BOSCALID (221)

The first draft was prepared by Dr Ursula Banasiak, Federal Institute for Risk Assessment, Berlin, Germany

EXPLANATION

Boscalid is a carboxamide fungicide. It was evaluated for the first time for toxicology and residues by the JMPR in 2006. The JMPR 2009 derived a lot of MRLs under consideration of the residue situation in rotational crops. The compound was listed for additional MRLs by the 2010 JMPR at the 41st Session of the CCPR. At the 42nd Session of the CCPR, the Committee noted the reservation of the EU regarding the proposed MRL for leafy vegetables in the light of their higher MRLs for lamb's lettuce (ALINORM 10/33/24, para 79). GAP information and residue data for citrus fruits, lamb's lettuce, celery and hops were submitted by the manufacturer.

RESIDUE ANALYSIS

Analytical methods

BASF analytical method no. 9908 (Abdel-Baky and Jones, 2001, BASF DocID 2001/5001019) was used for analyses of boscalid residues in oranges and orange processed commodities, grapefruit, lemons, celery and hops (dried cones). Residues were extracted from the samples with a 70:25:5 methanol/water/2 N HCI mixture. A 0.2% aliquot of the extract was removed and cleaned by liquid/liquid partition with cyclohexane. The samples were further cleaned using a silica micro-column. The final chromatographic analysis of residues was performed by LC/MS/MS with an LOQ of 0.05 mg/kg.

Lamb's lettuce samples were analysed with BASF methods no. 445/0 (Funk and Mackenroth, 2001, BASF DocID 2000/1012404) or 535/0 (Mackenroth and Lehmann, 2007, BASF DocID 2006/1039427) which quantify the relevant residues of boscalid with a LOQ of 0.05 mg/kg (445/0) or 0.01 mg/kg (535/0).

USE PATTERN

The information available to the 2010 JMPR on registered uses of boscalid is summarised in Table 1. Copies of labels were made available to the Meeting.

Table 1 Registered uses of boscalid

Crop	Country	Form	Method	No	Application			PHI, days
					kg ai/hl	Water L/ha	kg ai/ha	
Citrus fruits	USA	WG	Foliar spray	4	–	Not specified	0.28–0.33	0
Citrus	Korea	WG	Foliar spray	4	0.010	5000	0.50	15
Citrus	Korea	WG	Foliar spray	3	0.010	4000	0.51	50
Citrus	Japan	WG	Foliar spray	3	0.007	2000–7000	0.14–0.48	14
Citrus	Japan	WG	Foliar spray		0.033	2000–7000	2.3	14
Celery	USA	WG	Foliar spray	2	–	Not specified	0.22–0.44	0
Celery	USA	WG	Foliar spray	2	–	Not specified	0.39–0.44	0
Celery	Belgium	WG	Foliar spray	2	–	Not specified	0.4	14
Lamb's lettuce	Belgium	WG	Foliar spray	2	0.08	500	0.4	21
Lamb's lettuce	Germany	WG	Foliar spray	1	0.2	200–600	0.4	14
Lamb's lettuce	Netherlands	WG	Foliar spray	1			0.4	21

Crop	Country	Form	Method	No	Application			PHI, days
					kg ai/hl	Water L/ha	kg ai/ha	
Lamb's lettuce	France	WG	Foliar spray	1	0.2	200–500	0.4	14
Hops	USA	WG	Foliar spray	3	0.026	234–1868	0.49	14
Hops (pending)	Germany	WG	Foliar spray	3	0.019	1.appl: 600–1200 2.appl: 1200–2300 3.appl: 2300–2700	0.11–0.50	21
Hops (pending)	France	WG	Foliar spray	3	0.019	600–2700	0.11–0.50	21

RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS

The Meeting received information on supervised field trials for boscalid uses that produced residues on the following commodities.

Group	Commodity	Table No
FC Citrus fruits	Oranges, grapefruit and lemons	2
VL Leafy vegetables	Lamb's lettuce	3
VS Stalk and steam vegetable	Celery	4
DH Dried herbs	Hops	5

Trials were well documented with laboratory and field reports. Laboratory reports included method validation with procedural recoveries from spiking at residue levels similar to those occurring in samples from the supervised trials. Dates of analysis or duration of residue sample storage were also provided. Residue data are recorded unadjusted for recovery. Undetected residues were generally reported lower than the LOQ.

Residues and application rates have generally been rounded to two significant figures. Residue values from the trials conducted according to maximum GAP have been used for the estimation of maximum residue levels. Those results included in the evaluation are underlined.

