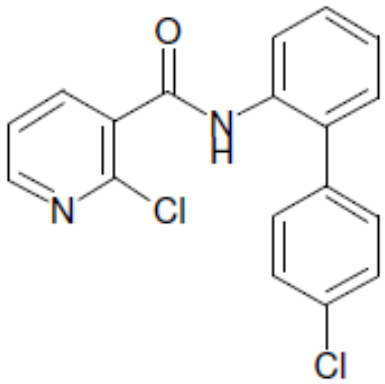
5.3 BOSCALID (221)

RESIDUE AND ANALYTICAL ASPECTS

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

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



The following abbreviations are used for the metabolites discussed below:

boscalid	2-chloro-N-(4'-chlorobiphenyl-2-yl)nicotinamide
M510F01	2-chloro-N-(4'-chloro-5-hydroxybiphenyl-2-yl)nicotinamide
M510F02	4'-chloro-6-{[(2-chloro-3-pyridinyl)carbonyl]amino}biphenyl-3-yl glycopyranosiduronic acid

Environmental fate in soil

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

The aerobic soil metabolism of boscalid is very limited. Most of the radioactivity used in the studies was either recovered as unchanged parent substance, $^{14}CO_2$, or remained as unextracted radioactivity. Metabolites were found, but their levels were less than 1% of the applied doses. Estimated half-life times under assumption of first order kinetics ranged from 133 to 384 days.

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

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

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

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

In a confined rotational crop study in Germany, soil was treated directly with [^{14}C]boscalid labelled in the diphenyl ring or the pyridine ring. Lettuce, radish and wheat were sown into the treated soil at intervals of 30, 120, 270 and 365 days after treatment, grown to maturity, and harvested for analysis. The residues in the edible parts of succeeding crops destined for human consumption were low for lettuce and radish root, and slightly higher for wheat grain after all four plant-back intervals. The major part of the residues was identified as parent. The concentration of boscalid in lettuce leaf ranged from 55.6–94.1% TRR, in radish leaf from 69.4–90.2% TRR, in radish root from 52.6–92.8% TRR and in wheat straw from 50.0–87.5% TRR. In wheat grain the concentration of parent was lower (1.9–35.4% TRR, < 0.028 mg/kg).

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

Group	Commodity	No. of trials	Mean in mg/kg	Median in mg/kg	Highest residue in mg/kg
Root and tuber vegetables	Radish roots	4	0.08	0.065	0.17
	Sugar beet roots	7	0.05	0.05	0.05
	Garden beet roots	2	0.05	0.05	0.05
	Turnip roots	5	0.05	0.05	0.05
	Potatoes	4	0.06	0.055	0.06
	Carrot roots	4	0.13	0.065	0.37
	TOTAL	26	0.07	0.05	0.37
Brassica vegetables	Cabbage	4	0.03	0.035	0.05
Fruiting vegetables	Sweet corn cobs	4	0.05	0.05	0.05
Pulses and oilseeds	Alfalfa seeds	1	0.05	0.05	0.05
	Soya bean seeds	15	0.05	0.05	0.06
	Cotton seed	9	0.05	0.05	0.05
	TOTAL	25	0.05	0.05	0.06

