

5.4 BUPROFEZIN (173)

RESIDUE AND ANALYTICAL ASPECTS

Buprofezin, (an insecticide), was evaluated by JMPR in 1991 for the first time and then in 1995 and 1999. It was reviewed under the Periodic Re-evaluation Programme of CCPR in 2008 for toxicity and residues. The 2008 JMPR allocated an ADI of 0–0.009 mg/kg bw and ARfD of 0.5 mg/kg bw. It concluded that the residue definition for compliance with the MRL and for estimation of dietary intake, both for animal and plant commodities should be buprofezin, and recommended eight maximum residue levels while withdrawing one previous recommendation.

The current Meeting received information on use patterns and trials concerning pome fruits, stone fruits, berry fruits, tropical fruits, cucurbits, fruiting vegetables other than cucurbits, beans, olives, tree nuts and coffee. The Meeting also received information on some storage stability studies additional to those submitted to the 2008 JMPR.

Stability of pesticide residues in stored analytical samples

The Meeting received storage stability studies conducted in 2006 on banana, potato, wheat, almond, grape, orange, and some of their processed products.

Buprofezin, which is the only component of the definition of residue, was generally stable when stored at $-20 \pm 5^\circ \text{C}$ for the longest interval tested for each matrix. Among those crops for which supervised residue trials were conducted and submitted to the current Meeting, buprofezin was stable up to 881 days in almond nutmeat, 78 days in almond hulls, 368 days in grapes and 374 days in dried grapes.

Results of supervised residue trials on crops

The Meeting received supervised residue trial data for buprofezin on apple, pear, peach, plum, cherry, grapes, strawberry, olive, lychee, avocado, guava, papaya, cucumber, cantaloupe, summer squash, tomato, peppers, common bean (pods and/or immature seeds), almond nutmeat and hulls, and coffee. The trials in the USA were conducted outdoors.

The NAFTA calculator was used as a tool in the estimation of the maximum residue level 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 statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was supplied. Some common factors that may lead to rejection of the statistical estimate include when the number of data points in a data set is < 15 or when there are a large number of values $< \text{LOQ}$.

Pome fruits

Supervised trials were conducted on apples in the USA with one application of 1.67–1.71 kg ai/ha in one trial with an exaggerated rate of 3.38 kg ai/ha. The residues of buprofezin from supervised trials in compliance with the maximum US GAP for apple (1.69 kg ai/ha \times 1, PHI 14 days) were in rank order: 0.02, 0.05, 0.11, 0.15, 0.18, 0.24, 0.32, 0.55, 0.58, 0.75, 0.85 and 0.99 mg/kg (n=12).

The Meeting estimated a maximum residue level of 3 mg/kg, a STMR of 0.28 mg/kg and a HR of 0.99 mg/kg for apples.

The value derived from use of the NAFTA calculator was 3.0 mg/kg (UCLMedian95th), which was in agreement with the maximum residue level of 3 mg estimated by the current Meeting.

Supervised trials were conducted on pears including oriental pears in the USA with two applications at 1.70–2.02 kg ai/ha. The residues of buprofezin from trials in accordance with the maximum US GAP for pears (2.26 kg ai/ha × 2, not more than 3.37 kg ai/ha per growing season, PHI 14 days) were: 0.40, 0.60, 0.86, 1.09, 1.11, 1.31 and 3.64 mg/kg (n=7).

The Meeting estimated a maximum residue level of 6 mg/kg, STMR of 1.09 mg/kg and HR of 3.64 mg/kg for pears.

The value derived from use of the NAFTA calculator was 6.0 mg/kg (95/99 Rule), which was in agreement with the maximum residue level of 6 mg by estimated by the present Meeting.

Stone fruits

Supervised trials were conducted on peaches, plums and cherries in the USA with two applications at 1.70–1.87 kg ai/ha except two trials on peaches.

In the two trials on peaches, one in California and the other in New Jersey, application was made three times and four times. However, since the last application contributes most to the residues of buprofezin in harvested fruits, the Meeting agreed to use the results of these trials despite more applications being made than specified in GAP. In the trial with three applications, the rate of the last application was not sufficiently high and lower than that of all other trials, but duplicate samples showed the high residues of 5.58 and 8.13 mg/kg.

