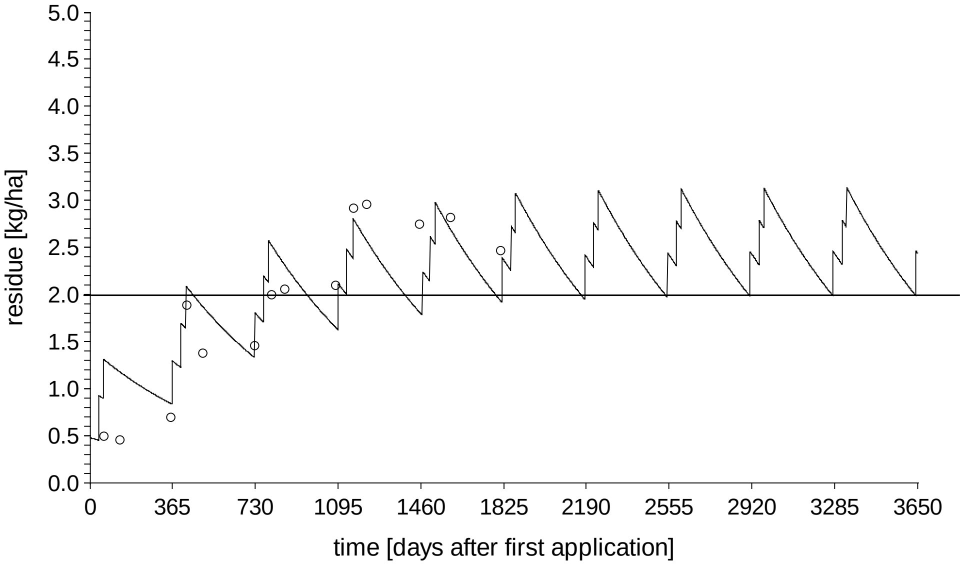
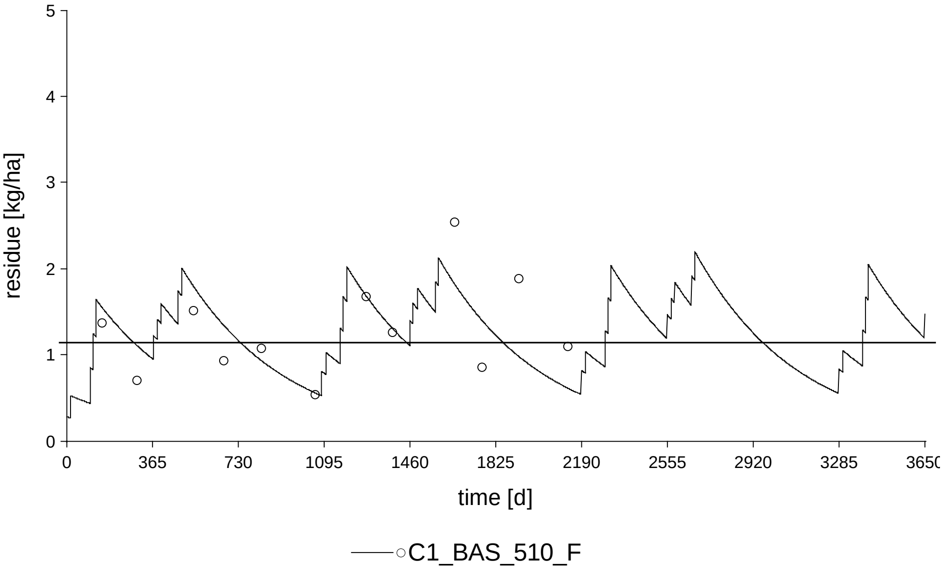


Figure B.8.6-4: Fitted curve for the residues of BAS 510 F observed in the vegetable accumulation study and the estimated minimum plateau amount



The plateau levels at steady state (i.e. representing the connecting line of curve minima) observed in the vegetable and the grapevine accumulation study are given in Table B.8.6-26. The plateau level is defined as the highest residue in soil after the winter period just before the first seasonal application in spring. As these plateau levels are clearly related to the annual average total application rate of the respective accumulation study, they can therefore be expressed as a percentage of this annual average application rate. This percentage, which was named “accumulation fraction at steady state” (f_{accu}), is also given in Table B.8.6-26.

Table B.8.6-26: Plateau values in soil as observed in the field accumulation studies related to the annual average application rate

Accumulation study	Plateau amount [kg/ha]	Annual average application rate[1] [kg/ha]	Accumulation fraction at steady state f_{accu} [%]
Grapevine	2.0	2.1	95
Vegetable	1.2	1.27	95

[1] Because of the varying total yearly application rates of BAS 510 F during the study period the annual average total application rate was taken into account

Under consideration of the annual average application rates, the grapevine and the vegetable accumulation studies show the same plateau percentage. The plateau values after long-term application of BAS 510 F amount to 95 % of the annual average application rate.

Adaptation of the soil concentrations of boscalid at runoff and drainage events

The period considered for PEC_{sw} and PEC_{sed} calculation in FOCUSsw modeling is preceded by a ‘warm-up’ period of several PRZM and MACRO modeling years. At the end of this ‘warm-up’ period, i.e. before the first application event of the period considered for PECsw and PECsed calculation, the simulated PRZM and MACRO soil concentrations were adjusted, in order to start FOCUSsw calculations with the appropriate plateau level at steady state before the annual application period (as deduced from the soil accumulation studies).
In doing so, an additional application of boscalid to bare soil was implemented in the PRZM and MACRO simulations for runoff/erosion and drainage entry into the surface water. The additional amount of boscalid was applied at the day before the first seasonal application. It was derived from the difference of the simulated soil load (originating from the warm-up period) and the experimental soil load of boscalid (as derived from the model description of the accumulation studies). Consequently, the experimental soil load was calculated by multiplying the total seasonal application rate by the accumulation fraction of 95 %. The simulated soil load of the substance was determined by analysing the output files of PRZM and MACRO after a standard FOCUS Step 3 simulation run as follows:

- In the PRZM output file (file extension: .out), the simulated soil load is available for the last day of the calendar year. Therefore, the concentration of boscalid in soil at the end of the year before the relevant PRZM year is taken as actual soil load. The respective concentration is given in the item “TOTAL PESTICIDE IN CORE” of the output file. If the relevant PRZM year is 1975 – the first year of the simulation period in PRZM – the simulated soil load is assumed to be 0 kg as/ha.
- In MACRO, the simulated soil load of a substance is available from the .bin output file by summing up the concentrations of boscalid in the solid and aqueous phase of the macro- and micropores. The concentrations at 9:30 a.m. at the day before the first application in the last year of the MACRO simulation period were considered to represent the simulated soil load.
- The additional application events were implemented in the input files of PRZM and MACRO at the day before the first application in the year relevant for PRZM and MACRO outputs to TOXSWA. Because of regular soil cultivation in previous years, the incorporation depth of the additional application in the PRZM model was set to a soil depth of 30 cm for vegetables (here: legumes) and field crops (here: oilseed rape) and of 10 cm for vine.

A closer description of the modified data is given in Table B.8.6-27 and Table B.8.6-28.

Table B.8.6-27: Additional application amounts of boscalid for runoff scenarios (PRZM model)

Scenario	Relevant PRZM year	Total seasonal application rate [kg as/ha]	Experimental soil load* 95% of tot. seasonal appl. rate [kg as/ha]	Simulated soil load from previous year** [kg as/ha]	Amount of additional application*** [kg as/ha]
Legumes (1 × 500 g as/ha)					
R1	1984	0.500	0.475	0.3292	0.1458
R2	1977	0.500	0.475	0.1688	0.3062
R3	1980	0.500	0.475	0.1084	0.3666
R4	1984	0.500	0.475	0.1801	0.2949
Legumes (2 × 500 g as/ha)					
R1	1984	1.000	0.950	0.6332	0.3168
R2	1977	1.000	0.950	0.1888	0.7612
R3	1980	1.000	0.950	0.2030	0.7470
R4	1984	1.000	0.950	0.3369	0.6131
Spring oilseed rape (1 × 250 g as/ha)					
R1	1984	0.250	0.2375	0.1674	0.0701
Spring oilseed rape (2 × 250 g as/ha)					
R1	1984	0.500	0.475	0.2729	0.2021
Winter oilseed rape (1 × 250 g as/ha)					
R1	1978	0.250	0.2375	0.3105	0.000****
R3	1980	0.250	0.2375	0.2528	0.000****
Winter oilseed rape (2 × 250 g as/ha)					
R1	1978	0.500	0.475	0.3936	0.0814
R3	1980	0.500	0.475	0.2901	0.1849
Vine (1 × 600 g as/ha)					
R1	1984	0.600	0.570	0.4192	0.1508
R2	1977	0.600	0.570	0.2774	0.2926
R3	1980	0.600	0.570	0.1905	0.3795
R4	1984	0.600	0.570	0.2486	0.3214

* The experimental soil load was derived by multiplying the total seasonal application rate by an accumulation fraction of 0.95 according to the results of field accumulation studies.

** The value is available in the item “TOTAL PESTICIDE IN CORE” of the PRZM output file.

*** Difference between “Experimental soil load” and “Simulated soil load”.

**** As the simulated soil load exceeds the experimental soil load, no additional application was carried out.

Table B.8.6-28: Additional application amounts of boscalid for drainage scenarios (MACRO model)

Scenario	Relevant MACRO year	Total seasonal application rate [kg as/ha]	Experimental soil load* 95% of tot. seasonal appl. rate [kg as/ha]	Simulated soil load at day before first seasonal application** [kg as/ha]	Amount of additional application*** [kg as/ha]
Legumes (1 × 500 g as/ha)					
D3	1992	0.500	0.475	0.2628	0.2122
D4	1985	0.500	0.475	0.3829	0.0921
D5	1978	0.500	0.475	0.2433	0.2317
D6	1986	0.500	0.475	0.1214	0.3536
Legumes (2 × 500 g as/ha)					
D3	1992	1.000	0.950	0.5265	0.4235
D4	1985	1.000	0.950	0.7654	0.1846
D5	1978	1.000	0.950	0.4830	0.4670

D6	1986	1.000	0.950	0.2321	0.7179
Spring oilseed rape (1 × 250 g as/ha)					
D1	1982	0.250	0.2375	0.2742	0.0000****
D3	1992	0.250	0.2375	0.1608	0.0767
D4	1985	0.250	0.2375	0.2109	0.0266
D5	1978	0.250	0.2375	0.1242	0.1133
Spring oilseed rape (2 × 250 g as/ha)					
D1	1982	0.500	0.475	0.4390	0.0360
D3	1992	0.500	0.475	0.2809	0.1941
D4	1985	0.500	0.475	0.3362	0.1388
D5	1978	0.500	0.475	0.2179	0.2571
Winter oilseed rape (1 × 250 g as/ha)					
D2	1986	0.250	0.2375	0.1858	0.0517
D3	1992	0.250	0.2375	0.1554	0.0821
D4	1985	0.250	0.2375	0.2533	0.0000****
D5	1978	0.250	0.2375	0.1454	0.0921
Winter oilseed rape (2 × 250 g as/ha)					
D2	1986	0.500	0.475	0.3529	0.1221
D3	1992	0.500	0.475	0.3104	0.1646
D4	1985	0.500	0.475	0.4662	0.0088
D5	1978	0.500	0.475	0.2711	0.2039
Vine (1 × 600 g as/ha)					
D6	1986	0.600	0.570	0.0932	0.4768

* The experimental soil load was derived by multiplying the total seasonal application rate by an accumulation fraction of 0.95 according to the results of field accumulation studies.

** The value represents the sum of the concentrations of boscalid in the solid and aqueous phase of the macro- and micropores at 9:30 a.m. at the day before the first application in the last year of the MACRO simulation period as given in the MACRO output file.

*** Difference between “Experimental soil load” and “Simulated soil load”.

**** As the simulated soil load exceeds the experimental soil load, no additional application was carried out.

The drainage and runoff entries into surface water were simulated again considering the additional application of boscalid by rerunning MACRO and PRZM with the modified input files. Afterwards, the PEC in surface water and sediment were calculated by TOXSWA using the results of the modified MACRO and PRZM simulations.

Results

The PEC_{sw} and PEC_{sed} values for the compound BAS 510 F – boscalid were calculated with the SWASH software package for the FOCUSsw Step 3 level considering the soil accumulation potential of boscalid as described above. Calculations were carried out for a twofold application of the active ingredient to legumes, spring oilseed rape and winter oilseed rape and for a single application to vine.

Additionally, single application scenarios for legumes and oilseed rape were considered. This step is necessary to check, if a single application scenario leads to higher concentrations than multiple applications since the absolute amounts of the overall 90th drift percentiles for single application are higher than for multiple applications. The results of the simulations of the single application scenarios are discussed below.