Citrus fruits

In 2001 to 2002 twenty-four field trials were conducted in the principal growing areas for citrus in the USA. There were a total of:

- thirteen orange trials, eight in Florida, one in Texas, and four in California
- six grapefruit trials, three in Florida, one in Texas and two in California
- five lemon trials, one in Florida, two in Arizona and two in California.

The interval between applications was a 10 (± 1) days, beginning 30 days prior to the harvest date. Applications were made using commercial or simulated commercial application equipment. Citrus fruits were collected after the spray from the last application dried, representing a 0-day pre-harvest interval (PHI). The results are summarised in Table 2.

Table 2 Boscalid residues in citrus fruits

Country, Year Location (variety), Trial No.	Application					PHI, days	Sample material	Residues, mg/kg	Author, Report, Year, Study No. Reg.DocID.
	Form	Method	kg ai/ha	water L/ha	No				
Oranges									
USA, 2002 Florida (Valencia) 2001339	WG	foliar spray	0.33–0.34	1393–1404	4	0	fruit peel pulp	0.68 4.0 0.12	J.M. Jordan, 2002, 64978, 2002/5002446
USA, 2002 Florida (Navel) 2001340	WG	foliar spray	0.34–0.38	839–870	4	0	fruit peel pulp	0.23 0.69 < 0.05	
USA, 2002 Florida (Hamlin) 2001341	WG	foliar spray	0.33–0.34	1396–1416	4	0	fruit peel pulp	0.56 2.6 0.05	
USA, 2002 Florida (Hamlin) 2001342	WG	foliar spray	0.34-0.35	813–842	4	0	fruit peel pulp	1.4 6.3 0.20	
USA, 2002 Florida (Valencia Swingle) 2001343	WG	foliar spray	0.34	1514–1549	4	0	fruit peel pulp	0.64 2.8 0.09	
USA, 2002 Florida (Hamlin) 2001344	WG	foliar spray	0.33-0.34	808–827	4	0	fruit peel pulp	1.2 2.6 0.09	
USA, 2002 Florida (Valencia) 2001345	WG	foliar spray	0.34	1859–1941	4	0	fruit peel pulp	0.33 0.76 < 0.05	
USA, 2002 Florida (Valencia) 2001346	WG	foliar spray	0.34	693–704	4	0	fruit peel pulp	0.71 1.7 0.06	
USA, 2002 Texas (Everhard Navel) 2001347	WG	foliar spray	0.34	2342–2375	4	0	fruit peel pulp	0.32 0.81 < 0.05	
USA, 2002 California (Navel) 2001348	WG	foliar spray	0.33-0.34	3285–3385	4	0	fruit peel pulp	0.30 0.98 < 0.05	
USA, 2002 California (Navel) 2001349	WG	foliar spray	0.33-0.34	722–760	4	0	fruit peel pulp	0.47 0.85 0.06	
USA, 2002 California (Navel) 2001350	WG	foliar spray	0.33–0.34	3234–3281	4	0	fruit peel pulp	0.35 1.2 < 0.05	
USA, 2002 California (Cutter) 2001351	WG	foliar spray	0.33–0.34	717–733	4	0	fruit peel pulp	0.26 1.1 < 0.05	
Grapefruit									
USA, 2002 Florida (Flame) 2001352	WG	foliar spray	0.34	1678–1687	4	0	fruit	0.27	J.M. Jordan, 2002, 64978, 2002/5002446

Country, Year Location (variety), Trial No.	Application					PHI, days	Sample material	Residues, mg/kg	Author, Report, Year, Study No. Reg.DocID.
	Form	Method	kg ai/ha	water L/ha	No				
USA, 2002 Florida (White Marsh) 2001353	WG	foliar spray	0.34–0.35	815–842	4	0	fruit	0.85	
USA, 2002 Florida (Flame) 2001354	WG	foliar spray	0.34	2548–2701	4	0	fruit	0.10	
USA, 2002 Texas (Rio Red) 2001355	WG	foliar spray	0.34–0.35	691–696	4	0	fruit	0.12	
USA, 2002 California (Mello Gold) 2001356	WG	foliar spray	0.33–0.34	835–844	4	0	fruit	0.15	
USA, 2002 California (Oroblanco) 2001356	WG	foliar spray	0.33–0.34	2077–2127	4	0	fruit	0.15	
Lemon									
USA, 2002 Florida (Bears) 2001358	WG	foliar spray	0.33–0.36	772–854	4	0	fruit	0.68	J.M. Jordan, 2002, 64978, 2002/5002446
USA, 2002 California (Prior) 2001359	WG	foliar spray	0.33–0.34	2077–2261	4	0	fruit	0.74	
USA, 2002 California (Lisbon) 2001360	WG	foliar spray	0.33–0.34	692–721	4	0	fruit	1.5	
USA, 2002 Arizona (Lisbon) 2001361	WG	foliar spray	0.33	717–727	4	0	fruit	0.59	
USA, 2002 Arizona (Limonair) 2001362	WG	foliar spray	0.33	1843–2077	4	0	fruit	0.94	

