BOSCALID (221)

First draft prepared by Prof. Dr. Arpad Ambrus, Hungarian Food Safety Office, Budapest, Hungary

EXPLANATION

Boscalid was first evaluated by the 2006 JMPR which established an ADI of 0-0.04 mg/kg bw and proposed maximum residue levels for a number of commodities.

The manufacturer submitted information on a new commercial product (BAS510 05F) containing boscalid at 500g ai/L, data was provided on approved use patterns and residue trials in banana, kiwi fruit and hops.

USE PATTERN

Boscalid may be used to control Black sigatoka (*Mycosphaerella fijiensis)* in bananas, Powdery mildew and Downy mildew in hops and for post-harvest treatment of kiwifruit to protect against Gray mould (*Botrytis* spp.).

The registered or authorized uses are summarized in Table 1.

Table 1 Registered uses of boscalid on banana, kiwi fruit and hops

Crop	Country	End use product [BASF code]	Use [a]	Application					PHI [days] [c]
				Method	No. per crop season max.	kg as/hL [b] max.	Water L/ha per appl. min. max.	kg as/ha per applic. [b] min. max.	
Banana [f]	USA	510 01 F	F	Spray	4	0.500–0.833	18–30 [d]	0.150	0
Banana	Colombia Ecuador	510 05 F	F	Aerial appl	4	0.750-1.666 (related to 9-20 L water) 0.500-0.833 (in the oil/water mixture)	18–30 L	0.150	0
Banana [g] (pending)	Philippines	510 05 F	F	ULV	4	0.833 for ULV spraying (related to 18 L water). 0.166	18 for ULV spraying, 90 for cannon spraying	0.150	0
Kiwifruit [h]	Italy	510 01 F	--	Dipping	1	0.0375	Not applicable	Not applicable	60 [e]
Hops	USA	516 04 F	F	Spray	3	0.026	234–1868	0.494	14
Hops [g]	Germany	516 04 F	F	Spray	3	0.019	600–2700 1.appl: 600–1200 2.appl: 1200–2300 3.appl: 2300–2700	0.114– 0.504	21
Hops [g]	France	516 04 F	F	Spray	3	0.019	600–2700	0.114–0.504	21

[a] F = outdoor or field use

[b] Information given on active substance (as) refers to boscalid only

[c] PHI = pre-harvest interval

[d] oil/water mixture, where oil is added as a constant with generally 7 - 9 sometimes 5 litre. The stability of the

emulsion is related to the amount of oil in the mixture. The greater the content of oil the greater the stability is, and less emulsifier is needed.

[e] Waiting period is 60 days after treatment and before selling the treated kiwifruit.

[f] Import tolerance

[g] Registration is pending

[h] Post-harvest treatment

RESIDUES RESULTING FROM SUPERVISED TRIALS

Banana

In 2004, a total of 12 trials were carried out on banana in Costa Rica (2 trials), Colombia (2 trials), Ecuador (two trials), Guatemala (one trial), Honduras (two trials), Martinique (two trials) and Mexico (one trial) covering a wide range of varieties including Williams, Giant Cavendish, Gran Enano, Ecuatoriano, Gran Nane and Cavendish. The application rate is in agreement with the new GAP in Colombia and Ecuador. These trials had been evaluated and reported by the 2006 JMPR, and they are not repeated in this evaluation. The banana whole fruit samples, which were bagged and all pulp samples both bagged and unbagged did not contain any boscalid residue above the LOQ of 0.05 mg/kg. The residues in unbagged whole banana fruits were, in rank order: < 0.05 (4), 0.05, 0.07, 0.07, 0.09, 0.10, 0.10, 0.11, and 0.18 mg/kg.

In the growing season of 2006/07, a bridging study was conducted with six trials in Costa Rica, Ecuador, Colombia, Honduras, Guatemala and Martinique comparing a WG formulation (BAS 510 01 F) to a SC formulation (BAS 510 05 F). In both variants, four ground applications at a rate of 150 g as/ha were done simulating aerial application. The spray intervals were 9–11 days, the spray volume was 25–30 L/ha.

Directly after the last application and one day later, both bagged and unbagged banana whole fruit, pulp and peel samples were collected and analysed using method No. D9908 (Abdel-Baky S., Jones J, 2001). The trials are summarized in Table 2.