Two sets of PEC values were simulated using two different degradation rates in the water phase which were derived from the standard water/sediment study in the dark (DT_{50} 1000 days, conservative assumption based on FOCUS recommendations) and the higher-tier irradiated water/sediment study (DT_{50} 32 days, see B.8.4.1.2).

In Step 3 of the assessment, eight out of the ten FOCUS scenarios were seen as relevant for legumes (D3, D4, D5, D6, R1, R2, R3 and R4). For spring oilseed rape, five scenarios are relevant (D1, D3, D4, D5 and R1). Six scenarios were considered for winter oilseed rape (D2, D3, D4, D5, R1 and R3) and five scenarios are relevant for vine (D6, R1, R2, R3 and R4). For each scenario, at least one water body type is defined (ditch, stream, pond). Cross references to the tables with results are given in Táble B.8.6-29.

Table B.8.6-29: Overview of the calculation approaches

Crop	**Application scenario**	**Considered w/s study**	**Results for PEC$_{sw,max}$**	**Results for PEC$_{sw,act}$ and PEC$_{sw,twa}$**	**Results for PEC$_{sed,max}$**
Vine	Single application	standard	Table B.8.6-8	Table B.8.6-9 Table B.8.6-10	Table B.8.6-24
		higher tier	Table B.8.6-11	-*	Table B.8.6-25
Leg.	Single application	standard	Table B.8.6-12	-*	-*
		higher tier	-*	-*	-*
	Twofold application	standard	Table B.8.6-13	Table B.8.6- Table B.8.6-15 Table B.8.6-16	Table B.8.6-26
		higher tier	Table B.8.6-23	-*	Table B.8.6-27
Spring oilseed rape	Single application	standard	Table B.8.6-12	-*	-*
		higher tier	-*	-*	-*
	Twofold application	standard	Table B.8.6-13	Table B.8.6-17 Table B.8.6-18 Table B.8.6-19	Table B.8.6-26
		higher tier	Table B.8.6-23	-*	Table B.8.6-27
Winter oilseed rape	Single application	standard	Table B.8.6-12	-*	-*
		higher tier	-*	-*	-*
	Twofold application	standard	Table B.8.6-13	Table B.8.6-20 Table B.8.6-21 Table B.8.6-22	Table B.8.6-26
		higher tier	Table B.8.6-23	-*	Table B.8.6-27

* No PEC values calculated for the respective approach

No higher-tier (Step 4) modelling of BAS 510 F concentration was required for the assessment.

B.8.6.2.1 PEC$_{sw}$ calculation for application in vine

Single application scenario

Degradation data from standard water/sediment study

Table B.8.6-30 lists the global maximum concentrations in the different surface water bodies (ditch, stream or pond) as associated with the scenario locations after single application of boscalid to vine. In Table B.8.6-31 and Table B.8.6-32, actual concentrations and time-weighted average concentrations for the respective time intervals after the global maximum concentration are provided. For the calculations, a degradation rate in water of 1000 days was taken into account.

Table B.8.6-30: Global maximum concentrations of BAS 510 F in different water bodies following single application of BAS 510 01 F to vine (considering DT_{50} in water of 1000 days)

Location	Type of water body	Step 3 $PEC_{sw,max}$ [µg L^{-1}]
Crop		Vine 1 × 600 g/ha
D6	ditch	10.169
R1	pond	0.366
R1	stream	7.474
R2	stream	9.908
R3	stream	10.574
R4	stream	7.471

Table B.8.6-31: $PEC_{sw,act}$ and $PEC_{sw,twa}$ of BAS 510 F following single application of BAS 510 01 F to vine (considering DT_{50} in water of 1000 days) FOCUS scenarios: D6 ditch, R1 pond and R1 stream

DAMC* [d]	Step 3					
	D6 Ditch		R1 Pond		R1 Stream	
	$PEC_{sw,act}$ [µg L^{-1}]	$PEC_{sw,twa}$ [µg L^{-1}]	$PEC_{sw,act}$ [µg L^{-1}]	$PEC_{sw,twa}$ [µg L^{-1}]	$PEC_{sw,act}$ [µg L^{-1}]	$PEC_{sw,twa}$ [µg L^{-1}]
0	10.169	-	0.366	-	7.474	-
1	0.260	4.051	0.353	0.359	0.002	1.332
2	0.089	2.098	0.344	0.354	0.001	0.670
4	0.050	1.450	0.329	0.345	< 0.001	0.336
7	0.023	1.177	0.312	0.334	< 0.001	0.192
14	0.015	0.753	0.283	0.315	< 0.001	0.143
21	0.011	0.534	0.260	0.301	< 0.001	0.096
28	0.009	0.512	0.252	0.290	< 0.001	0.085
42	0.009	0.424	0.235	0.275	< 0.001	0.080
50	0.007	0.361	0.218	0.267	< 0.001	0.067
100	0.002	0.236	0.158	0.230	< 0.001	0.047

* Days after maximum concentration

Table B.8.6-32: $PEC_{sw,act}$ and $PEC_{sw,twa}$ of BAS 510 F following single application of BAS 510 01 F to vine (considering DT_{50} in water of 1000 days) FOCUS scenarios: R2 stream, R3 stream and R4 stream

DAMC* [d]	Step 3					
	R2 Stream		R3 Stream		R4 Stream	
	$PEC_{sw,act}$ [µg L^{-1}]	$PEC_{sw,twa}$ [µg L^{-1}]	$PEC_{sw,act}$ [µg L^{-1}]	$PEC_{sw,twa}$ [µg L^{-1}]	$PEC_{sw,act}$ [µg L^{-1}]	$PEC_{sw,twa}$ [µg L^{-1}]
0	9.908	-	10.574	-	7.471	-
1	< 0.001	1.483	0.019	6.218	0.002	2.743
2	< 0.001	0.743	0.008	3.317	0.001	2.404
4	< 0.001	0.372	0.004	1.670	< 0.001	1.221
7	< 0.001	0.213	0.002	0.958	< 0.001	0.699
14	1.738	0.107	0.008	0.710	< 0.001	0.350
21	< 0.001	0.111	0.002	0.474	< 0.001	0.233
28	< 0.001	0.083	< 0.001	0.356	< 0.001	0.175
42	< 0.001	0.055	< 0.001	0.238	< 0.001	0.117

	Step 3					
	R2 Stream		R3 Stream		R4 Stream	
50	< 0.001	0.047	< 0.001	0.200	< 0.001	0.098
100	< 0.001	0.034	< 0.001	0.100	< 0.001	0.061

* Days after maximum concentration

Degradation data from outdoor water/sediment study

The global maximum concentrations in Table B.8.6-33 reflect the same scenarios as in the data in Table B.8.6-30. The DT_{50} in water of of 32 d from the outdoor water/sediment study was used instead of the assumption of 1000 d. No actual and time-weighted average PEC values were calculated for this approach.

Table B.8.6-33: Global maximum concentrations of BAS 510 F in different water bodies following single application of BAS 510 01 F to vine (considering DT_{50} in water of 32 days)

Location	Type of water body	Step 3 PEC$_{sw,max}$ [µg L^{-1}]
Crop		Vine 1 × 600 g/ha
D6	ditch	10.169
R1	pond	0.366
R1	stream	7.474
R2	stream	9.908
R3	stream	10.574
R4	stream	7.471

B.8.6.2.2 PEC$_{sw}$ calculation for application in legumes and oilseed rape

Single application scenario

Degradation data from standard water/sediment study

Table B.8.6-34 lists the global maximum concentrations in the different surface water bodies (ditch, stream or pond) as associated with the scenario locations after single application of boscalid to legumes or oilseed rape. For the calculations, a degradation rate in water of 1000 days was taken into account.

Table B.8.6-34: Global maximum concentrations of BAS 510 F in different water bodies following single application of BAS 510 01 F to legumes or oilseed rape (considering DT_{50} in water of 1000 days)

Location	Type of water body	Step 3 PEC$_{sw,max}$ [µg L^{-1}]		
Crop		Legumes 1 × 500 g/ha	Spring oilseed rape 1 × 250 g/ha	Winter oilseed rape 1 × 250 g/ha
D1	ditch	-[1]	2.699	-[1]
D1	stream	-[1]	1.436	-[1]
D2	ditch	-[1]	-[1]	3.073
D2	stream	-[1]	-[1]	1.926
D3	ditch	2.617	1.583	1.588
D4	pond	0.807	0.285	0.393
D4	stream	2.182	1.314	1.369

Location	Type of water body	Step 3 PEC$_{sw,max}$ [µg L^{-1}]		
D5	pond	0.326	0.143	0.223
D5	stream	2.165	1.248	1.477
D6	ditch	3.374	-[1]	-[1]
R1	pond	0.239	0.197	0.146
R1	stream	3.272	1.553	1.247
R2	stream	2.408	-[1]	-[1]
R3	stream	3.105	-[1]	2.328
R4	stream	6.396	-[1]	-[1]

[1] scenario not defined for the respective crop

Twofold application scenario

Degradation data from standard water/sediment study

Table B.8.6-35 lists the global maximum concentrations in the different surface water bodies (ditch, stream or pond) as associated with the scenario locations after twofold application of boscalid to legumes and oilseed rape. In Table B.8.6-36 to Table B.8.6-42, actual concentrations and time-weighted average concentrations for the respective time intervals after the global maximum concentration are provided. For the calculations, a degradation rate in water of 1000 days was taken into account.

Table B.8.6-35: Global maximum concentrations of BAS 510 F in different water bodies following twofold application of BAS 510 01 F to legumes and oilseed rape (considering DT$_{50}$ in water of 1000 days)

Location	Type of water body	Step 3 PEC$_{sw,max}$ [µg L^{-1}]		
Crop		Legumes 2 × 500 g/ha	Spring oilseed rape 2 × 250 g/ha	Winter oilseed rape 2 × 250 g/ha
D1	ditch	-[1]	3.970	-[1]
D1	stream	-[1]	2.483	-[1]
D2	ditch	-[1]	-[1]	5.488
D2	stream	-[1]	-[1]	3.435
D3	ditch	2.273	1.384	1.387
D4	pond	1.963	0.624	0.673
D4	stream	3.030	1.183	1.530
D5	pond	0.772	0.304	0.417
D5	stream	2.041	1.199	1.277
D6	ditch	7.669	-[1]	-[1]
R1	pond	0.485	0.355	0.218
R1	stream	7.191	2.167	1.437
R2	stream	2.506	-[1]	-[1]
R3	stream	6.785	-[1]	2.546
R4	stream	11.269	-[1]	-[1]

[1] scenario not defined for the respective crop

LEGUMES

Table B.8.6-36: PEC$_{sw,act}$ and PEC$_{sw,twa}$ of BAS 510 F following twofold application of BAS 510 01 F to legumes (considering DT$_{50}$ in water of 1000 days) FOCUS scenarios: D3 ditch, D4 pond, D4 stream and D5 pond

DAMC* [d]	Step 3							
	D3 Ditch		D4 Pond		D4 Stream		D5 Pond	
	$PEC_{sw,act}$ [$\mu g\ L^{-1}$]	$PEC_{sw,twa}$ [$\mu g\ L^{-1}$]	$PEC_{sw,act}$ [$\mu g\ L^{-1}$]	$PEC_{sw,twa}$ [$\mu g\ L^{-1}$]	$PEC_{sw,act}$ [$\mu g\ L^{-1}$]	$PEC_{sw,twa}$ [$\mu g\ L^{-1}$]	$PEC_{sw,act}$ [$\mu g\ L^{-1}$]	$PEC_{sw,twa}$ [$\mu g\ L^{-1}$]
0	2.273	-	1.963	-	3.030	-	0.772	-
1	1.022	1.741	1.960	1.963	1.110	2.540	0.769	0.772
2	0.131	1.110	1.954	1.962	2.530	2.245	0.762	0.771
4	0.015	0.576	1.937	1.959	0.865	2.062	0.748	0.766
7	0.006	0.333	1.902	1.953	0.969	1.769	0.728	0.758
14	0.002	0.290	1.813	1.934	1.381	1.339	0.690	0.739
21	0.001	0.222	1.734	1.909	0.880	1.278	0.659	0.721
28	< 0.001	0.167	1.770	1.878	0.458	1.166	0.632	0.705
42	< 0.001	0.112	1.646	1.837	0.318	0.896	0.594	0.676
50	< 0.001	0.094	1.565	1.815	0.543	0.827	0.579	0.662
100	< 0.001	0.047	1.186	1.649	0.033	0.504	-**	0.553

* Days after maximum concentration

** simulated period too short for calculation of $PEC_{sw,act}$

Table B.8.6-37: $PEC_{sw,act}$ and $PEC_{sw,twa}$ of BAS 510 F following twofold application of BAS 510 01 F to legumes (considering DT_{50} in water of 1000 days) FOCUS scenarios: D5 stream, D6 ditch, R1 pond and R1 stream