Group	Commodity	No. of trials	Mean in mg/kg	Median in mg/kg	Highest residue in mg/kg
Cereal grains	Maize grain	9	0.05	0.05	0.05
	Rice grain	6	0.06	0.05	0.12
	Sorghum grain	6	0.05	0.05	0.05
	Wheat grain	9	0.05	0.05	0.07
	TOTAL	30	0.05	0.05	0.12
Legume animal feeds	Soya bean forage	15	0.08	0.065	0.18
	Soybean hay	13	0.15	0.105	0.45
	Alfalfa forage	17	0.11	0.05	0.49
	Alfalfa hay	17	0.29	0.1	1.46
	Clover forage	7	0.15	0.01	0.53
	Clover hay	7	0.24	0.22	0.48
	Pea vines	9	0.05	0.05	0.05
	Pea hay	9	0.09	0.09	0.15
	Cow pea forage	9	0.24	0.05	1.0
	Cow pea hay	9	0.34	0.24	0.99
	TOTAL	112	0.17	0.08	1.46
Straw and fodder of cereal grains	Wheat Forage	11	0.45	0.29	1.1
	Wheat hay	11	0.50	0.265	1.5
	Wheat straw	11	1.1	0.81	2.8
	Maize forage	12	0.06	0.05	0.13
	Maize stover	13	0.12	0.06	0.49
	Rice straw	6	0.30	0.13	1.1
	Sorghum forage	6	0.08	0.05	0.23
	Sorghum stover	6	0.09	0.05	0.30
	Grass forage	12	0.46	0.25	1.9
	Grass hay	12	1.5	0.61	6.8
	Grass straw	2	0.18	0.175	0.2
	TOTAL	102	0.5	0.21	6.8
Root leaves and tops	Radish tops	4	0.26	0.14	0.77
	Sugar beet tops	7	0.05	0.05	0.05
	Garden beet tops	2	0.05	0.05	0.05
	Turnip tops	5	0.05	0.05	0.07
	Carrot tops	4	0.23	0.03	0.84
	TOTAL	22	0.12	0.05	0.84