Table 2 Results of supervised trials on banana with foliar application of WG and SC formulations of boscalid at 150 g/ha in spray volume of 25–30 L/ha

CROP Country, Year *Location* (variety)	Application		PHI [d]	Sample material	Residue boscalid [mg/kg]	Author Report Year Study No. Reg.DocID.
	Formulation	No.				
Costa Rica, 2006 Pococi (Valery)	BAS 510 01 F (50%, WG)	4	0	fruit, bagged	< 0.05	R. Gooding, J. Jordan 2007, 248496,
			0	fruit, unbagged	0.12	
			1	fruit, bagged	< 0.05	
			1	fruit, unbagged	0.19	
			0	pulp, bagged	< 0.05	2007/7001618
			0	pulp, unbagged	0.08	
			1	pulp, bagged	< 0.05	
			1	pulp, unbagged	< 0.05	
			0	peel, bagged	< 0.05	
			0	peel, unbagged	0.31	
			1	peel, bagged	< 0.05	
			1	peel, unbagged	0.47	
	BAS 510 05 F (500 g/L, SC)	4	0	fruit, bagged	< 0.05	
			0	fruit, unbagged	0.12	
			1	fruit, bagged	< 0.05	
			1	fruit, unbagged	< 0.05	

CROP Country, Year *Location* (variety)	Application Formulation	 No.	PHI [d]	Sample material	Residue boscalid [mg/kg]	Author Report Year Study No. Reg.DocID.
			0	pulp, bagged	< 0.05	
			0	pulp, unbagged	< 0.05	
			1	pulp, bagged	< 0.05	
			1	pulp, unbagged	< 0.05	
			0	peel, bagged	< 0.05	
			0	peel, unbagged	0.34	
			1	peel, bagged	< 0.05	
			1	peel, unbagged	0.35	
Ecuador, 2006 Guayas (Giant Cavendish)	BAS 510 01 F (50%, WG)	4	0	fruit, bagged	< 0.05	
			0	fruit, unbagged	< 0.05	
			1	fruit, bagged	< 0.05	
			1	fruit, unbagged	< 0.05	
			0	pulp, bagged	< 0.05	
			0	pulp, unbagged	< 0.05	
			1	pulp, bagged	< 0.05	
			1	pulp, unbagged	< 0.05	
			0	peel, bagged	< 0.05	
			0	peel, unbagged	0.10	
			1	peel, bagged	< 0.05	
			1	peel, unbagged	0.07	
	BAS 510 05 F (500 g/L, SC)	4	0	fruit, bagged	< 0.05	
			0	fruit, unbagged	< 0.05	
			1	fruit, bagged	< 0.05	
			1	fruit, unbagged	< 0.05	
			0	pulp, bagged	< 0.05	
			0	pulp, unbagged	< 0.05	
			1	pulp, bagged	< 0.05	
			1	pulp, unbagged	< 0.05	
			0	peel, bagged	< 0.05	
			0	peel, unbagged	0.11	
			1	peel, bagged	< 0.05	
			1	peel, unbagged	0.15	
Colombia, 2006 Magdalena (Gran Enano)	BAS 510 01 F (50%, WG)	4	0	fruit, bagged	< 0.05	
			0	fruit, unbagged	< 0.05	
			1	fruit, bagged	< 0.05	
			1	fruit, unbagged	0.08	
			0	pulp, bagged	< 0.05	
			0	pulp, unbagged	< 0.05	
			1	pulp, bagged	< 0.05	
			1	pulp, unbagged	< 0.05	
			0	peel, bagged	< 0.05	
			0	peel, unbagged	0.24	
			1	peel, bagged	< 0.05	

CROP Country, Year *Location* (variety)	Application		PHI [d]	Sample material	Residue boscalid [mg/kg]	Author Report Year Study No. Reg.DocID.
	Formulation	No.				
			1	peel, unbagged	< 0.05	
	BAS	4	0	fruit, bagged	< 0.05	
	510 05 F		0	fruit, unbagged	0.18	
	(500 g/L, SC)		1	fruit, bagged	< 0.05	
			1	fruit, unbagged	0.12	
			0	pulp, bagged	< 0.05	
			0	pulp, unbagged	< 0.05	
			1	pulp, bagged	< 0.05	
			1	pulp, unbagged	< 0.05	
			0	peel, bagged	< 0.05	
			0	peel, unbagged	0.34	
			1	peel, bagged	< 0.05	
			1	peel, unbagged	0.23	
Honduras, 2006	BAS	4	0	fruit, bagged	< 0.05	
Cortés	510 01 F		0	fruit, unbagged	< 0.05	
(Williams)	(50%, WG)		1	fruit, bagged	0.06	
			1	fruit, unbagged	< 0.05	
			0	pulp, bagged	< 0.05	
			0	pulp, unbagged	< 0.05	
			1	pulp, bagged	< 0.05	
			1	pulp, unbagged	< 0.05	
			0	peel, bagged	< 0.05	
			0	peel, unbagged	0.07	
			1	peel, bagged	< 0.05	
			1	peel, unbagged	0.09	
	BAS	4	0	fruit, bagged	0.07	
	510 05 F		0	fruit, unbagged	< 0.05	
	(500 g/L, SC)		1	fruit, bagged	< 0.05	
			1	fruit, unbagged.	< 0.05	
			0	pulp, bagged	< 0.05	
			0	pulp, unbagged	< 0.05	
			1	pulp, bagged	< 0.05	
			1	pulp, unbagged	< 0.05	
			0	peel, bagged	< 0.05	
			0	peel, unbagged	0.06	
			1	peel, bagged	< 0.05	
			1	peel, unbagged	< 0.05	
Guatemala,	BAS	4	0	fruit, bagged	< 0.05	
2006	510 01 F		0	fruit, unbagged	0.06	
Escuintla	(50%, WG)		1	fruit, bagged	< 0.05	
(Gran Naine)			1	fruit, unbagged	0.08	
			0	pulp, bagged	< 0.05	