DAMC* [d]	Step 3							
	D5 Stream		D6 Ditch		R1 Pond		R1 Stream	
	$PEC_{sw,act}$ [$\mu g\ L^{-1}$]	$PEC_{sw,twa}$ [$\mu g\ L^{-1}$]	$PEC_{sw,act}$ [$\mu g\ L^{-1}$]	$PEC_{sw,twa}$ [$\mu g\ L^{-1}$]	$PEC_{sw,act}$ [$\mu g\ L^{-1}$]	$PEC_{sw,twa}$ [$\mu g\ L^{-1}$]	$PEC_{sw,act}$ [$\mu g\ L^{-1}$]	$PEC_{sw,twa}$ [$\mu g\ L^{-1}$]
0	2.041	-	7.669	-	0.485	-	7.191	-
1	0.028	0.722	1.963	4.988	0.477	0.481	0.010	3.746
2	0.028	0.662	1.023	3.889	0.471	0.478	0.006	1.877
4	0.028	0.505	0.655	2.839	0.460	0.472	0.002	0.940
7	0.026	0.459	2.483	2.347	0.445	0.464	0.005	0.793
14	0.020	0.353	0.466	1.746	0.415	0.448	0.003	0.594
21	0.023	0.294	0.096	1.248	0.389	0.433	< 0.001	0.396
28	0.018	0.259	0.057	1.006	0.365	0.423	< 0.001	0.305
42	0.006	0.211	0.034	0.934	0.332	0.422	< 0.001	0.260
50	< 0.001	0.195	1.007	0.809	0.311	0.416	< 0.001	0.223
100	< 0.001	0.129	0.105	0.680	0.314	0.362	< 0.001	0.122

* Days after maximum concentration

Table B.8.6-38: $PEC_{sw,act}$ and $PEC_{sw,twa}$ of BAS 510 F following twofold application of BAS 510 01 F to legumes (considering DT_{50} in water of 1000 days) FOCUS scenarios: R2 stream, R3 stream and R4 stream

DAMC* [d]	Step 3					
	R2 Stream		R3 Stream		R4 Stream	
	$PEC_{sw,act}$ [$\mu g\ L^{-1}$]	$PEC_{sw,twa}$ [$\mu g\ L^{-1}$]	$PEC_{sw,act}$ [$\mu g\ L^{-1}$]	$PEC_{sw,twa}$ [$\mu g\ L^{-1}$]	$PEC_{sw,act}$ [$\mu g\ L^{-1}$]	$PEC_{sw,twa}$ [$\mu g\ L^{-1}$]
0	2.506	-	6.785	-	11.269	-
1	1.031	2.490	0.062	5.643	0.014	7.624
2	0.006	1.333	0.027	3.001	9.554	4.523
4	0.002	0.668	0.012	1.513	0.008	3.245
7	0.001	0.383	0.005	0.869	0.181	3.148
14	< 0.001	0.192	0.002	0.485	0.003	1.912
21	< 0.001	0.128	0.001	0.330	0.002	1.336
28	0.007	0.151	< 0.001	0.331	0.019	1.012
42	< 0.001	0.101	0.002	0.225	< 0.001	0.710

	Step 3					
	R2 Stream		R3 Stream		R4 Stream	
50	< 0.001	0.085	< 0.001	0.190	< 0.001	0.602
100	< 0.001	0.058	< 0.001	0.132	0.000	0.302

* Days after maximum concentration

SPRING OILSEED RAPE

Table B.8.6-39: $PEC_{sw,act}$ and $PEC_{sw,twa}$ of BAS 510 F following twofold application of BAS 510 01 F to spring oilseed rape (considering DT_{50} in water of 1000 days) FOCUS scenarios: D1 ditch, D1 stream and D3 ditch

DAMC* [d]	Step 3					
	D1 Ditch		D1 Stream		D3 Ditch	
	$PEC_{sw,act}$ [µg L^{-1}]	$PEC_{sw,twa}$ [µg L^{-1}]	$PEC_{sw,act}$ [µg L^{-1}]	$PEC_{sw,twa}$ [µg L^{-1}]	$PEC_{sw,act}$ [µg L^{-1}]	$PEC_{sw,twa}$ [µg L^{-1}]
0	3.970	-	2.483	-	1.384	-
1	3.886	3.927	2.422	2.454	0.794	1.121
2	3.839	3.894	2.393	2.432	0.172	0.782
4	3.855	3.871	2.414	2.415	0.016	0.419
7	3.752	3.845	2.325	2.398	0.006	0.244
14	3.545	3.751	2.188	2.333	0.002	0.124
21	3.393	3.671	2.094	2.282	0.001	0.083
28	3.444	3.606	2.144	2.243	< 0.001	0.062
42	3.108	3.517	1.897	2.187	< 0.001	0.076
50	2.952	3.456	1.857	2.146	< 0.001	0.064
100	1.962	3.084	0.518	1.882	< 0.001	0.032

* Days after maximum concentration

Table B.8.6-40: $PEC_{sw,act}$ and $PEC_{sw,twa}$ of BAS 510 F following twofold application of BAS 510 01 F to spring oilseed rape (considering DT_{50} in water of 1000 days) FOCUS scenarios: D4 pond, D4 stream and D5 pond

DAMC* [d]	Step 3					
	D4 Pond		D4 Stream		D5 Pond	
	$PEC_{sw,act}$ [µg L^{-1}]	$PEC_{sw,twa}$ [µg L^{-1}]	$PEC_{sw,act}$ [µg L^{-1}]	$PEC_{sw,twa}$ [µg L^{-1}]	$PEC_{sw,act}$ [µg L^{-1}]	$PEC_{sw,twa}$ [µg L^{-1}]
0	0.624	-	1.183	-	0.304	-
1	0.623	0.623	0.001	0.854	0.303	0.304
2	0.620	0.623	< 0.001	0.766	0.300	0.303
4	0.614	0.622	< 0.001	0.682	0.294	0.301
7	0.602	0.620	< 0.001	0.579	0.285	0.298
14	0.572	0.614	< 0.001	0.424	0.269	0.290
21	0.546	0.606	< 0.001	0.404	0.257	0.283
28	0.569	0.595	< 0.001	0.365	0.246	0.276
42	0.534	0.583	< 0.001	0.277	0.229	0.264
50	0.507	0.578	< 0.001	0.259	0.222	0.258
100	0.382	0.528	< 0.001	0.160	-**	0.211

* Days after maximum concentration

** simulated period too short for calculation of $PEC_{sw,act}$

Table B.8.6-41: PEC$_{sw,act}$ and PEC$_{sw,twa}$ of BAS 510 F following twofold application of BAS 510 01 F to spring oilseed rape (considering DT$_{50}$ in water of 1000 days) FOCUS scenarios: D5 stream, R1 pond and R1 stream

DAMC* [d]	Step 3					
	D5 Stream		R1 Pond		R1 Stream	
	PEC$_{sw,act}$ [µg L^{-1}]	PEC$_{sw,twa}$ [µg L^{-1}]	PEC$_{sw,act}$ [µg L^{-1}]	PEC$_{sw,twa}$ [µg L^{-1}]	PEC$_{sw,act}$ [µg L^{-1}]	PEC$_{sw,twa}$ [µg L^{-1}]
0	1.199	-	0.355	-	2.167	-
1	0.005	0.288	0.347	0.351	0.039	1.730
2	0.005	0.259	0.341	0.348	0.005	0.872
4	0.005	0.193	0.331	0.342	0.002	0.438
7	0.004	0.170	0.318	0.335	0.001	0.251
14	0.003	0.127	0.294	0.321	< 0.001	0.154
21	< 0.001	0.105	0.274	0.311	< 0.001	0.109
28	< 0.001	0.093	0.265	0.305	< 0.001	0.117
42	< 0.001	0.076	0.263	0.292	0.002	0.101
50	< 0.001	0.069	0.244	0.285	< 0.001	0.085
100	< 0.001	0.045	0.294	0.270	< 0.001	0.061

* Days after maximum concentration

WINTER OILSEED RAPE

Table B.8.6-42: PEC$_{sw,act}$ and PEC$_{sw,twa}$ of BAS 510 F following twofold application of BAS 510 01 F to winter oilseed rape (considering DT$_{50}$ in water of 1000 days) FOCUS scenarios: D2 ditch, D2 stream, D3 ditch and D4 pond

DAMC* [d]	Step 3							
	D2 Ditch		D2 Stream		D3 Ditch		D4 Pond	
	PEC$_{sw,act}$ [µg L^{-1}]	PEC$_{sw,twa}$ [µg L^{-1}]	PEC$_{sw,act}$ [µg L^{-1}]	PEC$_{sw,twa}$ [µg L^{-1}]	PEC$_{sw,act}$ [µg L^{-1}]	PEC$_{sw,twa}$ [µg L^{-1}]	PEC$_{sw,act}$ [µg L^{-1}]	PEC$_{sw,twa}$ [µg L^{-1}]
0	5.488	-	3.435	-	1.387	-	0.673	-
1	1.864	3.552	0.988	2.033	0.997	1.194	0.672	0.673
2	2.448	2.867	1.300	1.571	0.421	0.952	0.670	0.672
4	2.142	2.665	1.312	1.504	0.046	0.561	0.664	0.671
7	1.681	2.466	0.932	1.368	0.011	0.330	0.653	0.669
14	1.294	2.251	0.717	1.314	0.003	0.168	0.622	0.661
21	1.173	2.214	0.664	1.237	0.002	0.112	0.599	0.652
28	-**	2.163	-**	1.168	-**	0.085	-**	0.642
42	-**	2.041	-**	1.139	-**	0.057	-**	0.636
50	-**	1.978	-**	1.114	-**	0.048	-**	0.632
100	-**	1.810	-**	0.993	-**	0.024	-**	0.576

* Days after maximum concentration

** simulated period too short for calculation of PEC$_{sw,act}$

Table B.8.6-43: $PEC_{sw,act}$ and $PEC_{sw,twa}$ of BAS 510 F following twofold application of BAS 510 01 F to winter oilseed rape (considering DT_{50} in water of 1000 days) FOCUS scenarios: D4 stream, D5 pond and D5 stream

DAMC* [d]	Step 3					
	D4 Stream		D5 Pond		D5 Stream	
	$PEC_{sw,act}$ [µg L^{-1}]	$PEC_{sw,twa}$ [µg L^{-1}]	$PEC_{sw,act}$ [µg L^{-1}]	$PEC_{sw,twa}$ [µg L^{-1}]	$PEC_{sw,act}$ [µg L^{-1}]	$PEC_{sw,twa}$ [µg L^{-1}]
0	1.530	-	0.417	-	1.277	-
1	0.545	0.966	0.415	0.417	0.008	0.490
2	0.336	0.693	0.410	0.416	0.002	0.333
4	0.295	0.690	0.401	0.413	< 0.001	0.283
7	0.446	0.527	0.389	0.408	< 0.001	0.228
14	0.453	0.494	0.367	0.396	< 0.001	0.159
21	0.297	0.479	0.349	0.386	< 0.001	0.120
28	-**	0.433	-**	0.376	-**	0.097
42	-**	0.333	-**	0.359	-**	0.074
50	-**	0.318	-**	0.351	-**	0.068
100	-**	0.194	-**	0.289	-**	0.046

* Days after maximum concentration
** simulated period too short for calculation of $PEC_{sw,act}$

Table B.8.6-44: $PEC_{sw,act}$ and $PEC_{sw,twa}$ of BAS 510 F following twofold application of BAS 510 01 F to winter oilseed rape (considering DT_{50} in water of 1000 days) FOCUS scenarios: R1 pond, R1 stream and R3 stream

DAMC* [d]	Step 3					
	R1 Pond		R1 Stream		R3 Stream	
	$PEC_{sw,act}$ [µg L^{-1}]	$PEC_{sw,twa}$ [µg L^{-1}]	$PEC_{sw,act}$ [µg L^{-1}]	$PEC_{sw,twa}$ [µg L^{-1}]	$PEC_{sw,act}$ [µg L^{-1}]	$PEC_{sw,twa}$ [µg L^{-1}]
0	0.218	-	1.437	-	2.546	-
1	0.213	0.216	0.002	0.803	2.115	1.684
2	0.210	0.214	0.001	0.403	0.007	1.298
4	0.204	0.210	< 0.001	0.229	0.003	0.651
7	0.197	0.206	0.028	0.131	0.002	0.435
14	0.184	0.198	< 0.001	0.066	< 0.001	0.243
21	0.172	0.192	< 0.001	0.046	< 0.001	0.163
28	-**	0.186	-**	0.038	-**	0.192
42	-**	0.172	-**	0.036	-**	0.137
50	-**	0.163	-**	0.031	-**	0.124
100	-**	0.133	-**	0.021	-**	0.067

* Days after maximum concentration
** simulated period too short for calculation of $PEC_{sw,act}$

Degradation data from outdoor water/sediment study

The global maximum concentrations in Table B.8.6-45 reflect the same scenarios as in the data in Table B.8.6-35. The DT_{50} in water of of 32 d from the outdoor water/sediment study was used instead of the assumption of 1000 d. No actual and time-weighted average PEC values were calculated for this approach.