Lamb's lettuce

During the growing seasons 2005 and 2006, eight trials (field and greenhouse) were conducted in different representative growing areas for lamb's lettuce in France to determine the residue levels of boscalid. Whole plants without roots were collected at 0, 6–7, 13–15 and 20–21 days after the last application. The results are summarised in Table 3.

Table 3 Boscalid residues in lamb's lettuce

Country, Year *Location* (variety), Trial No.	Application					Sample	PHI, days	Residues, mg/kg	Author, Report, Year, Study No. Reg.Doc ID.
	Form	G/F	kg ai/ha	Water L/ha	No				
France, 2005 (Vit)	WG	G	0.4		1	leaves	0 7 15 21	38 37 29 25	Perny, 2006, 230422, Doc ID 2006/1024416

Country, Year *Location* (variety), Trial No.	Application					Sample	PHI, days	Residues, mg/kg	Author, Report, Year, Study No. Reg.Doc ID.
	Form	G/F	kg ai/ha	Water L/ha	No				
France, 2005 (Vit)	WG	G	0.4		1	leaves	0 7 14 21	28 16 16 11	
France, 2005 (Murphy)	WG	G	0.4		1	leaves	0 7 14 21	16 3.4 2.4 1.8	
France, 2005 (Trophy)	WG	G	0.4		1	leaves	0 7 14 21	27 6.5 4.1 1.9	
France, 2005 (Macholong)	WG	G	0.4		1	leaves	0 7 13 21	23 0.36 0.26 0.17	
France, 2005 (Mache a grosses graines)	WG	G	0.4		1	leaves	0 7 14 21	13 4.9 3.2 2.1	
France, 2006 (Vit)	WG	F	0.4		1	leaves	0 6 13 21	19 10 4.1 1.1	Perny, 2007, 230428, Doc ID 2007/1006114
France, 2006 (Macholong)	WG	F	0.4		1	leaves	0 7 14 21	31 1.6 0.85 0.38	

Celery

In 2001, a study with 12 US trials was conducted. All applications were made as foliar broadcast sprays, 6 to 9 days apart. Celery plants were sampled directly after the application as well as 7 ± 1 and 14 ± 1 days after the last application. For each trial at each sampling date, two treated samples of mature celery plants were collected. Control samples were taken at 0 days only. The results are summarised in Table 4.

Table 4 Boscalid residues in celery

Country, Year Location (variety) Trial No.	Application					PHI, days	Sample	Residues, mg/kg	Author, Report, Year Study No., Reg.DocID.
	Form	Method	kg ai/ha	water L/ha	No				
USA 2001 Florida (June Bell 1622) FL22	WG	spray	0.46	578	2	0 7 14	plant	13 11 3.3	Hong, 2003, IR-4 PR No. 08091 2003/5000655
USA 2001 Florida (June Bell 1622) FL23	WG	spray	0.45–0.46	578	2	0 7 14	plant	18 4.5 3.1	
USA 2001 California (Conquistador) CA36	WG	spray	0.45–0.46	916	2	0 7 14	plant	9.7 8.3 9.8	
USA 2001 California (Conquistador) CA37	WG	spray	0.46–0.47	970–1290	2	0 7 14	plant	2.7 0.88 0.40	
USA 2001 California	WG	spray	0.45–0.47	968	2	0 6	plant	1.9 0.79	