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

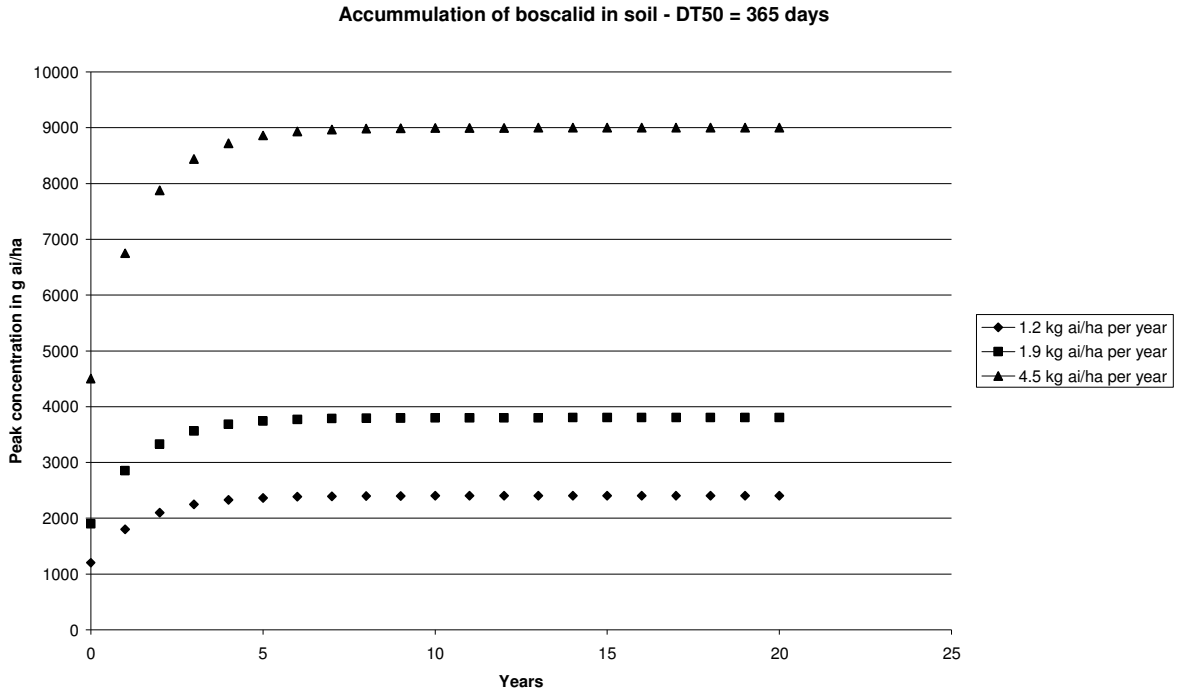
Estimation of boscalid residues in soil

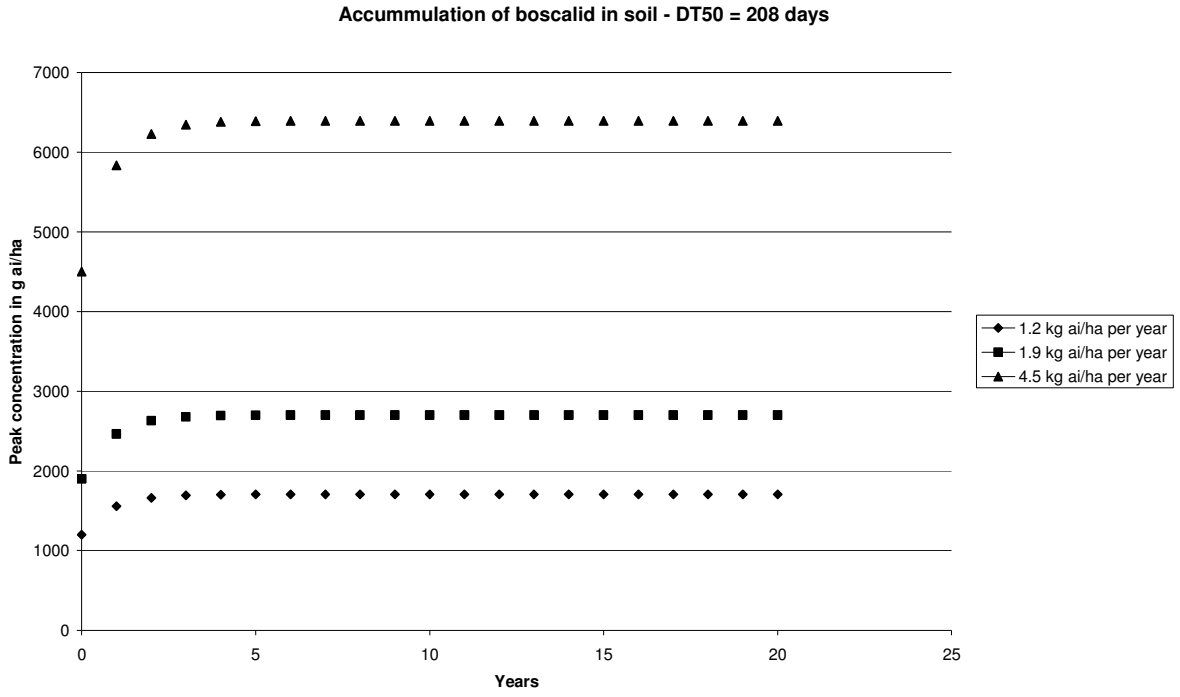
Boscalid is used in a broad variety of crops at various annual application rates. For the estimation of the highest boscalid levels in soil relevant for the evaluation of residues in follow crops, it must be assumed that boscalid is applied for several consecutive years due to the broad use pattern.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