Table B.8.6-45: Global maximum concentrations of BAS 510 F in different water bodies following twofold application of BAS 510 01 F to legumes and oilseed rape (considering DT_{50} in water of 32 days)

Location	**Type of water body**	**Step 3 $PEC_{sw,max}$ [µg L^{-1}]**		
Crop		**Legumes 2 × 500 g/ha**	**Spring oilseed rape 2 × 250 g/ha**	**Winter oilseed rape 2 × 250 g/ha**
D1	ditch	-[1]	3.968	-[1]
D1	stream	-[1]	2.483	-[1]
D2	ditch	-[1]	-[1]	5.487
D2	stream	-[1]	-[1]	3.435
D3	ditch	2.273	1.384	1.387
D4	pond	1.760	0.552	0.604
D4	stream	3.030	1.183	1.530
D5	pond	0.656	0.256	0.365
D5	stream	2.041	1.199	1.277
D6	ditch	7.665	-[1]	-[1]
R1	pond	0.429	0.307	0.175
R1	stream	7.190	2.167	1.437
R2	stream	2.505	-[1]	-[1]
R3	stream	6.781	-[1]	2.546
R4	stream	11.266	-[1]	-[1]

[1] scenario not defined for the respective crop

B.8.6.2.3 PEC_{sed} calculation for application in vine

Single application scenario

Degradation data from standard water/sediment study

Table B.8.6-46 lists the global maximum concentrations in the sediment of different surface water bodies (ditch, stream or pond) as associated with the scenario locations after application to vine. For the calculations, degradation rates in water and in sediment of 1000 days were taken into account.

Table B.8.6-46: Global maximum concentrations of BAS 510 F in sediment following single application of BAS 510 01 F to vine (considering DT_{50} in water of 1000 days)

Location	**Type of water body**	**Step 3 $PEC_{sed,max}$ [µg kg^{-1}]**
Crop		**Vine 1 × 600 g/ha**
D6	ditch	3.638
R1	pond	2.374
R1	stream	1.280
R2	stream	1.824
R3	stream	4.949
R4	stream	2.912

Degradation data from outdoor water/sediment study

The global maximum concentrations in Table B.8.6-47 reflect the same scenarios as in the data in Table B.8.6-46. The DT_{50} in water of of 32 d from the outdoor water/sediment study was used instead of the assumption of 1000 d. No actual and time-weighted average PEC values were calculated for this approach.

Table B.8.6-47: Global maximum concentrations of BAS 510 F in sediment following single application of BAS 510 01 F to vine (considering DT_{50} in water of 32 days)

Location	**Type of water body**	**Step 3 $PEC_{sed,max}$ [µg kg^{-1}]**
Crop		**Vine 1 × 600 g/ha**
D6	ditch	3.631
R1	pond	1.582
R1	stream	1.279
R2	stream	1.824
R3	stream	4.945
R4	stream	2.911

B.8.6.2.4 PEC_{sw} calculation for application in legumes and oilseed rape

Twofold application scenario

Degradation data from standard water/sediment study

Table B.8.6-48 lists the global maximum concentrations in the sediment of different surface water bodies (ditch, stream or pond) as associated with the scenario locations after application to legumes and oilseed rape. For the calculations, degradation rates in water and in sediment of 1000 days were taken into account.

Table B.8.6-48: Global maximum concentrations of BAS 510 F in different water bodies following twofold application of BAS 510 01 F (considering DT_{50} in water of 1000 days)

Location	**Type of water body**	**Step 3 $PEC_{sed,max}$ [µg kg^{-1}]**		
Crop		**Legumes 2 × 500 g/ha**	**Spring oilseed rape 2 × 250 g/ha**	**Winter oilseed rape 2 × 250 g/ha**
D1	ditch	-[1]	45.621	-[1]
D1	stream	-[1]	25.075	-[1]
D2	ditch	-[1]	-[1]	32.422
D2	stream	-[1]	-[1]	18.166
D3	ditch	1.644	1.050	1.164
D4	pond	17.984	6.367	7.052
D4	stream	6.317	2.081	2.484
D5	pond	10.127	4.142	4.938
D5	stream	1.937	0.763	0.996
D6	ditch	9.313	-[1]	-[1]
R1	pond	4.683	4.118	2.565
R1	stream	3.522	3.325	1.204

Location	**Type of water body**	**Step 3 PEC$_{sed,max}$ [µg kg^{-1}]**		
R2	stream	4.818	-[1]	-[1]
R3	stream	4.881	-[1]	2.657
R4	stream	9.726	-[1]	-[1]

[1] scenario not defined for the respective crop

Degradation data from outdoor water/sediment study

The global maximum concentrations in Table B.8.6-49 reflect the same scenarios as in the data in Table B.8.6-48. The DT$_{50}$ in water of of 32 d from the outdoor water/sediment study was used instead of the assumption of 1000 d. No actual and time-weighted average PEC values were calculated for this approach.

Table B.8.6-49: Global maximum concentrations of BAS 510 F in sediment following twofold application of BAS 510 01 F to legumes and oilseed rape (considering DT$_{50}$ in water of 32 days)

Location	**Type of water body**	**Step 3 PEC$_{sed,max}$ [µg kg^{-1}]**		
Crop		**Legumes 2 × 500 g/ha**	**Spring oilseed rape 2 × 250 g/ha**	**Winter oilseed rape 2 × 250 g/ha**
D1	ditch	-[1]	43.887	-[1]
D1	stream	-[1]	25.062	-[1]
D2	ditch	-[1]	-[1]	31.265
D2	stream	-[1]	-[1]	17.817
D3	ditch	1.631	1.040	1.149
D4	pond	13.029	4.532	4.982
D4	stream	6.316	2.080	2.483
D5	pond	5.852	2.335	3.003
D5	stream	1.937	0.763	0.996
D6	ditch	9.297	-[1]	-[1]
R1	pond	2.495	2.189	1.680
R1	stream	3.521	3.325	1.203
R2	stream	4.818	-[1]	-[1]
R3	stream	4.875	-[1]	2.657
R4	stream	9.724	-[1]	-[1]

[1] scenario not defined for the respective crop

Discussion

Comparison single vs. twofold application to legumes and oilseed rape

In addition to the twofold application to legumes and oilseed rape, single application scenarios were simulated for the respective crops. This step is necessary to check, if a single application scenario leads to higher concentrations than multiple applications, since the absolute amounts of the overall 90th drift percentiles for single application are higher than for multiple applications. Table B.8.6-34 shows the results of the simulations of the single application scenarios. The PEC$_{sw,max}$ calculated in the twofold application scenarios are given in Table B.8.6-35.

For some of the scenarios, the PEC$_{sw,max}$ are indeed higher in the single than in the twofold application situation, most pronounced for D3 ditch in legumes (PEC$_{sw,max}$ by 0.344 µg L^{-1}

higher in the single application scenario). However, markedly higher concentrations are reached in other scenarios due to run-off or drainage after the second application (up to 11.269 µg l^{-1} in the R4 stream scenario, legumes). Isolated spray-drift entries after a single application of boscalid to legumes and oilseed rape range from 1.248 µg L^{-1} (D5 stream in spring oilseed rape) to 2.699 µg L^{-1} (D1 ditch in spring oilseed rape), whereas actual $PEC_{sw,max}$ simulated after single application range from 0.143 µg L^{-1} (D5 pond in spring oilseed rape) to 6.396 µg L^{-1} (R4 stream in legumes). Thus, the highest PEC_{sw} overall are based on drainage or runoff events and single application scenarios are of lesser interest for the EU exposure assessment.

Comparison of the PEC calculated with the DT_{50} deduced from the standard and the higher tier water/sediment study

Two sets of PEC values were simulated using two different degradation rates in the water phase which were derived from the standard water/sediment study in the dark (DT_{50} 1000 days, conservative assumption according to FOCUS) and the higher tier irradiated water/sediment study (DT_{50} 32 days). Simulations were carried out for the twofold application of boscalid to legumes and oilseed rape and for the single application to vine.

PEC in surface water

The predicted concentrations in surface water simulated on the basis of the degradation rate derived from the standard water/sediment study (DT_{50} 1000 days) are presented in Table B.8.6-30 and Table B.8.6-35. The simulation results considering a half-life in water of 32 days derived from the irradiated water/sediment study are given in Table B.8.6-33 and Table B.8.6-45.

The different degradation rates in water have only low effects on the resulting $PEC_{sw,max}$ values. The maximum concentrations calculated under consideration of the longer half-life are slightly above the results based on the half-life derived from the irradiated study:

For stream and ditch scenarios, the differences are marginal. The maximum difference is 0.004 µg L^{-1} for the scenario R3 stream in legumes ($PEC_{sw,max}$ 6.785 µg L^{-1} considering a half-life of 1000 days and $PEC_{sw,max}$ 6.781 µg L^{-1} considering a half-life of 32 days). This is due to the short average residence time of water in ditches (5 days) and streams (0.1 days) proposed by the FOCUS surface water document.

For pond scenarios, the effect of the calculations using different degradation rates is slightly higher. The maximum difference is 0.203 µg L^{-1} for the scenario D4 pond in legumes ($PEC_{sw,max}$ 1.963 µg L^{-1} considering a half-life of 1000 days and $PEC_{sw,max}$ 1.760 µg L^{-1} considering a half-life of 32 days).

PEC in sediment

The predicted concentrations in sediment simulated on the basis of the degradation rate derived from the standard water/sediment study (DT_{50} 1000 days) are presented in Table B.8.6-44 and Table B.8.6-46. The simulation results considering a half-life in water of 32 days derived from the irradiated water/sediment study are given in Table B.8.6-45 and Table B.8.6-47. For the degradation in sediment, a half-life of 1000 days was considered in both approaches.

The effects of different degradation rates in the water phase on the PEC sediment are more visible than in the surface water. The $PEC_{sed,max}$ values calculated under consideration of the longer half-life are above the results based on the half-life derived from the irradiated study:

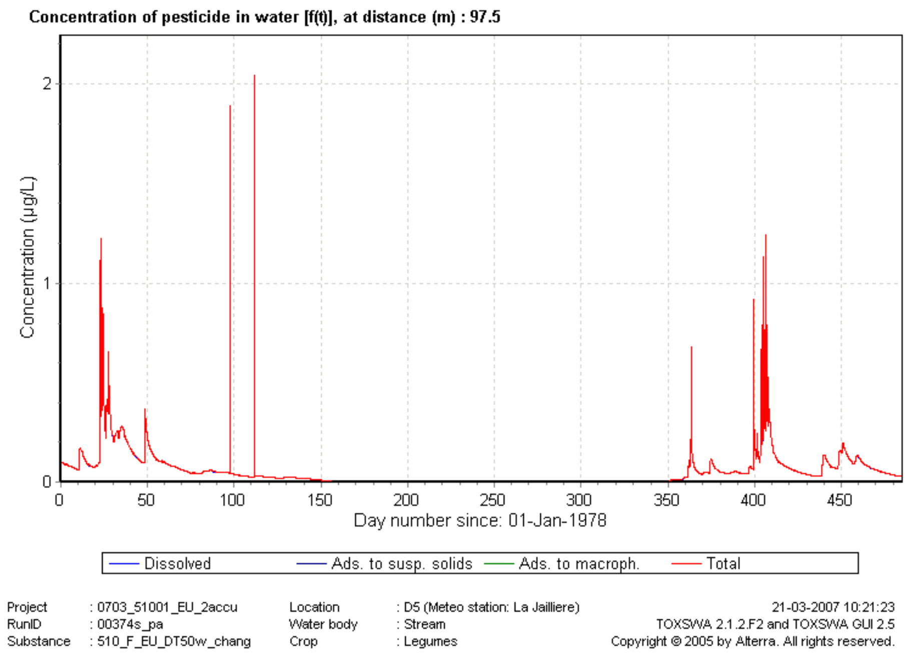
Similar to the results of the PEC in water, the differences depend on the kind of water body which is used in the simulations.

For stream and ditch scenarios, the effects are marginal. The maximum difference between both calculation approaches occurs in the scenario D1 ditch for spring oilseed rape and amounts to 1.734 µg kg^{-1} (PEC$_{sed,max}$ 45.621 µg kg^{-1} considering a half-life of 1000 days and PEC$_{sed,max}$ 43.887 µg kg^{-1} considering a half-life of 32 days). Here, the PEC$_{sed,max}$ based on the shorter half-life reaches 96.2 % of the PEC$_{sed,max}$ based on the longer half-life.
For the pond scenarios, the differences between the two simulation approaches are more distinct. The maximum difference between the PEC$_{sed,max}$ based on the longer half-life and the PEC$_{sed,max}$ based on the shorter half-life is 4.955 µg kg^{-1} as shown in the scenario D4 pond for legumes (PEC$_{sed,max}$ 17.984 µg kg^{-1} considering a half-life of 1000 days and PEC$_{sed,max}$ 13.029 µg kg^{-1} considering a half-life of 32 days). The PEC$_{sed,max}$ based on the shorter half-life reaches 72.45 % of the PEC$_{sed,max}$ based on the longer half-life. The effects are caused by the longer time period during which the active ingredient is available in the water body for sorption to the sediment in the pond as compared to stream and ditch scenarios.