Country, Year Location (variety) Trial No.	Application					PHI, days	Sample	Residues, mg/kg	Author, Report, Year Study No., Reg.DocID.
	Form	Method	kg ai/ha	water L/ha	No				
(Conquistador) CA38						13		0.47	
USA 2001 California (Conquistador) CA80	WG	spray	0.46	595–637	2	0 7 14	plant	8.3 5.5 5.0	
USA 2001 Oregon (Picador) OR07	WG	spray	0.45–0.46	473	2	0 7 14	plant	5.6 3.7 2.4	
USA 2001 Ohio (Ventura) OH12	WG	spray	0.44	1360	2	0 8 14	plant	8.6 4.0 0.78	
USA 2001 Quebec (Calmario) QC01	WG	spray	0.43–0.45	750	2	0 8 15	plant	2.0 0.39 0.23	
USA 2001 Quebec (Calmario) QC02	WG	spray	0.44–0.45	750	2	0 7 14	plant	6.7 1.9 0.68	
USA 2001 Ontario (Florida 683) ON02	WG	spray	0.45	625	2	0 7 14	plant	20 3.5 1.4	
USA 2001 Ontario (Florida 683) ON06	WG	spray	0.45	625	2	0 7 14	plant	13 2.7 1.5	

Hops

In 2001 and 2009 five trials on hops were carried out in representative growing areas in the US using two formulations: UCF (70% boscalid w/w) and F (25.2% boscalid w/w), both WG formulations. Three applications of 0.49 to 0.50 kg ai/ha were made in spray volumes of 470 to 1890 L/ha with an application interval of 10 ± 1 days, beginning 20 days prior to the first cone harvest. In the trials performed in 2001 different water volumes (470–750 L/ha versus 1420–1890 L/ha) were compared. In 2001, hop cones were sampled directly after the last application as well as at crop maturity (BBCH ≥ 89) 7 and 14 days thereafter. In 2009, hop cones were sampled 12–13 days after the last application. The results are summarised in Table 5.

Table 5 Boscalid residues in hops, foliar application

Country, Year *Location* (variety)	Application				PHI days	Sample	Residues, mg/kg	Author, Report, Year, Study No. Reg.DocID.
	Form	kg ai/ha	L water/ha	No				
USA 2001 Washington (Warrior) 2001150	WG "UCF"	0.50	710	3	0 7 14	dried cones	52 25 29	Jordan, 2002, 64550, 2001/5002574
		0.50	1890	3	0 7 14	dried cones	40 16 11	
USA 2001 Idaho (Zeus) 2001151	WG "UCF"	0.50	470	3	0 7 14	dried cones	52 40 31	
		0.50	1420	3	0 7 14	dried cones	49 15 12	
USA 2001	WG	0.50	750	3	0	dried	17	

Country, Year *Location* (variety)	Application				PHI days	Sample	Residues, mg/kg	Author, Report, Year, Study No. Reg.DocID.
	Form	kg ai/ha	L water/ha	No				
Oregon (Liberty) 2001152	"UCF"				7	cones	7.6	
		0.50	1420	3	0 7	dried cones	17 9.9	
USA 2009 Washington (Nugget) 2 replicates	WG "F"	0.49 0.49 0.50	1113 1122 1141	3	13 13	dried cones	13 15	Gooding, 2010, Study No. 08889 2010/7003179
USA 2009 Idaho (Nugget) 2 replicates	WG "F"	0.49 0.50 0.49	926 945 935	3	12	dried cones	18, 28	

FATE OF RESIDUES IN STORAGE AND PROCESSING

In processing

One field trial with oranges was conducted in Florida in 2008, to determine residue levels of boscalid after processing. Boscalid was applied as two foliar spray treatments of 0.34 kg ai/ha per application, beginning 11 days prior to normal harvest with an application interval of 10 days. Commercially mature orange samples (whole fruit) were collected 1 day after the last application (PHI 1 day). One untreated control and duplicated, independently collected, treated bulk-sized orange RAC samples for processing were harvested. The samples were processed according to commercial practices into dried pulp, oil and juice. The results of boscalid residues in RAC and processed fractions of orange are shown in Table 6.

During the 2001 growing season four field trials were conducted in different representative hops growing areas in Germany and The Netherlands to determine the residue level of boscalid in hops and processed fractions thereof. The results of boscalid residues in RAC and processed fractions of hops are shown in Table 6.