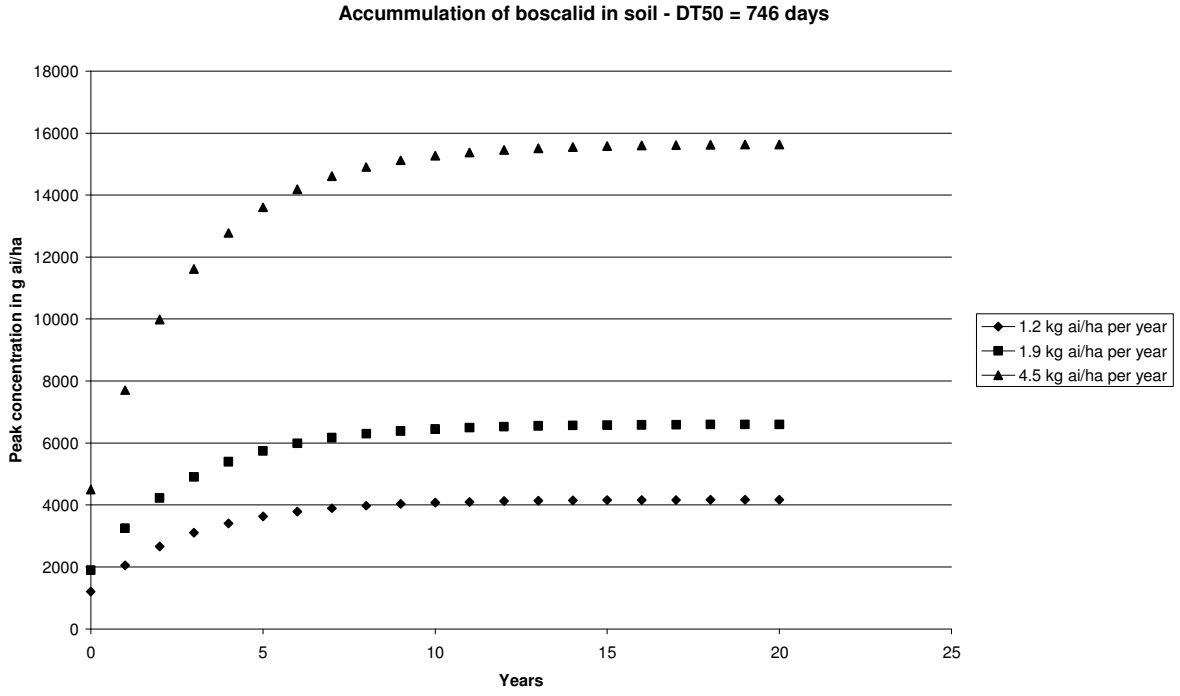
Annual application rates of boscalid on non-permanent crops are normally in the magnitude of 0.9 to 1.2 kg ai/ha per year (see GAP list in JMPR Evaluation 2006). The only uses involving higher application rates are reported from the US for bulb vegetables with 1.9 kg ai /ha per year (6 × 0.32 kg ai/ha)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

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

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







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

Under the assumption of a DT_{50} value of 1 year (365 days) mainly found in aerobic soil metabolism and dissipation studies on soil treated for the first time plateau levels equivalent to an

application rate to bare soil were estimated at 2.4 kg ai/ha for a treatment rate of 1.2 kg ai/ha per year, 3.8 kg ai/ha for 1.9 kg ai/ha per year and 9 kg/ha for 4.5 kg ai/ha per year.

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

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

Application rate	Assumed DT_{50} value in days	Predicted plateau level equivalent to an application to bare soil	Adjusted plateau level equivalent to an application to bare soil available for uptake from aged soil (factor 0.5)
1.2 kg ai/ha per year	208	1.7 kg ai/ha	0.85 kg ai/ha
	365	2.4 kg ai/ha	1.2 kg ai/ha
	746	4.1 kg ai/ha	2.05 kg ai/ha
1.9 kg ai/ha per year	208	2.7 kg ai/ha	1.35 kg ai/ha
	365	3.8 kg ai/ha	1.9 kg ai/ha
	746	6.6 kg ai/ha	3.3 kg ai/ha
4.5 kg ai/ha per year	208	6.4 kg ai/ha	3.2 kg ai/ha
	365	9 kg ai/ha	4.5 kg ai/ha
	746	15.6 kg ai/ha	7.8 kg ai/ha

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

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

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

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

Definition of the residue

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

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

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

The residue is fat soluble.

[a] Metabolite code: M510F01

Estimation of residues in plant commodities grown as potential succeeding crops

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

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

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

Apples

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

Stone fruit

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

Berries and other small fruits

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

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

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

For strawberries supervised field trials according to GAP were available, but no recommendation could be given due to the outstanding evaluation of the uptake through the soil. In

2006 the Meeting identified the following residues of boscalid in strawberries: 0.15, 0.19, 0.20, 0.23, 0.27 (2), 0.28, 0.31, 0.34, 0.35, 0.38, 0.41, 0.42, 0.45, 0.46 (2), 0.47, 0.49, 0.55, 0.57, 0.68 (2), 0.69, 0.89, 1.74 and 1.87 mg/kg.