Impact of runoff and drainage entries on the predicted concentrations

Twofold application to legumes
The PEC$_{sw,max}$ for the legumes scenarios range from 0.485 µg L^{-1} for the scenario R1 pond to 11.269 µg L^{-1} for the scenario R4 stream. The highest concentrations are caused by both drift entry as well as entry via drainage and runoff.
The highest concentrations in the scenarios D3 ditch and D5 stream are caused by spray drift, whereupon the entry via drainage is higher for the scenario D5 stream. In Figure B.8.6-5, the concentration of boscalid in surface water for this scenario is shown. The respective PEC$_{sw,max}$ of 2.041 µg L^{-1} is caused by entry via spray drift at the day of the second application (22 April 1978). The concentrations due to drainage entry in the following winter do not reach the peak due to spray drift entry in April.

Figure B.8.6-5: Concentration of boscalid in water for the scenario D5 stream in legumes



Project : 0703_51001_EU_2accu
RunID : 00374s_pa
Substance : 510_F_EU_DT50w_chang
Location : D5 (Meteo station: La Jailliere)
Water body : Stream
Crop : Legumes
21-03-2007 10:21:23
TOXSWA 2.1.2.F2 and TOXSWA GUI 2.5
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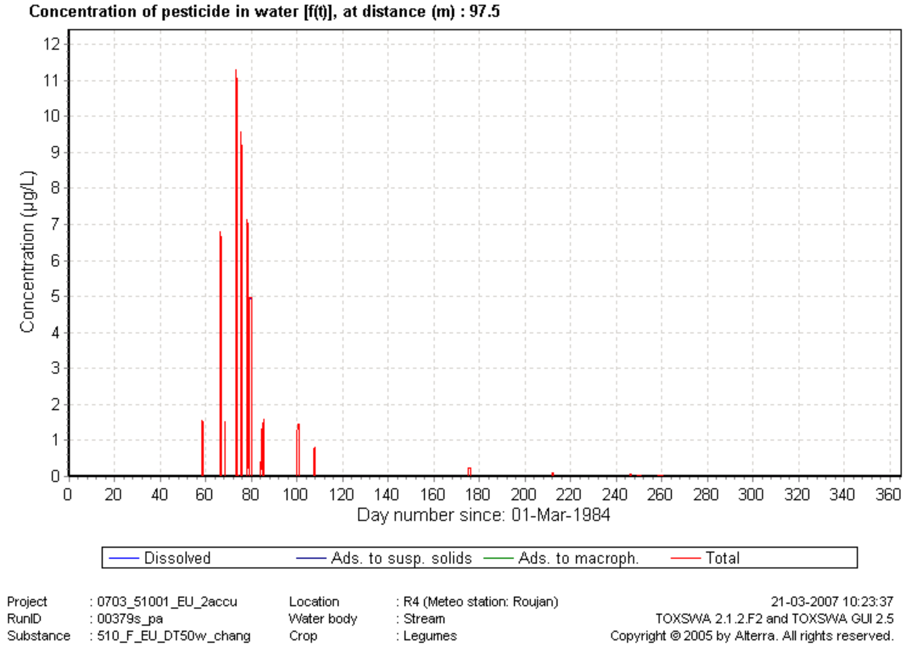
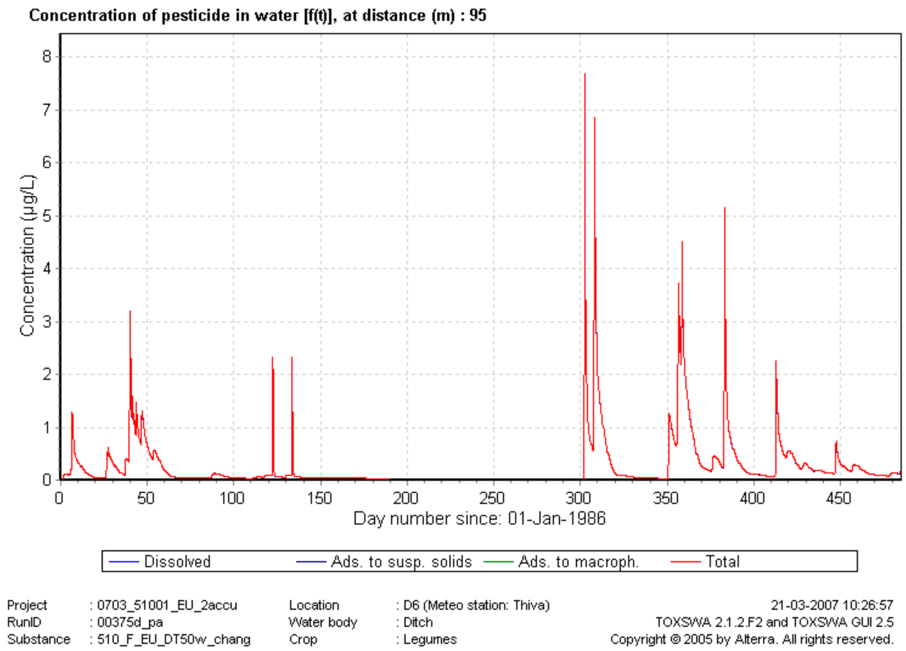
In the scenarios R1 pond and stream, R2 stream, R3 stream and R4 stream, the $PEC_{sw,max}$ are caused by runoff events. The highest $PEC_{sw,max}$ occurs in the R4 stream scenario with 11.269 µg L^{-1} due to a runoff event on 13 May 1984, a few days after the second application on 8 May 1984. As shown in Figure B.8.6.-4, the entry via spray drift is markedly lower. Runoff events, which cause input of the active ingredient into the water body, take place in spring and summer within a short time period.

Figure B.8.6-6: Concentration of boscalid in water for the scenario R4 stream in legumes



In the scenarios D4 pond and stream, D5 pond and D6 ditch, the highest concentrations of boscalid in surface water are induced by drainage entries. The highest $PEC_{sw,max}$ occurs in scenario D6 ditch with 7.669 µg L^{-1} in autumn (see Figure B.8.6-7).

Figure B.8.6-7: Concentration of boscalid in water for the scenario D6 ditch in legumes

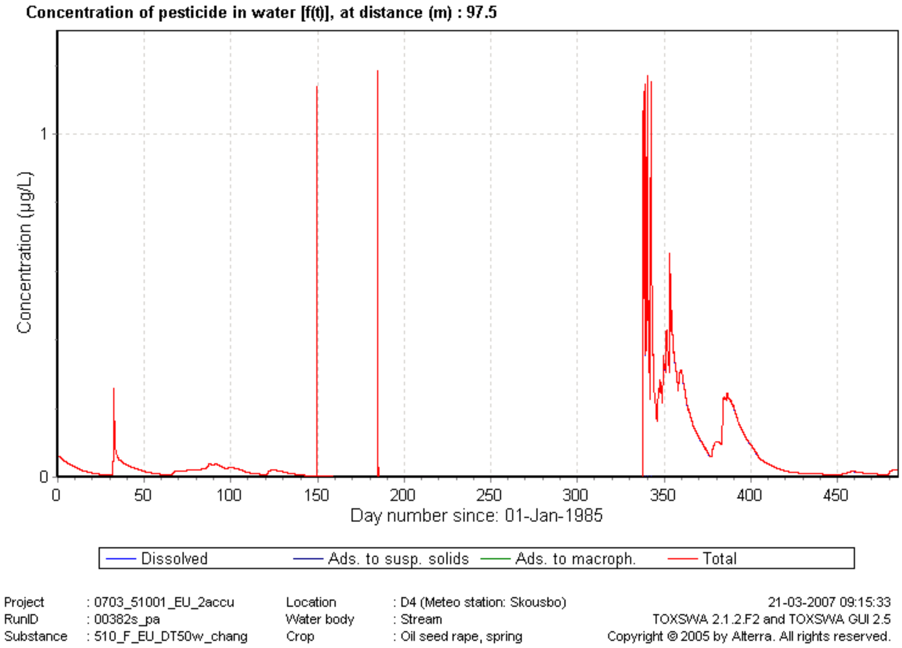


<u>Twofold application to spring oilseed rape</u>

The $PEC_{sw,max}$ for the spring oilseed rape scenarios range from 0.304 µg L^{-1} for the scenario D5 pond to 3.970 µg L^{-1} for the scenario D1 ditch. The $PEC_{sw,max}$ are caused by both drift entry as well as entry via drainage and runoff.

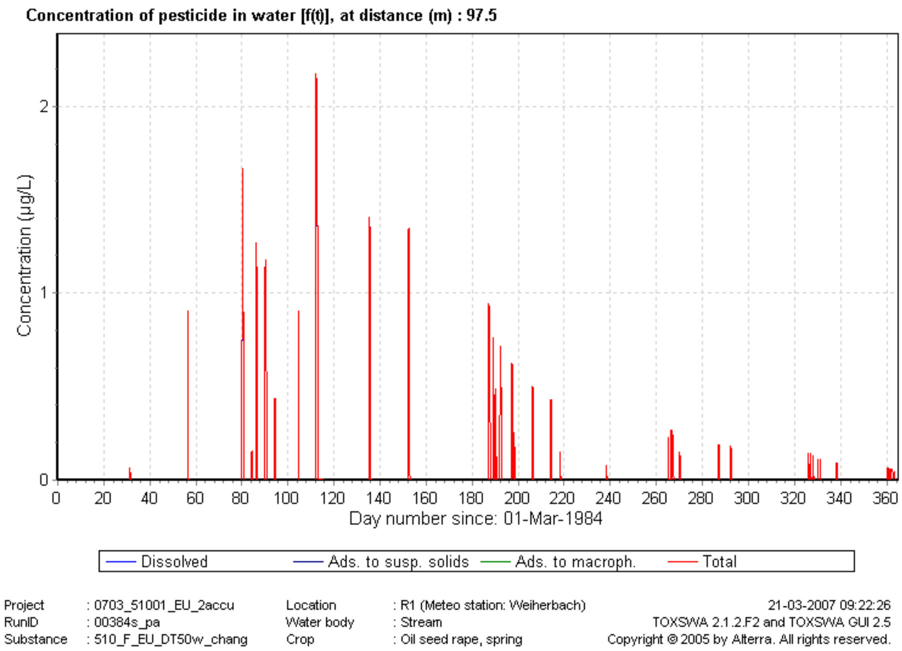
In the scenarios D3 ditch, D4 stream and D5 stream, the highest concentrations of boscalid in the surface water are induced by drift entries, whereupon the substance entry by drainage is highest in the scenario D4 stream. In Figure B.8.6-8, the concentration of boscalid in surface water for this scenario is shown. The respective $PEC_{sw,max}$ of 1.183 µg L^{-1} is caused by entry via spray drift at the day of the second application (4 July 1985). The concentrations due to drainage entry in the following winter are slightly lower than the peak due to spray drift entry in July.

Figure B.8.6-8: Concentration of boscalid in water for the scenario D4 stream in spring oilseed rape



In the runoff scenarios R1 pond and stream, the PEC$_{sw,max}$ (2.167 µg L^{-1} for the stream scenario and 0.355 µg L^{-1} for the pond scenario) is induced by runoff events. The peak concentration in the water body is higher in the stream scenario, due to the lower distance of the treated field from the water body (1.5 m for stream vs. 3.5 m for pond). In Figure B.8.6-9, the concentrations of boscalid in the stream water body of the R1 stream scenario is shown. The PEC$_{sw,max}$ occurs several days (21 June 1984) after the second application (13 June 1984) in the early summer.

