

5.3 BOSCALID (221)

RESIDUE AND ANALYTICAL ASPECTS

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 summarized 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.

| | 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.

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 Cluster Diets, based on the estimated STMRs were 10–40% of the maximum ADI of 0.04 mg/kg bw (Annex 3). 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.