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

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

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

Bananas

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

Kiwifruit

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

Bulb vegetables

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

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

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

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

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

In field studies on succeeding crops data for root and tuber vegetables are available indicating mean, median and highest residues of 0.07 mg/kg, 0.05 mg/kg and 0.37 mg/kg, respectively in the roots, and 0.12 mg/kg, 0.05 mg/kg and 0.84 mg/kg respectively in the tops of the plants. In

view of these residue levels the Meeting decided that in comparison to the STMR value of 2.2 mg/kg for bulb vegetables (based on the use on green onions) the impact on the overall residue levels due to an additional uptake from soil is insignificant for the estimation of the dietary intake.

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

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

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

Brassica vegetables

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Leafy vegetables

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

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

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

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

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

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

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

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

Legume vegetables

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

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

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

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

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

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

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

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

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

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

Meeting concluded that the STMR value of 0.5 mg/kg for boscalid in green beans with pods may be used directly for the estimation of the dietary intake of the whole group.

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

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

Pulses

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

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

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

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

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

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

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

Root and tuber vegetables

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

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

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

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

In all field studies on succeeding crops mean, median and highest residues in root and tuber vegetables were 0.07 mg/kg, 0.05 mg/kg and 0.37 mg/kg, respectively. For carrot roots residues found were slightly higher with mean, median and highest residues of 0.13 mg/kg, 0.065 mg/kg and 0.37 mg/kg, respectively. The Meeting concluded that residues in carrots are the representative

commodity for all root and tuber vegetables and may be influenced significantly by an additional uptake of boscalid from the soil. It was decided to add the mean residue found in field studies on succeeding crops of 0.13 mg/kg to the median residue obtained from supervised field trials on carrot roots of 0.175 mg/kg for an overall STMR for boscalid in carrot roots of 0.305 mg/kg.

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

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

Barley, oats, rye and wheat grain

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

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

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

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

In all field studies on succeeding crops mean, median and highest residues in wheat grain were 0.05 mg/kg, 0.05 mg/kg and 0.07 mg/kg, respectively. The Meeting concluded that residues in barley and wheat grain may be influenced significantly by an additional uptake of boscalid from soil. It was decided to add the mean residue found in field studies on succeeding crops of 0.05 mg/kg to the median residue obtained from supervised field trials of 0.025 mg/kg for an overall STMR for boscalid in barley and wheat grain of 0.075 mg/kg.

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

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

Cereal grain except barley, oats, rye and wheat

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

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

Tree nuts

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

Oilseeds

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

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

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

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

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

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

Coffee

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

Animal feedstuffs

Almond hulls

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

Straw and fodder of barley, oats, rye and wheat

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

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

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

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

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

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

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

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

Although boscalid is not used for treatment of further cereal straw and fodder plants (except barley, oats, rye and wheat), these crops may still be subject to crop rotation and therefore contain boscalid residues after uptake via the roots. The Meeting decided to use the mean, median and maximum residues found in wheat straw in field studies on succeeding crops of 1.1 mg/kg, 0.81 mg/kg and 2.8 mg/kg (fresh-weight) respectively for an estimation of STMR and maximum residue values in straw and fodder of cereal grain, except barley, oats, rye and wheat.