Figure B.8.6-9: **Concentration of boscalid in water for the scenario R1 stream in spring oilseed rape**



Project : 0703_51001_EU_2accu
RunID : 00384s_pa
Substance : 510_F_EU_DT50w_chang
Location : R1 (Meteo station: Weiherbach)
Water body : Stream
Crop : Oil seed rape, spring
21-03-2007 09:22:26
TOXSWA 2.1.2.F2 and TOXSWA GUI 2.5
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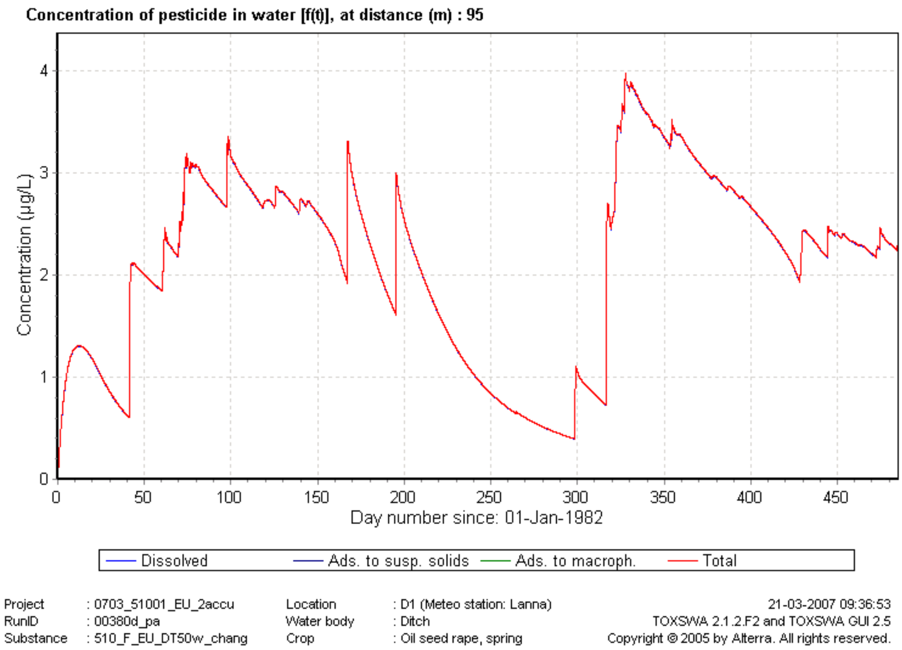
In the drainage scenarios D1 ditch and stream, D4 pond and D5 pond, the $PEC_{sw,max}$ after application of boscalid to spring oilseed rape are caused by drainage entries. The highest $PEC_{sw,max}$ occurs in scenario D1 ditch with 3.970 µg L^{-1} (see Figure B.8.6-10).

Figure B.8.6-10: **Concentration of boscalid in water for the scenario D1 ditch in spring oilseed rape**



Project : 0703_51001_EU_2accu
RunID : 00380d_pa
Substance : 510_F_EU_DT50w_chang
Location : D1 (Meteo station: Lanna)
Water body : Ditch
Crop : Oil seed rape, spring
21-03-2007 09:36:53
TOXSWA 2.1.2.F2 and TOXSWA GUI 2.5
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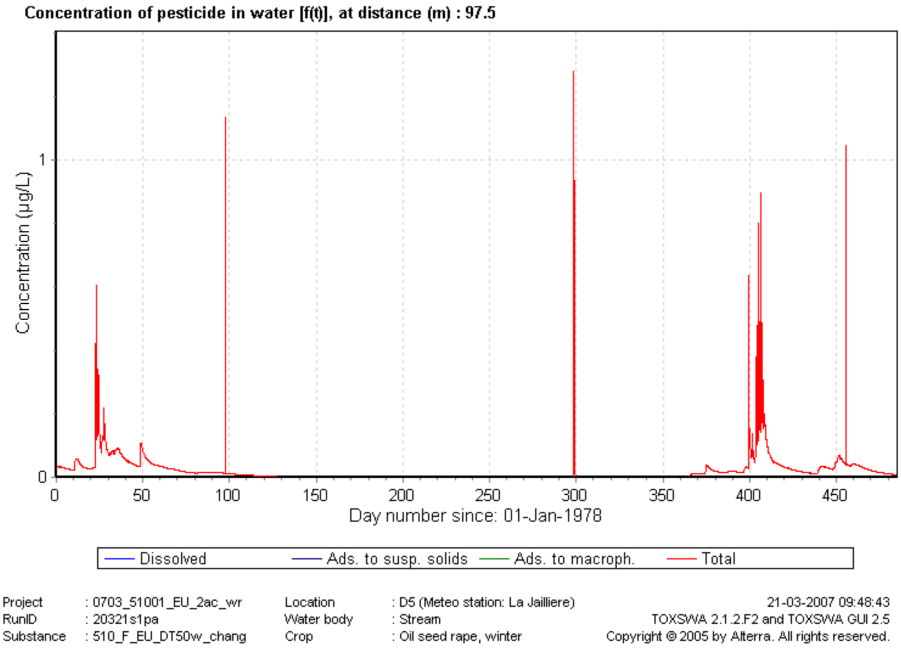
Twofold application to winter oilseed rape

The $PEC_{sw,max}$ for the winter oilseed rape scenarios range from 0.218 µg L^{-1} for the scenario R1 pond to 5.488 µg L^{-1} for the scenario D2 ditch. The $PEC_{sw,max}$ are caused by both drift entry as well as entry via drainage and runoff.

In the scenarios D3 ditch and D5 stream, the highest concentrations of boscalid in surface water are induced by spray drift entries, whereupon the substance entry by drainage is the higher in the scenario D5 stream. In Figure B.8.6-11, the concentration of boscalid in surface water for this scenario is shown. The respective $PEC_{sw,max}$ of 1.277 µg L^{-1} is caused by entry via spray drift at the day of the first seasonal application (26 October 1978). The concentrations due to drainage entry in the following winter period do not reach the peak due to spray drift entry in October.

Figure B.8.6-11: Concentration of boscalid in water for the scenario D5 stream in winter oilseed rape



Project : 0703_51001_EU_2ac_wr
RunID : 20321s1pa
Substance : 510_F_EU_DT50w_chang
Location : D5 (Meteo station: La Jailliere)
Water body : Stream
Crop : Oil seed rape, winter
21-03-2007 09:48:43
TOXSWA 2.1.2.F2 and TOXSWA GUI 2.5
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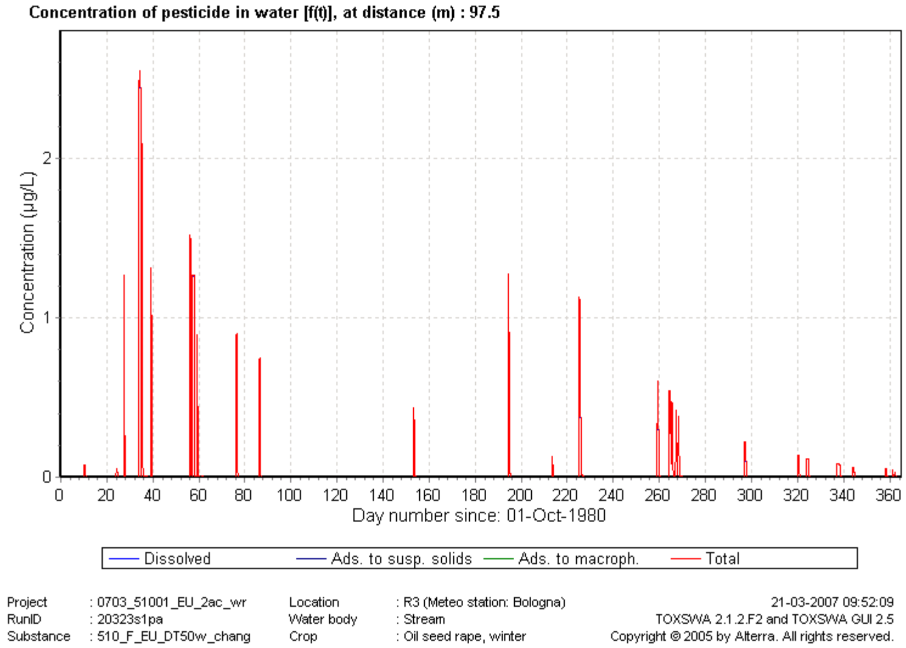
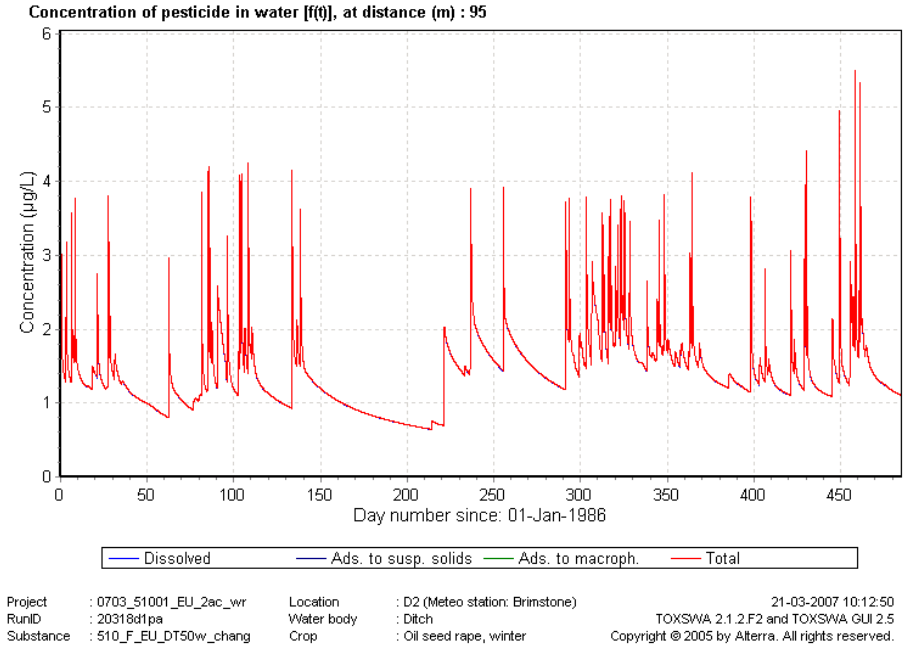
In the runoff scenarios R1 pond and stream and R3 stream for the application to winter oilseed rape, the $PEC_{sw,max}$ are caused by runoff events. The highest $PEC_{sw,max}$ occurs in the R3 stream scenario with 2.546 µg L^{-1} due to a runoff event on 4 November 1980, a few days after the first application in autumn (28 October 1980) – see Figure B.8.6-12.

Figure B.8.6-12: Concentration of boscalid in water for the scenario R3 stream in winter oilseed rape



In the drainage scenarios D2 ditch and stream, D4 pond and stream and D5 pond, the $PEC_{sw,max}$ in surface water after application of boscalid to winter oilseed rape is caused by drainage entries. The highest $PEC_{sw,max}$ occurs in scenario D2 ditch with 5.488 µg L^{-1} on 4 April 1987 in spring shortly after the last application (1 April 1987) – see Figure B.8.6-13.

Figure B.8.6-13: Concentration of boscalid in water for the scenario D2 ditch in winter oilseed rape

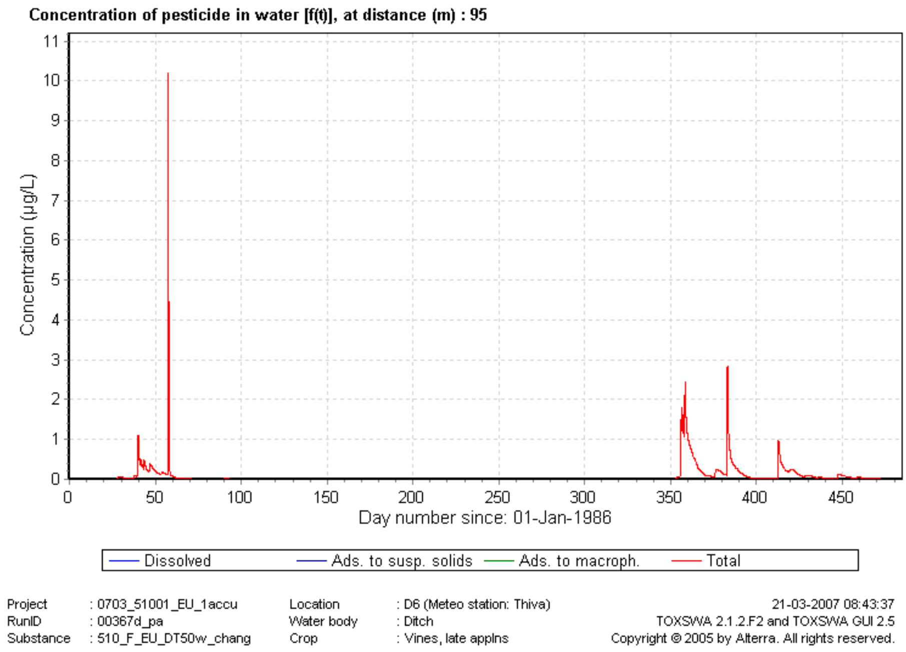


Single application to vine

The $PEC_{sw,max}$ for the vine scenarios range from 0.366 µg L^{-1} for the scenario R1 pond to 10.574 µg L^{-1} for the scenario R3 stream. The highest concentrations are caused by substance entry into the water body via spray drift in all cases, meaning that substance input via runoff and drainage has no great influence on the $PEC_{sw,max}$ in vine scenarios. Therefore, accumulation in soil is not relevant for application of boscalid to vine.