Table 6 Summary of residues in processed fractions of oranges and hops

Commodity, Country, year, location	Application			PHI, days	Commodity	Residues, mg/kg	Author, Study no, Doc Id No
	Form	kg ai/ha	No				
Orange, USA, 2008, Florida 2 replicates	WG	0.34	2	1	Fruit Dried pulp Juice Oil	0.22 0.60 < 0.05 14	White and Gooding, 2008, 32457, Doc ID 2008/7005478
	WG	0.34	2	1	Fruit Dried pulp Juice Oil	0.22 0.80 < 0.05 12	
Hops, Germany, 2001	SE	0.5, 0.6, 0.6	3	15	Cones, dry Beer yeast Beer	21 0.24 < 0.05	Schulz, 2001, IF-101/23712-00 Doc ID 2001/1015048
	SE	0.5, 0.6, 0.6	3	15	Cones, dry Beer yeast Beer	20 0.24 < 0.05	
Hops, Netherlands, 2001	SE	0.19, 0.23, 0.23	3	22	Cones, dry Beer yeast Beer	5.9 < 0.05 < 0.05	Schulz, 2001, IF-101/24112-00 Doc Id 2001/1015049
	SE	0.19, 0.23, 0.23	3	21	Cones, dry Beer yeast Beer	6.8 0.06 < 0.05	

The transfer factors reflect commercial processing as outlined below.

Table 7 Summary of processing factors for boscalid residues. The factors are calculated from the data recorded in Tables in this section

Raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors	Mean or best estimate
Orange	Dried pulp	2.7, 3.6	3.2
Orange	Juice	< 0.23, < 0.23	< 0.23
Orange	Oil	55, 63	59
Hops	Yeast	< 0.008, 0.0088, 0.011, 0.012	0.01
Hops	Beer	< 0.0024, < 0.0025, < 0.0074, < 0.0085	< 0.005

APPRAISAL

Boscalid was evaluated for the first time for toxicology and residues by the JMPR in 2006. The 2009 JMPR then derived a number of MRLs following consideration of the residue situation in rotational crops. The compound was listed for additional residue assessment by the 2010 JMPR at the Forty-first Session of the CCPR. At the Forty-second Session of the CCPR, the Committee noted the reservation of the EU regarding the proposed maximum residue level for leafy vegetables in light of their higher MRLs for lamb's lettuce (ALINORM 10/33/24, para 79). GAP information and residue data for citrus fruits, lambs lettuce, celery and hops were submitted by the manufacturer.

Results of supervised trials on crops

The 2009 JMPR evaluated the boscalid residue data according the following principles:

- For a maximum residue level recommendation for boscalid in plant commodities, the addition of probable residues arising from direct treatment in combination with root uptake of boscalid applied in previous years must be taken into account.
- Use of crop groupings for plant food and feed, as established in the Codex Classification System, to give recommendations based on the overall anticipated residue levels of boscalid in these commodities rather than for single commodities.
- That the use of statistical methods, for the estimation of maximum residue levels, is not possible in cases where the potential for carryover residues in following crops exist. All maximum residue levels recommended for boscalid are based on the expertise of the Meeting only.
- The residues arising from direct treatment of permanent (perennial) crops were used for estimation of a maximum residue levels as the uptake of boscalid from the soil is not considered a significant factor.

The current Meeting also applied the above mentioned evaluation principles. New data was submitted for citrus fruits and hops (permanent crops) as well as for lamb's lettuce and celery which are plant commodities grown as potential succeeding crops.

The NAFTA calculator was used as a tool in the estimation of the maximum residue levels for the permanent crops citrus and hops from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the NAFTA calculator was employed. If the value derived from use of the statistical calculation spreadsheet was different from that recommended by the JMPR, a brief explanation of the deviation was provided. Some common factors that may lead to rejection of the statistical estimate include those situations where the number of data points was less than 15 or where there a large number of values are below the LOQ.

Citrus fruits

The registered use of boscalid in citrus fruits in the USA is as foliar spray treatment of 0.28–0.33 kg ai/ha (a maximum of 4 treatments with an application interval of 10–21 days) and a PHI of 0 days.

In six US trials on grapefruit matching GAP, boscalid residues in whole fruit were: 0.10, 0.12, 0.15, 0.15, 0.27 and 0.85 mg/kg. No data were received for the edible portion.

In five US trials on lemon matching GAP, boscalid residues in whole fruit were: 0.59, 0.68, 0.74, 0.94 and 1.5 mg/kg. No data were received for the edible portion.

In 13 US trials on oranges matching GAP, boscalid residues in whole fruit were: 0.23, 0.26, 0.30, 0.32, 0.33, 0.35, 0.47, 0.56, 0.64, 0.68, 0.71, 1.2 and 1.4 mg/kg. The residues in pulp were < 0.05 (6), 0.05, 0.06, 0.06, 0.09, 0.09, 0.12 and 0.20 mg/kg.