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

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

Legume animal feeds

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

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

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

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

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

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

Fate of residues during processing

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

Raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors	Median or best estimate
Apples	Fresh juice	0.05, 0.06, 0.08(2), < 0.09, < 0.10	0.08
	Wet pomace	2.08, 3.90, 5.73, 6.38, 6.77, 8.26	6.06
Plums	Prunes	0.52, 2.42, 2.80, 3.15, 3.66	2.8
Grapes	Raisins	2.42	2.42
	Wet pomace	1.95, 2.40, 2.60, 3.41	2.5
	Wine	0.09, 0.34, 0.36, 0.47	0.35
	Juice	0.42	0.42
Tomato	Canned juice	0.09, 0.13, 0.16, 0.27	0.15
	Puree	0.19, 0.24(2), 0.73	0.24
	Paste	0.53, 0.63, 0.82, 2.24	0.73
Soya bean	Hulls	1.74	1.74
	Meal	< 0.16	0.16
	Refined oil	0.42	0.42
Barley	Pot barley	0.22, 0.29, 0.37(2)	0.33
	Beer	0.01, 0.02, 0.02, 0.02	0.02
Wheat	Wholemeal flour	1.10, 1.14, 1.29, 1.82	1.22
	Flour type 550	0.22, 0.23, 0.45, 0.47	0.34
	Wheat bran	3.29, 3.87, 4.64, 5.44	4.26
	Wheat germs	0.97, 1.29, 1.36, 1.58	1.33

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

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

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

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

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

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

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

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

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

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

Residues in animal commodities

Livestock dietary burden

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

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

Lactating Holstein cows were dosed with boscalid at the equivalent of 1.5 (1×), 4.5 (3×) and 18 (12×) ppm in the dry-weight diet for 28 consecutive days. Milk was collected twice daily for analysis. Animals were sacrificed within 23 hours after the final dosing, except for one cow of the 12× group which was sacrificed seven days after the final dose to determine residue levels post dosing.

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

Separation of milk and cream indicated that residues are only detectable in cream (0.03 mg/kg, 0.11 mg/kg and 0.32 mg/kg for 1×, 3× and 10× samples, respectively) while most of the

results in skim milk were below the LOQ of 0.01 mg/kg. In all cream samples only boscalid parent was found.

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

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

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

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

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

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

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

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

Estimated maximum and mean dietary burdens of livestock

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

	Livestock dietary burden, boscalid, ppm of dry matter diet					
	US-Canada		EU		Australia	
	max.	mean	max.	mean	max.	mean
Beef cattle	28.4	9.3	25.8	9.3	34.0[a]	12.1[b]
Dairy cattle	27.0	8.8	27.1	9.5	33.4	12.0
Poultry - broiler	0.13	0.14	0.82	0.41	0.13	0.13

	Livestock dietary burden, boscalid, ppm of dry matter diet					
	US-Canada		EU		Australia	
	max.	mean	max.	mean	max.	mean
Poultry - layer	0.11	0.12	8.4[c]	2.82[d]	0.13	0.13

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

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

[c] Highest maximum broiler or laying hens burden suitable for MRL estimates for poultry meat and eggs

[d] Highest mean broiler or laying hens burden suitable for STMR estimates for poultry meat and eggs

Animal commodities, MRL estimation

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

Dietary burden (ppm) Feeding level [ppm]	Milk	Cream	Muscle	Liver	Kidney	Fat
MRL	mean	mean	highest	highest	highest	highest
MRL beef or dairy cattle [a] (34.0) [18]	0.055 [0.029]	0.62 [0.33]	0.062 [0.033]	0.15 [0.08]	0.083 [0.044]	0.51 [0.27]
STMR	mean	mean	mean	mean	mean	mean
STMR beef or dairy cattle [b] (12.1) [4.5, 18]	0.033 [0.02, 0.05]	0.32 [0.12, 0.34]	0.035 [< 0.05, 0.053]	0.12 [0.057, 0.177]	0.16 [0.074, 0.236]	0.18 [0.105, 0.268]

[a] based on boscalid

[b] based on sum of boscalid and M510F01

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

Under consideration of an average fat content in cream of 40–60% resulting in a factor of 2 the Meeting estimated a maximum residue level for boscalid (parent only) in whole milk and milk fat of 0.1 mg/kg and 2 mg/kg respectively. On the fat basis, the Meeting estimated maximum residue levels for meat (fat) from mammals (other than marine mammals) of 0.7 mg/kg. For edible offal (mammalian) the maximum residue level was estimated at 0.2 mg/kg based on liver.

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

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

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

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.

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

Short-term intake

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