For vine, only one drainage scenario – D6 ditch – is defined by the FOCUS surface water work group. In Figure B.8.6-14, the concentration of boscalid in surface water for this scenario is shown. The respective $PEC_{sw,max}$ of 10.169 µg L^{-1} is caused by entry via spray drift on the day of the application (27 February 1986). The concentrations due to drainage entry in the following winter do not reach the peak due to spray drift entry.

Figure B.8.6-14: Concentration of boscalid in water for the scenario D6 ditch in vine



With respect to entry via runoff, the highest $PEC_{sw,max}$ of the relevant scenarios (R1, R2, R3 and R4) was calculated to be 10.574 µg L^{-1} for the scenario R3 stream. Figure B.8.6-15 shows the concentration in water for the respective scenario. The highest concentration is caused by a spray drift event at the day of the application (11 April 1980). The concentration due to the runoff entry 9 days later does not reach the peak due to spray drift entry.

Figure B.8.6-16 shows the concentration in water for the scenario R1 pond. The highest concentration (0.366 µg L^{-1}) is caused by a spray drift event at the day of the application (26 April 1984). The concentration due to the runoff entries in the following days does not reach the peak due to spray drift entry. Dissipation from the water body is slower than in the stream scenario due to the longer average residence time of the water in the pond (50 days).

Figure B.8.6-15: Concentration of boscalid in water for the scenario R3 stream in vine

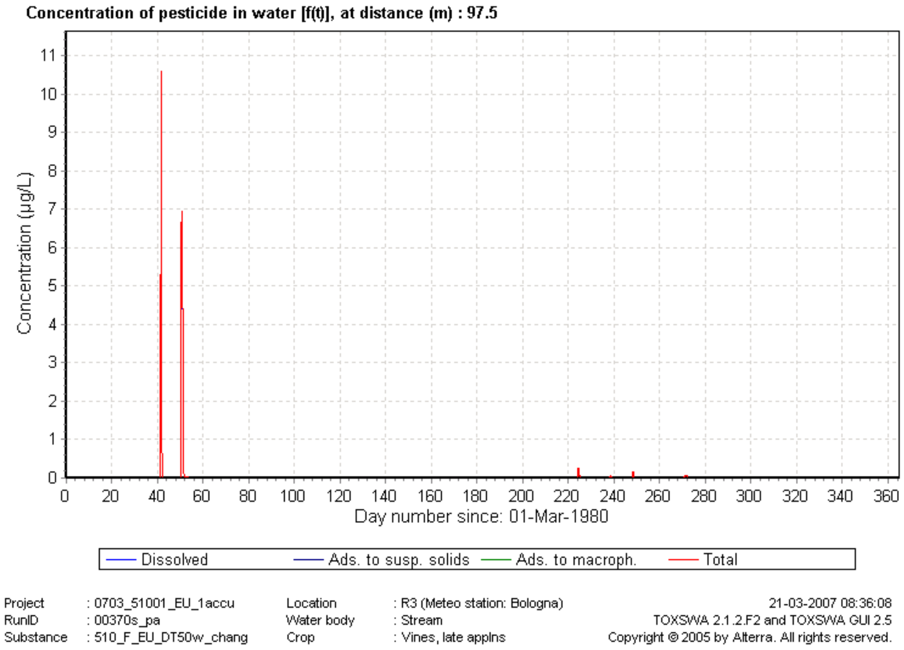
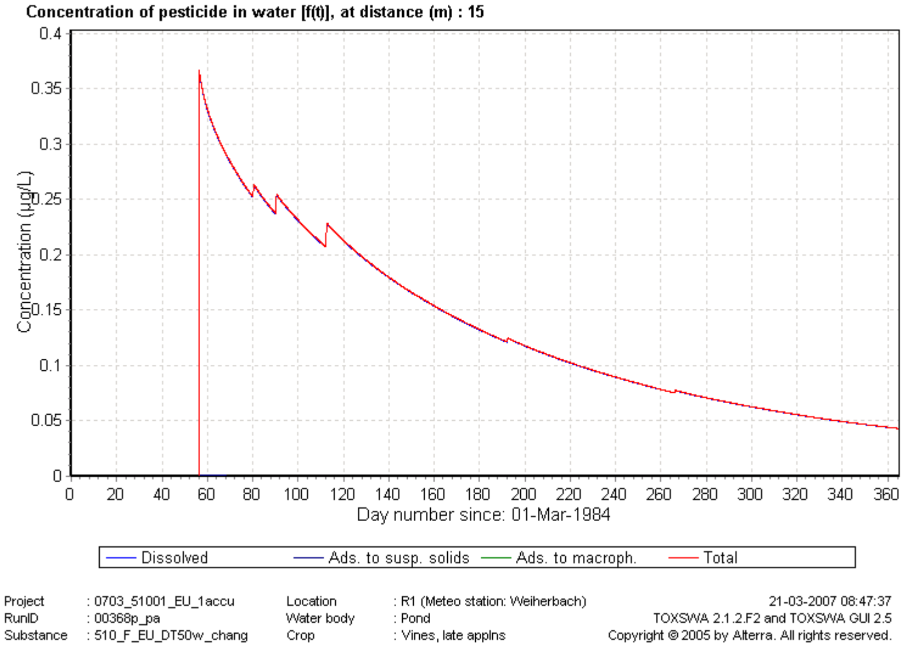


Figure B.8.6-16: Concentration of boscalid in water for the scenario R1 pond in vine



Conclusion

The comparison of the single and the twofold application scenarios for legumes and oil seed rape show that multiple application scenarios result in the highest global maximum concentrations in the overall view. Single applications only lead to higher global PEC_{max} values for single vs. twofold application in cases where the scenario is dominated by substance entry via spray drift.
The simulation results based on a DT_{50} value in the water phase of 1000 days (representative for the standard water/sediment study) are slightly higher than the PEC values based on the DT_{50} value of 32 days derived from the higher-tier outdoor water/sediment study. This can be explained by short residence times in the different surface water bodies (ditches and streams) and fast sorption processes onto sediment that are considered in the TOXSWA model.
Only the vine scenarios are dominated by substance entry via spray drift into the surface water body. The highest global PEC_{sw} of the scenarios defined for oil seed rape and legumes were caused by drainage and runoff events.

To ease risk assessment, only the relevant PEC_{sw} and PEC_{sed} values are compiled in Table B.8.6-50 to Table B.8.6-53. These comprise the highest $PEC_{sw,max}$ and PEC_{sed} values considering all modelling variants as discussed above (for the risk assessment based on initial concentrations) as well as the $PEC_{sw,twa}$ values for 7-d and 14-d interval (for the long-term risk assessment for fish that is hitherto based on a 11-day twa interval).

Table B.8.6-50: Relevant PEC_{sw} and PEC_{sed} values for the risk assessment for the application of boscalid in vine

Location	Type of water body	$PEC_{sw,max}$* [µg L^{-1}]	$PEC_{sw,twa}$** 7 d / 14 d [µg L^{-1}]	$PEC_{sed,max}$*** [µg kg^{-1}]
Crop		Vine 1 × 600 g/ha		
D6	ditch	10.169	1.177 0.753	3.638
R1	pond	0.366	0.334 0.315	2.374
R1	stream	7.474	0.192 0.143	1.280
R2	stream	9.908	0.213 0.107	1.824
R3	stream	10.574	0.958 0.710	4.949
R4	stream	7.471	0.699 0.350	2.912
range		0.366 – 10.574	0.107 – 1.177	1.280 – 4.949

* DT_{50} in water 1000 d, same values as for DT_{50} in water 32 d
** DT_{50} in water 1000 d, no values available for DT_{50} in water 32 d
*** DT_{50} in water 1000 d, values slightly higher than for DT_{50} in water 32 d

Table B.8.6-51: Relevant PEC_{sw} and PEC_{sed} values for the risk assessment for the application of boscalid in legumes

Location	**Type of water body**	**$PEC_{sw,max}$*,(a/b)** **[µg L^{-1}]**	**$PEC_{sw,twa}$**,b** **7 d / 14 d** **[µg L^{-1}]**	**$PEC_{sed,max}$ *,b** **[µg kg^{-1}]**
Crop		**Legumes** **2 × 500 g/ha**		
D3	ditch	2.617[a]	0.333 0.290	1.644
D4	pond	1.963[b]	1.953 1.934	17.984
D4	stream	3.030[b]	1.769 1.339	6.317
D5	pond	0.772[b]	0.758 0.739	10.127
D5	stream	2.165[a]	0.459 0.353	1.937
D6	ditch	7.669[b]	2.347 1.746	9.313
R1	pond	0.485[b]	0.464 0.448	4.683
R1	stream	7.191[b]	0.793 0.594	3.522
R2	stream	2.506[b]	0.383 0.192	4.818
R3	stream	6.785[b]	0.869 0.485	4.881
R4	stream	11.269[b]	3.148 1.912	9.726
range		0.485 – 11.269	0.192 – 3.148	1.644 – 17.984

* DT_{50} in water 1000 d, values slightly higher than for DT_{50} in water 32 d
** DT_{50} in water 1000 d, no values available for DT_{50} in water 32 d
[a] considering single application
[b] considering twofold application

Table B.8.6-52: Relevant PEC_{sw} and PEC_{sed} values for the risk assessment for the application of boscalid in spring oilseed rape

Location	**Type of water body**	**$PEC_{sw,max}$*,(a/b)** **[µg L^{-1}]**	**$PEC_{sw,twa}$**,b** **7 d / 14 d** **[µg L^{-1}]**	**$PEC_{sed,max}$ *,b** **[µg kg^{-1}]**
Crop		**Spring oilseed rape** **2 × 250 g/ha**		
D1	ditch	3.970[b]	3.845 3.751	45.621
D1	stream	2.483[b]	2.398 2.333	25.075
D3	ditch	1.583[a]	0.244 0.124	1.050
D4	pond	0.624[b]	0.620 0.614	6.367
D4	stream	1.314[a]	0.579 0.424	2.081
D5	pond	0.304[b]	0.298 0.290	4.142

Location	**Type of water body**	**$\mathrm{PEC}_{sw,max}$*,(a/b)** **[µg L^{-1}]**	**$\mathrm{PEC}_{sw,twa}$**,b** **7 d / 14 d** **[µg L^{-1}]**	**$\mathrm{PEC}_{sed,max}$ *,b** **[µg kg^{-1}]**
D5	stream	1.248[a]	0.170 0.127	0.763
R1	pond	0.355[b]	0.335 0.321	4.118
R1	stream	2.167[b]	0.251 0.154	3.325
range		0.355 – 3.970	0.124 – 3.845	0.763 – 45.621

* DT_{50} in water 1000 d, values slightly higher than for DT_{50} in water 32 d
** DT_{50} in water 1000 d, no values available for DT_{50} in water 32 d
[a] considering single application
[b] considering twofold application

Table B.8.6-53: Relevant PEC_{sw} and PEC_{sed} values for the risk assessment for the application of boscalid in winter oilseed rape

Location	**Type of water body**	**$\mathrm{PEC}_{sw,max}$*,(a/b)** **[µg L^{-1}]**	**$\mathrm{PEC}_{sw,twa}$**,b** **7 d / 14 d** **[µg L^{-1}]**	**$\mathrm{PEC}_{sed,max}$ *,b** **[µg kg^{-1}]**
Crop		**Winter oilseed rape** **2 × 250 g/ha**		
D2	ditch	5.488[b]	2.466 2.251	32.422
D2	stream	3.435[b]	1.368 1.314	18.166
D3	ditch	1.588[a]	0.330 0.168	1.164
D4	pond	0.673[b]	0.669 0.661	7.052
D4	stream	1.530[b]	0.527 0.494	2.484
D5	pond	0.417[b]	0.408 0.396	4.938
D5	stream	1.477[a]	0.228 0.159	0.996
R1	pond	0.218[b]	0.206 0.198	2.565
R1	stream	1.437[b]	0.131 0.066	1.204
R3	stream	2.546[b]	0.435 0.243	2.657
range		0.218 – 5.488	0.066 – 2.466	0.996 – 32.422

* DT_{50} in water 1000 d, values slightly higher than for DT_{50} in water 32 d
** DT_{50} in water 1000 d, no values available for DT_{50} in water 32 d
[a] considering single application
[b] considering twofold application

B.8.10 References relied on

Annex point/ reference number	Author(s)	Year	Title source (where different from company) report no. GLP or GEP status (where relevant), published or not BVL registration number	Data protection claimed Y/N	Owner
AIIIA-9.2.3	J. Bangert	2007	Predicted environmental concentrations in surface water and sediment of BAS 510 F (boscalid) following application of BAS 510 01 F (CANTUS) to beans, peas, spring oilseed rape, winter oilseed rape and vine according to FOCUS considering soil accumulation of boscalid BASF DocID 2007/1017347 no GLP, not published		

B.9 Ecotoxicology

B.9.2 Effects on aquatic organisms (Annex IIA 8.2; Annex IIIA 10.2)

B.9.2.1 Summary of aquatic toxicity data

Data are listed in Table B.9.2-4 in the context of the revised risk assessment due to recalculated PEC values. The respective studies have already been assessed in the DAR and in Addendum 2.