CROP Country, Year *Location* (variety)	Application		PHI [d]	Sample material	Residue boscalid [mg/kg]	Author Report Year Study No. Reg.DocID.
	Formulation	No.				
			0	pulp, unbagged	< 0.05	
			1	pulp, bagged	< 0.05	
			1	pulp, unbagged	< 0.05	
			0	peel, bagged	< 0.05	
			0	peel, unbagged	0.31	
			1	peel, bagged	< 0.05	
			1	peel, unbagged	0.13	
	BAS 510 05 F (500 g/L, SC)	4	0	fruit, bagged	< 0.05	
			0	fruit, unbagged	0.28	
			1	fruit, bagged	< 0.05	
			1	fruit, unbagged	0.42	
			0	pulp, bagged	< 0.05	
			0	pulp, unbagged	< 0.05	
			1	pulp, bagged	< 0.05	
			1	pulp, unbagged	< 0.05	
			0	peel, bagged	< 0.05	
			0	peel, unbagged	0.56	
			1	peel, bagged	< 0.05	
			1	peel, unbagged	0.93	
French W. Indies, 2006 Martinique (Cavendish)	BAS 510 01 F (50%, WG)	4	0	fruit, bagged	< 0.05	
			0	fruit, unbagged	0.09	
			1	fruit, bagged	< 0.05	
			1	fruit, unbagged	0.08	
			0	pulp, bagged	< 0.05	
			0	pulp, unbagged	< 0.05	
			1	pulp, bagged	< 0.05	
			1	pulp, unbagged	< 0.05	
			0	peel, bagged	< 0.05	
			0	peel, unbagged	0.21	
			1	peel, bagged	< 0.05	
			1	peel, unbagged	0.10	
	BAS 510 05 F (500 g/L, SC)	4	0	wh. fruit, bagged	< 0.05	
			0	wh. fruit, unbagged.	0.05	
			1	wh. fruit, bagged	< 0.05	
			1	wh. fruit, unbagged	< 0.05	
			0	pulp, bagged	< 0.05	
			0	pulp, unbagged	< 0.05	
			1	pulp, bagged	< 0.05	
			1	pulp, unbagged	< 0.05	
			0	peel, bagged	< 0.05	
			0	peel, unbagged	0.08	

CROP Country, Year *Location* (variety)	Application		PHI [d]	Sample material	Residue boscalid [mg/kg]	Author Report Year Study No. Reg.DocID.
	Formulation	No.				
			1	peel, bagged	< 0.05	
			1	peel, unbagged	0.07	

Kiwi fruits

In kiwifruit, boscalid is used for post-harvest protection applying one dipping treatment with 0.0375 kg ai/hL solution.

Kiwifruits were sampled directly after the application as well as about 60 days thereafter. Kiwi whole fruits as well as peel and pulp were analysed with method No. 445/0. The average of the procedural recoveries for boscalid was between 101 and 106%.

The results of trials are summarized in Table 3.