Based on the orange residue data, the Meeting estimated a maximum residue level of 2 mg/kg for citrus fruits. On the basis of the residues in orange pulp, the Meeting estimated an STMR of 0.05 mg/kg.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 1.84 mg/kg, which when rounded up, was in agreement with the Meeting's estimation.

Leafy vegetables

The 2009 JMPR evaluated boscalid residue data on mustard greens, head lettuce and leafy lettuce. The residues found following direct treatment were:

- mustard greens: 0.45, 0.54, 0.92, 2.8, 3.1, 6.04, 12.9 and 14.4 mg/kg
- head and leafy lettuce (US GAP): 0.11, 0.74, 0.98, 1.6, 1.63, 1.77, 1.91, 2.53, 2.68, 2.73, 3.18, 4.87, 5.14, 5.42, 9.36 and 9.55 mg/kg
- lettuce (EU GAP, outdoor): < 0.05, 0.09, 0.15, 0.21, 0.33, 0.36, 0.38, 0.39, 0.43, 0.45, 0.50, 0.64, 0.65, 0.73, 0.76, 0.86, 1.19 and 1.58 mg/kg
- lettuce (EU GAP, indoor): 0.37, 0.71, 1.52, 2.31, 2.5, 5.63, 5.96 and 6.11 mg/kg.

The 2009 JMPR concluded that the application of boscalid to mustard greens results in the highest population in leafy vegetables and used the mustard greens data to recommend a maximum residue level and an STMR of 30 mg/kg and 2.95 mg/kg respectively for the crop group.

At the Forty-second Session of CCPR, the Committee noted the reservation of the EU regarding the proposed MRL for leafy vegetables in light of their higher MRLs for lamb's lettuce. The French GAP allows one boscalid treatment of 0.4 kg ai/ha with a PHI of 14 days.

Eight trials on lamb's lettuce (six indoor and two outdoor) in line with the French GAP were submitted. The boscalid residues in ranked order (median underlined) were: 0.26, 0.85, 2.4, 3.2, 4.1, 4.1, 16 and 29 mg/kg.

The Meeting concluded that the application of boscalid to lamb's lettuce (instead of mustard greens) results in the highest residue population in leafy vegetables and should be used to recommend a maximum residue level and an STMR for the crop group.

For leafy vegetables no data from studies on follow crops are available. In field studies on succeeding crops mean, median and highest residues in brassica vegetables were 0.03 mg/kg, 0.035 mg/kg and 0.05 mg/kg, respectively. The 2009 JMPR concluded that the results obtained for brassica vegetables would also be applicable in estimating possible residues of boscalid in leafy vegetables. In line with the decision of the 2009 JMPR, the Meeting concluded that residues due to an additional uptake of boscalid via roots could be considered insignificant, in comparison to residue levels arising from direct foliar treatment.

The Meeting estimated a maximum residue level and an STMR value for boscalid in leafy vegetables of 40 mg/kg and 3.65 mg/kg, respectively. The previous recommendation of 30 mg/kg as maximum residue level was withdrawn.

Stalk and stem vegetables

The US GAP allows the use of boscalid on celery at an application rate of 2 × 0.22–0.44 kg ai/ha with a 0 day PHI.

Residues from twelve US trials, matching the US GAP, (median underlined) were: of 1.9, 2.0, 2.7, 5.6, 6.7, 8.3, 8.6, 9.8, 13, 13, 18 and 20 mg/kg.

For stalk and stem vegetables no data from studies on following crops were available. In field studies on succeeding crops mean, median and highest residues in brassica vegetables were 0.03 mg/kg, 0.035 mg/kg and 0.05 mg/kg, respectively. The Meeting concluded that the results obtained for brassica vegetables would also be applicable in estimating possible residues of boscalid in stalk and stem vegetables. The Meeting concluded that residues due to root uptake of boscalid would be insignificant in comparison to residue levels arising from direct foliar treatment.

As per the decision made by the 2009 JMPR, the Meeting decided to give a crop group recommendation on the basis of celery residue data.

The Meeting estimated a maximum residue level of 30 mg/kg and an STMR of 8.55 mg/kg for stalk and stem vegetables.

Hops

The registered use of boscalid in hops in the USA is as a foliar spray treatment of 3 × 0.026 kg ai/hL (0.49 kg ai/ha) with a PHI of 14 days. Eight US trials were submitted, six matching the US GAP. The residues found, in rank order (median underlined) were: 11, 12, 15, 28, 29 and 31 mg/kg.