The residues of buprofezin in peaches from trials in accordance with the maximum US GAP for stone fruits (2.26 kg ai/ha × 2, not more than 3.37 kg ai/ha per growing season, PHI 14 days) and the two other trials were: 0.12, 0.40, 0.45, 0.84, 0.89, 1.31, 1.40, 1.77, 2.20, 2.36, 3.11 and 8.13 mg/kg (n=12).

The residues of buprofezin in plums from trials in accordance with the maximum US GAP for stone fruits were: 0.05, 0.08, 0.08, 0.23, 0.26 and 0.55 mg/kg (n=6).

The residues of buprofezin in cherries, both sweet and tart, from trials in accordance with the maximum US GAP for stone fruits were: 0.31, 0.45, 0.46, 0.54, 0.57, 0.89, 1.00, 1.01, 1.20 and 1.32 mg/kg (n=10).

Two trials were conducted on cherries in Italy but no GAP information was available for Southern Europe.

Since the residue populations of peaches, plums and cherries were significantly different (Kruskal-Wallis test), the Meeting agreed to estimate maximum residue levels separately for these commodities.

The Meeting estimated a maximum residue level, STMR and HR of 9, 1.355 and 8.13 mg/kg respectively for peaches. The Meeting agreed to extrapolate this maximum residue level for peaches to nectarines.

The value derived from use of the NAFTA calculator was 9.0 mg/kg (UCLMedian95th) which was in agreement with the maximum residue level estimated by the current Meeting.

The Meeting estimated a maximum residue level, STMR and HR of 2, 0.155 and 0.55 mg/kg respectively, for plums.

The value derived from use of the NAFTA calculator was 1.3 mg/kg (95/99 Rule and UCLMedian 95th). With the maximum application rate in the trials about 25% less than that specified in GAP, the Meeting agreed there was a need for a higher maximum residue level and with rounding up the value obtained from the calculator was in agreement with the estimate of the current Meeting.

The Meeting estimated a maximum residue level, STMR and HR of 3, 0.73 and 1.32 mg/kg respectively for cherries.

The value derived from use of the NAFTA calculator was 2.5 mg/kg (95/99 Rule). With the maximum application rate in the trials about 25% less than that specified in GAP, the Meeting agreed there was a need for a higher maximum residue level. Rounding up the value obtained from use of the calculator results in 3 mg/kg which was in agreement with the maximum residue level estimated by the current Meeting.

Berries and other small fruits

Supervised trials were conducted on grapes in the USA with two applications at 0.52–0.56 kg ai/ha. The residues of buprofezin from trials in accordance with the maximum US GAP for grapes (0.59 kg ai/ha × 2, PHI 7 days) were: 0.04, 0.05, 0.09, 0.13, 0.14, 0.14, 0.17, 0.18, 0.28, 0.38, 0.39, 0.55 and 0.74 mg/kg (n=13). The Meeting estimated a maximum residue level, STMR and HR at 1, 0.17 and 0.74 mg/kg respectively for grapes.

The value derived from use of the NAFTA calculator was 1.1 mg/kg (UCLMedian95th) which was comparable to the 1 mg/kg estimate of the current Meeting.

Supervised trials on strawberries were conducted in the USA with two applications at a rate of 0.38–0.40 kg ai/ha. The residues of buprofezin from trials in accordance with the maximum US GAP for low-growing berries (0.38 kg ai/ha × 2, 10 days apart, PHI 3 days) were: 0.09, 0.15, 0.39, 0.44, 0.55, 0.85 and 1.24 mg/kg (n=7). The Meeting estimated a maximum residue level, STMR and HR at 3, 0.44 and 1.24 mg/kg respectively for strawberries.

The value derived from use of the NAFTA calculator was 3.5 mg/kg (95/99 Rule, UCLMedian95th). However, based on experience of previously evaluated residue data on strawberries for a range of pesticides the Meeting agreed that a value of 3 mg/kg was sufficiently high to cover residues arising from the use of buprofezin.

Assorted tropical and sub-tropical fruit-edible peel

Supervised trials were conducted on olives in the USA with two applications at 2.37–2.44 kg ai/ha. One trial was conducted at an exaggerated rate in order to investigate effect of processing on residues. The residues of buprofezin from trials in accordance with the maximum US GAP for olives (2.26 kg ai/ha × 2, PHI 21 days) were: 0.56, 1.10, 1.15 and 1.66 mg/kg (n=4).