Table 3 Results of residue trials with BAS 510-01 formulation conducted on kiwifruit with one dipping treatment

CROP Country, Year *Location* (variety)	Application			PHI [d]	Sample material	Residue [mg/kg]	Author Report Year Study No. Reg.DocID.
	Rate [kg as/ hl]	Spray volume [L/ha]	No.				
Italy, 2004 Veneto (Hayward)	0.0375	-	1	0	fruit	1.126	E. Schroth, 2005, 208420, 2005/1007588
				0	peel	4.549	
				0	pulp	0.116	
				59	fruit	0.804	
				59	peel	5.439	
				59	pulp	0.055	
Italy, 2004 Veneto (Hayward)	0.0375	-	1	0	fruit	2.254	
				0	peel	9.378	
				0	pulp	0.145	
				59	fruit	2.384	
				59	peel	8.225	
				59	pulp	0.142	
Italy, 2004 Abruzzo (Hayward)	0.0375	-	1	0	fruit	1.034	
				0	peel	4.580	
				0	pulp	0.103	
				60	fruit	1.162	
				60	peel	8.132	
				60	pulp	0.063	
Italy, 2004 Abruzzo (Hayward)	0.0375	-	1	0	fruit	1.163	
				0	peel	6.218	
				0	pulp	0.122	
				60	fruit	1.325	
				60	peel	7.478	
				60	pulp	0.083	

Hops

The product is registered in the USA with 3 applications per season at 0.5 kg/ha (total maximum seasonal application of 1482 g as/ha) and a PHI of 14 days.

Three trials were conducted in the USA according to the registered use pattern. The cones were dried and analysed with a method providing 98% recovery and an LOQ of 0.05 mg/kg.

The results of the trials are summarized in Table 4.

Table 4 Results of residue trials in hops applying BAS 510 UC formulation of boscalid for foliar treatment at 0.5 kg as/ha

CROP Country, Year *Location* (variety)	Application Rate [kg as/ ha]	Spray volume [L/ha]	No.	PHI [d]	Sample material	Residue [mg/kg]	Author Report Year Study No. Reg.DocID.
USA, 2001 WA, EPA region 11 (Warrior)	0.50	710	3	0	dried hop cones	51.9	J.M. Jordan, 2002, 64550, 2001/5002574
				7		24.8*	
				14		29.4*	
	0.50	1890	3	0	dried hop cones	40.4	
				7		16.4	
				14		10.7	
ID, EPA region 11 (Zeus)	0.50	470	3	0	dried hop cones	52.1	
				7		39.7*	
				14		31.1*	
	0.50	1420	3	0	dried hop cones	48.7	
				7		14.9	
				14		11.8	
OR, EPA region 12 (Liberty)	0.50	750		0	dried hop cones	17.0	
				7		7.6	
	0.50	1420		0	dried hop cones	16.6	
				7		9.9	

* average of multiple analysis

APPRAISAL

Boscalid was first evaluated by the 2006 JMPR which established an ADI of 0-0.04 mg/kg bw and proposed maximum residue levels for a number of commodities.

Results of additional supervised trials on banana, kiwi and hops were evaluated by the present Meeting.

Results of supervised residue trials on crops

New registrations have been obtained for banana, kiwi and hops. Trials conducted complying with the registered uses were evaluated and the relevant residues considered for the estimation of maximum residue level and STMR values.

Banana

The 2006 JMPR evaluated and reported the results of 12 trials on banana, were performed in accordance with the recently registered uses in Colombia and Ecuador (0.15 kg as/ha, 0 day PHI). The

banana whole fruit samples which were bagged and all pulp samples both bagged and unbagged did not contain any boscalid residue above the limit of quantification of 0.05 mg/kg.

In the 2006/07 growing season, a bridging study with six trials was conducted, according to the GAP in Costa Rica and Colombia, comparing a WG formulation (BAS 510 01 F) with a SC formulation (BAS 510 05 F). Immediately after and one following the last application, fruit from both bagged and unbagged treatments were sampled. Banana whole fruit, pulp and peel samples were then analysed.

The results show that of all bagged samples only two whole fruit samples contained detectable boscalid residues at 0.06 and 0.07 mg/kg. These values were selected for the estimation of a maximum residue level as they were higher than the residues in unbagged bananas. The residue in/on peel confirmed there was no difference between residues derived from the WG and SC formulations.

As the magnitude of residues was similar on day 0 and day 1, regardless of which formulation was used (the WG or SC), the highest residue was selected from each trial carried out at one site. The residues found in rank order were: < 0.05, < 0.05, 0.05, 0.06, 0.07, 0.08, 0.08, 0.09, 0.12, 0.18, 0.19 and 0.42 mg/kg.

The residues from the trials in 2004 were: < 0.05 (4), 0.05, 0.07, 0.07, 0.09, 0.10, 0.10, 0.11, and 0.18 mg/kg.

The two data sets are not statistically different and can be combined for the estimation of a maximum residue level. The combined data (24) in rank order were: < 0.05 (6), 0.05 (2), 0.06, 0.07 (3), 0.08 (2), 0.09 (2), 0.10 (2), 0.11, 0.12, 0.18 (2), 0.19 and 0.42 mg/kg.