The Meeting estimated a maximum residue level and an STMR for boscalid residues in hops, dry of 60 mg/kg and 21.5 mg/kg, respectively.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 58 mg/kg and was in agreement with the Meeting's estimation.

Fate of residues during processing

The Meeting received information on the fate of boscalid residues during the processing of oranges to juice, oil and dried pulp and of hops to beer. The processing factors and the derived STMR-P values are summarised as follows:

RAC	Processed commodity	Calculated processing factors	PF (median or best estimate)	RAC STMR, mg/kg	STMR-P mg/kg
Orange	Dried pulp	2.7, 3.6	3.2	0.47[a]	1.5
	Juice	< 0.23, < 0.23	< 0.23		0.108
	Oil	55, 63	59		27.7
Hops	Beer	< 0.0024, < 0.0025, < 0.0074, < 0.0085	< 0.005	21.5	0.108

[a] RAC STMR and highest residue based on orange, whole fruit

On processing, boscalid was found to concentrate in orange pulp dried and orange oil.

Based on the highest residue of 1.4 mg/kg (whole fruit), an STMR of 0.47 mg/kg (whole fruit) and a processing factor of 3.2, the Meeting estimated a maximum residue level of 6 mg/kg and an STMR-P of 1.5 mg/kg for citrus pulp, dry.

Based on the STMR of 0.47 mg/kg (whole fruit) and a processing factor of 59, the Meeting estimated a maximum residue level of 50 mg/kg and an STMR-P of 27.7 mg/kg for citrus oil.

For orange juice, a STMR-P value of 0.108 mg/kg was estimated.

Residues in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of boscalid in farm animals on the basis of the diets listed in Appendix X of the FAO Manual (OECD Feedstuffs Derived from Field Crops) for feed commodities evaluated by the JMPR in 2009 and 2010 (citrus pulp, dry, only). Calculation from highest residue, STMR (some bulk commodities) and STMR-P values provides the levels in feed suitable for estimating MRLs, while calculation from STMR and STMR-P values for feed is suitable for estimating STMR values for animal commodities. Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are provided in Annex 6 of the 2010 JMPR Report.

	Livestock dietary burden, boscalid, ppm of dry matter diet							
	US/CAN		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	6.6	2.3	17.3	7.1	34.9 [a]	12.1 [b]	1.9	0.85
Dairy cattle	18.9	6.5	16.6	6.5	34.5 [c]	12.0 [d]	2.5	0.94
Poultry - broiler	0.23	0.23	1.01	0.54	0.19	0.19	0.08	0.08
Poultry - layer	0.23	0.23	8.7 [e]	3.04 [f]	0.19	0.19	0.15	0.15

[a] Highest maximum beef or dairy cattle burden suitable for MRL estimates for mammalian meat

[b] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat.

[c] Highest maximum dairy cattle dietary burden suitable for MRL estimates for milk.

[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

[e] Highest maximum poultry dietary burden suitable for MRL estimates for poultry meat and eggs.

[f] Highest mean poultry dietary burden suitable for STMR estimates for poultry meat and eggs.

Animal commodities, maximum residue levels

The dietary burdens for the estimation of maximum residue levels for boscalid in cattle commodities calculated by the 2009 JMPR are 34.0 ppm and for the estimation of STMR values 12.1 ppm for beef or dairy cattle.

The only additional feed item evaluated by the 2010 JMPR was citrus pulp, dry. The maximum and mean dietary burdens for cattle calculated by the 2010 JMPR did not differ from the values calculated in 2009 (maximum 34.9 ppm, mean 12.1 ppm for beef or dairy cattle).

The Meeting noted that a revision of the maximum residue levels and STMRs for animal products, like meat (from mammals other than marine mammals), milk fats, milks and edible offal (mammalian) was not necessary. The previous recommendations were confirmed.

The dietary burdens for the estimation of maximum residue levels and STMR values for boscalid in poultry commodities calculated by the 2009 JMPR were 8.4 ppm and 2.82 ppm, respectively. The 2009 Meeting estimated maximum residue levels and STMRs of 0.02 mg/kg for poultry meat, fat and edible offal as well as for eggs on the basis of a metabolism study on laying hens with a dose rate of 12.5 ppm.

The maximum and mean dietary burdens for cattle calculated by the 2010 JMPR did not differ from the values calculated in 2009 (maximum 8.7 ppm, mean 3.04 ppm for poultry).