Table B.9.2-4: Laboratory toxicity data for aquatic species (most sensitive species of each group)

Taxon	Test substance	Time-scale	Endpoint	Toxicity (mg/L)
O. mykiss	boscalid	static – 96 h	LC_{50}	2.7
O. mykiss		flow-through – 97 d (ELS)	NOEC	0.125
D. magna		static – 48 h	EC_{50}	5.33
D. magna		semi-static – 21 d	NOEC	1.31
P. subcapitata		static – 96 h	E_rC_{50}	3.75
			E_bC_{50}	1.34
C. riparius		static – 28 d spiked water	NOEC	1.0
C. riparius		static – 28 d spiked sediment	NOEC	23.26 mg/kg
Activated slugde		static – 0.5 h	Respiration rate	> 1000

B.9.2.8 Risk assessment for aquatic organisms

In connection with the recalculation of PEC_{sw} and PEC_{sed} values according to FOCUSsw (see above), an additional risk asessment is presented. It should be understood as supplementary to the risk assessment provided in the DAR and in Addendum 2.

Except for the long-term effects on fish and on sediment organisms (with respect to accumulation of boscalid in the sediment), the risk assessment is based on initial $PEC_{sw,max}$

values according to FOCUSsw. The TER values for long-term effects on fish are calculated on the basis of a PEC$_{twa,7\ d}$ and a PEC$_{twa,14\ d}$ (see explanation in Addendum 2; the relevant twa interval would be 11 d, but such values are not provided by FOCUSsw). The TER values reflecting the risk to sediment dwellers from accumulation of boscalid in the sediment are based on the modelled PEC$_{sed,max}$ values. All relevant figures are compiled in Table B.9.2-5 to Table B.9.2-8.

Table B.9.2-5: Relevant PEC$_{sw}$ and PEC$_{sed}$ values for the risk assessment for the application of boscalid in vine

Location	**Type of water body**	**PEC$_{sw,max}$* [µg L^{-1}]**	**PEC$_{sw,twa}$** 7 d / 14 d [µg L^{-1}]**	**PEC$_{sed,max}$ *** [µg kg^{-1}]**
Crop		**Vine 1 × 600 g/ha**		
D6	ditch	10.169	1.177 0.753	3.638
R1	pond	0.366	0.334 0.315	2.374
R1	stream	7.474	0.192 0.143	1.280
R2	stream	9.908	0.213 0.107	1.824
R3	stream	10.574	0.958 0.710	4.949
R4	stream	7.471	0.699 0.350	2.912
range		0.366 – 10.574	0.107 – 1.177	1.280 – 4.949

* DT$_{50}$ in water 1000 d, same values as for DT$_{50}$ in water 32 d

** DT$_{50}$ in water 1000 d, no values available for DT$_{50}$ in water 32 d

*** DT$_{50}$ in water 1000 d, values slightly higher than for DT$_{50}$ in water 32 d

Table B.9.2-6: Relevant PEC$_{sw}$ and PEC$_{sed}$ values for the risk assessment for the application of boscalid in legumes

Location	**Type of water body**	**PEC$_{sw,max}$*$^{,(a/b)}$ [µg L^{-1}]**	**PEC$_{sw,twa}$**^{,b} 7 d / 14 d [µg L^{-1}]**	**PEC$_{sed,max}$ *^{,b} [µg kg^{-1}]**
Crop		**Legumes 2 × 500 g/ha**		
D3	ditch	2.617^{a}	0.333 0.290	1.644
D4	pond	1.963^{b}	1.953 1.934	17.984
D4	stream	3.030^{b}	1.769 1.339	6.317
D5	pond	0.772^{b}	0.758 0.739	10.127
D5	stream	2.165^{a}	0.459 0.353	1.937
D6	ditch	7.669^{b}	2.347 1.746	9.313
R1	pond	0.485^{b}	0.464 0.448	4.683
R1	stream	7.191^{b}	0.793 0.594	3.522

Location	**Type of water body**	**$PEC_{sw,max}$*,(a/b)** [µg L^{-1}]	**$PEC_{sw,twa}$**,b** 7 d / 14 d [µg L^{-1}]	**$PEC_{sed,max}$ *,b** [µg kg^{-1}]
R2	stream	2.506[b]	0.383 0.192	4.818
R3	stream	6.785[b]	0.869 0.485	4.881
R4	stream	11.269[b]	3.148 1.912	9.726
range		0.485 – 11.269	0.192 – 3.148	1.644 – 17.984

* DT_{50} in water 1000 d, values slightly higher than for DT_{50} in water 32 d
** DT_{50} in water 1000 d, no values available for DT_{50} in water 32 d
[a] considering single application
[b] considering twofold application

Table B.9.2-7: Relevant PEC_{sw} and PEC_{sed} values for the risk assessment for the application of boscalid in spring oilseed rape

Location	**Type of water body**	**$PEC_{sw,max}$*,(a/b)** [µg L^{-1}]	**$PEC_{sw,twa}$**,b** 7 d / 14 d [µg L^{-1}]	**$PEC_{sed,max}$ *,b** [µg kg^{-1}]
Crop		**Spring oilseed rape 2 × 250 g/ha**		
D1	ditch	3.970[b]	3.845 3.751	45.621
D1	stream	2.483[b]	2.398 2.333	25.075
D3	ditch	1.583[a]	0.244 0.124	1.050
D4	pond	0.624[b]	0.620 0.614	6.367
D4	stream	1.314[a]	0.579 0.424	2.081
D5	pond	0.304[b]	0.298 0.290	4.142
D5	stream	1.248[a]	0.170 0.127	0.763
R1	pond	0.355[b]	0.335 0.321	4.118
R1	stream	2.167[b]	0.251 0.154	3.325
range		0.355 – 3.970	0.124 – 3.845	0.763 – 45.621

* DT_{50} in water 1000 d, values slightly higher than for DT_{50} in water 32 d
** DT_{50} in water 1000 d, no values available for DT_{50} in water 32 d
[a] considering single application
[b] considering twofold application

Table B.9.2-8: Relevant PEC_{sw} and PEC_{sed} values for the risk assessment for the application of boscalid in winter oilseed rape

Location	Type of water body	$PEC_{sw,max}$*,(a/b) [µg L^{-1}]	$PEC_{sw,twa}$**,b 7 d / 14 d [µg L^{-1}]	$PEC_{sed,max}$ *,b [µg kg^{-1}]
Crop		Winter oilseed rape 2 × 250 g/ha		
D2	ditch	5.488[b]	2.466 2.251	32.422
D2	stream	3.435[b]	1.368 1.314	18.166
D3	ditch	1.588[a]	0.330 0.168	1.164
D4	pond	0.673[b]	0.669 0.661	7.052
D4	stream	1.530[b]	0.527 0.494	2.484
D5	pond	0.417[b]	0.408 0.396	4.938
D5	stream	1.477[a]	0.228 0.159	0.996
R1	pond	0.218[b]	0.206 0.198	2.565
R1	stream	1.437[b]	0.131 0.066	1.204
R3	stream	2.546[b]	0.435 0.243	2.657
range		0.218 – 5.488	0.066 – 2.466	0.996 – 32.422

* DT_{50} in water 1000 d, values slightly higher than for DT_{50} in water 32 d
** DT_{50} in water 1000 d, no values available for DT_{50} in water 32 d
[a] considering single application
[b] considering twofold application

The TER values compiled in Table B.9.2-9 to Table B.9.2-12 relate to the ecotoxicological endpoints listed in Table B.9.2-4 above. It could already be demonstrated that the assessment is driven by the acute and long-term toxicity to fish (*O. mykiss*, acute LC_{50} = 2.7 mg/L, NOEC = 0.125 mg/L from ELS test). Thus, TER values for other taxa were not calculated, except for the sediment dweller *C. riparius* (NOEC = 23.26 mg/kg), based on FOCUSsw-$PEC_{sed,max}$ values. It should be noted that these values do not explicitly address the potential accumulation of boscalid in sediment after several years of use. In that respect, the risk assessment provided in Addendum 2 is considered more relevant.

Table B.9.2-9: Relevant TER values for the application of boscalid in vine, based on toxicity to *O. mykiss* (acute LC_{50}, NOEC from ELS test) and *C. riparius* (NOEC from development test with spiked sediment)

Location	**Type of water body**	**TERa** *O. mykiss* LC_{50} = 2.7 mg/L	**TERlt** *O. mykiss* NOEC = 0.125 mg/L twa: 7 d / 14 d	**TERsed** *C. riparius* NOEC = 23.26 mg/kg
Crop		**Vine** 1 × 600 g/ha		
D6	ditch	266	106 166	6394
R1	pond	7377	374 397	9798
R1	stream	361	651 874	18172
R2	stream	273	587 1168	12752
R3	stream	255	130 176	4700
R4	stream	361	179 357	7988
range		255 – 7377	106 – 1168	4700 – 18172

Table B.9.2-10: Relevant TER values for the application of boscalid in legumes, based on toxicity to *O. mykiss* (acute LC_{50}, NOEC from ELS test) and *C. riparius* (NOEC from development test with spiked sediment)

Location	**Type of water body**	**TERa** *O. mykiss* LC_{50} = 2.7 mg/L	**TERlt** *O. mykiss* NOEC = 0.125 mg/L twa: 7 d / 14 d	**TERsed** *C. riparius* NOEC = 23.26 mg/kg
Crop		**Legumes** 2 × 500 g/ha		
D3	ditch	1032	375 431	14148
D4	pond	1375	64 65	1293
D4	stream	891	71 93	3682
D5	pond	3497	165 169	2297
D5	stream	1247	272 354	12008
D6	ditch	352	53 72	2498
R1	pond	5567	269 279	4967
R1	stream	375	158 210	6604
R2	stream	1077	326 651	4828
R3	stream	398	144 258	4765

Location	**Type of water body**	**TERa** *O. mykiss* LC$_{50}$ = 2.7 mg/L	**TERlt** *O. mykiss* NOEC = 0.125 mg/L twa: 7 d / 14 d	**TERsed** *C. riparius* NOEC = 23.26 mg/kg
R4	stream	240	40 65	2392
range		240 – 5567	40 – 651	1293 – 14148

Table B.9.2-11: Relevant TER values for the application of boscalid in spring oilseed rape, based on toxicity to *O. mykiss* (acute LC$_{50}$, NOEC from ELS test) and *C. riparius* (NOEC from development test with spiked sediment)

Location	**Type of water body**	**TERa** *O. mykiss* LC$_{50}$ = 2.7 mg/L	**TERlt** *O. mykiss* NOEC = 0.125 mg/L twa: 7 d / 14 d	**TERsed** *C. riparius* NOEC = 23.26 mg/kg
Crop		**Spring oilseed rape 2 × 250 g/ha**		
D1	ditch	680	33 33	510
D1	stream	1087	52 54	928
D3	ditch	1706	512 1008	22152
D4	pond	4327	202 204	3653
D4	stream	2055	216 295	11177
D5	pond	8882	419 431	5616
D5	stream	2163	735 984	30485
R1	pond	7606	373 389	5648
R1	stream	1246	498 812	6995
range		680 – 7606	33 – 1008	510 – 30485

Table B.9.2-12: Relevant TER values for the application of boscalid in winter oilseed rape, based on toxicity to *O. mykiss* (acute LC_{50}, NOEC from ELS test) and *C. riparius* (NOEC from development test with spiked sediment)

Location	**Type of water body**	**TERa** *O. mykiss* LC_{50} = 2.7 mg/L	**TERlt** *O. mykiss* NOEC = 0.125 mg/L twa: 7 d / 14 d	**TERsed** *C. riparius* NOEC = 23.26 mg/kg
Crop		**Winter oilseed rape 2 × 250 g/ha**		
D2	ditch	492	51 56	717
D2	stream	786	91 95	1280
D3	ditch	1700	379 744	19983
D4	pond	4012	187 189	3298
D4	stream	1765	237 253	9364
D5	pond	6475	306 316	4710
D5	stream	1828	548 786	23353
R1	pond	12385	607 631	9068
R1	stream	1879	954 1894	19319
R3	stream	1060	287 514	8754
range		492 – 12385	51 – 1894	717 – 23353

Conclusion

All calculated TER values are all well above the respective Annex VI acceptability criteria already under the assumptions of FOCUSsw Step 3 (i.e. no additional risk mitigation measures). Thus, no unacceptable effects are expected for aquatic organisms as a result of the proposed uses of boscalid. This risk assessment also covers the potential accumulation of boscalid in soil after several years of use.

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Addendum 1

to the Draft Assessment Report

of 08 November 2002

(relating to Volume 4)

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