Banana pulp contained residues below the LOQ of 0.05 mg/kg in all but one of 18 trials, where the residue was found to be 0.08 mg/kg.

Based on the residue data available, the Meeting confirmed its previous recommendation for an STMR value of 0.05 mg/kg for banana pulp, withdrew its previous recommendation for a maximum residue level of 0.2 mg/kg and proposed a value of 0.6 mg/kg for bagged and unbagged bananas.

Kiwi fruit

In kiwifruit, boscalid is used as a post-harvest treatment applied as a dip treatment at a rate of 0.0375 kg ai/hL. Four Italian trials were conducted according to GAP.

Kiwi fruits were sampled directly after the application and again at about 60 days thereafter. Kiwi whole fruit, as well as peel and pulp were analysed. The average of the procedural recoveries for boscalid was between 101 and 106%.

The residues in whole fruits 59–60 days after the post-harvest treatment were 0.80, 1.16, 1.32, and 2.38 mg/kg.

The pulp contained residues of 0.055, 0.063, 0.083 and 0.142 mg/kg.

The Meeting took into account that post harvest treatment normally produces more uniform residue distributions than foliar applications, and estimated a maximum residue level of 5 mg/kg and an STMR of 0.073 mg/kg for kiwi fruits.

Hops

Boscalid is approved for use on hops in the USA (US GAP: maximum of 3 applications per season at 0.5 kg/ha with a total maximum seasonal application rate of 1482 g ai/ha and a PHI of 14 days).

Three trials were conducted in the USA according to the registered use pattern. The cones were dried and analysed with a method providing 98% recovery and an LOQ of 0.05 mg/kg.

In addition eight trials were carried out in Germany corresponding to the target rate specified in a pending registration (three foliar applications of maximum 504 g ai/ha each with a maximum seasonal application rate of 1512 g ai/ha and a PHI of 21 days). These results were reported by the

2006 JMPR. As the product is not registered in Germany or other countries with comparable growing practice, those results could not be used for estimation of maximum residue levels.

The US trials were conducted with application volumes of 750 and 1420 L/ha. The treatments with the lower spray volume resulted in higher residues, and therefore were considered. The residues determined at 14 day PHI in the two trials were: 29.4 and 31.1 mg/kg.

The Meeting concluded that two trials were insufficient for the estimation of a maximum residue level.

RECOMMENDATIONS

On the basis of the data from supervised trials, the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for dietary intake assessment.

CCN	Commodity	Recommended MRL, mg/kg		STMR, mg/kg
		New	Previous	
FI 0327	Banana	0.6	0.2	0.05
FI 0344	Kiwi Fruit	5	-	0.073

DIETARY RISK ASSESSMENT

Long-term intake

The 2006 JMPR could not recommend STMR values for a large number of following or rotational crops in which residue may be present above the LOQ, that Meeting decided that the estimation of the long-term intake would not be realistic.

In the absence of any new data on soil carryover the current Meeting also decided that no long-term intake calculations could be undertaken.

REFERENCES

Report No	Author	Year	Title, Institute & report number, Submitting manufacturer and report code, GLP/Non-GLP. Published/Unpublished
2000/5001019	Abdel-Baky S., and Jones J.E.	2001	Boscalid: Method for Determination of BAS 500 F, BF 500-3 and BAS 510 F Residues in Plant Matrices using LC/MS/MS. Method D9908, BASF Corporation, Agricultural Products Center, NC 27709-3528, USA. BASF unpublished report
2000/1012404	Funk H., Mackenroth C.,	2001	Boscalid: Validation of BASF Method 445/0: Determination of BAS 510 in plant matrices. Method 445/0, BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed. Rep. BASF unpublished report 41840, issued 19.02.2001.
2007/7001618	Jordan J., Gooding R.	2007	A Bridging Study to Compare the Magnitude of Boscalid Residues in Bananas Following Applications with BAS 510 01 F and BAS 510 05 F BASF Agro Research RTP; Research Triangle Park, NC 27709; United Stated of America 2007/7001618, unpublished
2005/1007588	Schroth E.	2005	Study on the residue behavior of Boscalid in kiwi after the post harvest application of BAS 510 01 F under field conditions in Italy, 2004, Agrologia SL; Palomares; Spain, 2005/1007588, unpublished

Report No	Author	Year	Title, Institute & report number, Submitting manufacturer and report code, GLP/Non-GLP. Published/Unpublished
2001/5002574	Jordan J.	2002	Magnitude of the residue of BAS 500 02 F and BAS 510 UCF in hops BASF Agro Research RTP; Research Triangle Park, NC 27709; United Stated of America, 2001/5002574, unpublished