The Meeting noted that a revision of the maximum residue levels and STMRs for animal products, like poultry meat, fat and edible offal as well as for eggs was not necessary. The previous recommendations were confirmed.

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 IEDI assessment.

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

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

The residue is fat soluble.

CCN	Commodity	MRL, mg/kg		STMR or STMR-P, mg/kg
		New	Previous	
FC 0001	Citrus fruits	2		0.05
AB 0001	Citrus pulp, dry	6		1.5
DH 1100	Hops, dry	60		21.5
VL 0053	Leafy vegetables	40	30	3.65
	Orange juice			0.108
VS 0078	Stalk and stem vegetables	30		8.55
	Citrus oil	50		27.7

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of boscalid resulted in recommendations for MRLs and STMR values for raw and processed commodities. Where data on consumption were available for the listed food commodities, dietary intakes were calculated for the 13 GEMS/Food Consumption Cluster Diets. The results are shown in Annex 3 of the 2010 JMPR Report.

The IEDIs in the thirteen Cluster Diets, based on the estimated STMRs were 10–40% of the maximum ADI of 0.04 mg/kg bw. The Meeting concluded that the long-term intake of residues of boscalid from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

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

REFERENCES

Author	Year	Title	Code
Abdel-Baky, S and Jones, J	2001	BASF analytical method no. 9908. Method for determination of BAS 500F, BF 500-3 and BAS 510 F residues in plant matrices using LC/MS/MS. Unpublished.	BASF Doc ID 2001/5001019
Anonymous	2010	Report of the 42nd Session of the Codex Committee on Pesticide Residues (paragraph 79). Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission. Xian, China 19–24 April 2010.	ALINORM 10/33/24

Author	Year	Title	Code
Funk, H and Mackenroth, C	2001	BASF analytical method no. 445/0. Validation of method 445/0: Determination of BAS 510 F in plant matrices. Unpublished.	BASF Doc ID 2000/1012404
Gooding, RF	2010	Boscalid and Pyraclostrobin: Magnitude of the residue on hops (PR# 08889). BASF Agro Research RTP; Research Triangle Park, NC 27709; USA, BASF Study No. 08889. Unpublished	BASF Doc ID 2010/7003179
Hong, C	2003	BAS 516 (BAS 510F plus BAS 500F): Magnitude of the residue on celery. Center for Minor Crop Pest Management, North Brunswick, USA. IR-4 PR No. 08091. Unpublished.	BASF Doc ID 2003/5000655
Jordan, JM	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; USA, BASF Study Code 64550. Unpublished.	BASF Doc ID 2001/5002574
Jordan, JM	2002	Magnitude of BAS 50002 F and BAS 51002 F residues in citrus. BASF Agro Research RTP; Research Triangle Park, NC 27709; USA, BASF Study Code 64978. Unpublished.	BASF Doc ID 2002/5002446
Mackenroth, C and Lehmann, A	2007	BASF analytical method no. 531/1. Validation of method 531/1: Determination of BAS 510 F in plant matrices. Unpublished.	BASF Doc ID 2006/1039427
Perny, A	2006	Study on the residue behaviour of boscalid and pyraclostrobin in lamb's lettuce after treatment with BAS 516 00 F under field or glasshouse conditions in Northern and Southern France, 2005 and 2006. BASF Study Code 230422. Unpublished.	BASF Doc ID 2006/1024416
Perny, A	2007	Study on the residue behaviour of boscalid and pyraclostrobin in lamb's lettuce after treatment with BAS 516 00 F under field conditions in Northern and Southern France, 2006. BASF Study Code 230428. Unpublished.	BASF Doc ID 2007/1006114
Schulz, H	2001	Determination of the residues of BAS 510 F and BAS 500 F in hops and processed products following treatment with BAS 516 01 F under field conditions in Germany 2001, IF-101/23712-00. Unpublished.	BASF Doc ID 2001/1015048
Schulz, H	2001	Determination of the residues of BAS 510 F and BAS 500 F in hops and processed products following treatment with BAS 516 01 F under field conditions in The Netherlands, IF-101/24112-00. Unpublished.	BASF Doc ID 2001/1015049
White, MT and Gooding, RF	2008	Magnitude of boscalid residues in citrus processed fractions following applications of BAS 510 04 F BASF Agro Research RTP; Research Triangle Park, NC 27709; USA. BASF Study Code 32457. Unpublished	BASF Doc ID 2008/7005478