The Meeting estimated a maximum residue level, STMR and HR at 5, 1.125 and 1.66 mg/kg respectively.

The value derived from use of the NAFTA calculator was 3.0 mg/kg (95/99 Rule). The number of trials is smaller than 5. To accommodate the likely variation of residues a higher maximum residue level was estimated.

Assorted tropical and sub-tropical fruit-inedible peel

Supervised trials were conducted on lychees in the USA with two applications at 1.72–1.78 kg ai/ha. The residues of buprofezin from trials, in accordance with the maximum US GAP for lychees (1.69 kg ai/ha × 2, PHI 21 days) were: 0.26 mg/kg. The Meeting concluded that data were insufficient to recommend a maximum residue level.

Supervised trials were conducted on avocados in the USA with two applications at 1.70–1.91 kg ai/ha. The residues of buprofezin from trials, in accordance with the maximum US GAP for avocados (1.69 kg ai/ha × 2, PHI 21 days) were: 0.23 mg/kg. The Meeting concluded that the data were insufficient to recommend a maximum residue level for avocados.

Supervised trials were conducted on guavas in the USA with two applications at 1.77 kg ai/ha. No trial matched the maximum US GAP for guava (1.69 kg ai/ha × 2, PHI 21 days). The Meeting concluded that data were insufficient to recommend a maximum residue level.

Supervised trials were conducted on papaya in the USA with five applications at 0.42–0.47 kg ai/ha. As only one trial (residues: 0.62 mg/kg) matched the US GAP, the Meeting concluded that data were insufficient to recommend a maximum residue level.

Fruiting vegetables, Cucurbits

The Meeting received information on supervised trials conducted on cucumber, cantaloupe and summer squash in the USA with two applications at 0.39–0.47 kg ai/ha, except that in one trial the rate of the last application was 0.71 kg ai/ha. The GAP in the USA for cucurbits requires the maximum application rate of 0.43 kg ai/ha, maximum of four applications with the minimum of a 7 day interval, and PHI of 7 days except in California where PHI is 10 days for crops other than cucumber.

In most trials, the interval between applications was five days—shorter than the minimum interval of seven days specified in GAP. The 2008 JMPR reviewed the same US trial data on cucumber as those provided to the current Meeting and regarded them not in compliance with US GAP. Nonetheless, the current Meeting decided to use the results of those trials with 5 day intervals between applications for estimating a maximum residue level as, for the fast growing fruits, 5 day intervals were acceptable.

Supervised trials were conducted on cucumbers, (both cucumbers for consuming fresh and for pickling), in the USA with four applications at 0.43 kg ai/ha. The residues of buprofezin from trials on cucumbers for consuming fresh in accordance with the maximum US GAP for cucurbits were: 0.01, 0.03, 0.04, 0.08 and 0.20 mg/kg. The residues of buprofezin from trials on cucumbers for pickling in accordance with the maximum US GAP for cucurbits were: 0.02, 0.02, 0.03, 0.03, 0.03, 0.03, 0.05, 0.09, 0.09 and 0.30 mg/kg (n=10). The residue populations from trials on cucumbers for consuming fresh and for pickling were not significantly different (Mann-Whitney U-test).

Supervised trials were conducted on cantaloupes in the USA with four applications at 0.41–0.46 kg ai/ha. The residues of buprofezin from trials in accordance with the maximum US GAP for cucurbits were: 0.15, 0.16, 0.18, 0.19, 0.19, 0.20, 0.21, 0.33, 0.37 and 0.41 mg/kg (n=10).

Supervised trials were conducted on summer squash in the USA with four applications at 0.41–0.47 kg ai/ha. The residues of buprofezin from trials in accordance with the maximum US GAP for cucurbits were: 0.02, 0.03, 0.03, 0.04, 0.04, 0.04, 0.05, 0.05, 0.05 and 0.11 mg/kg (n=10).

The Meeting estimated a maximum residue level, STMR and HR for cucurbits, on a basis of trials on cantaloupe which led to higher residues, to be 0.7, 0.195 and 0.41 mg/kg. The Meeting withdrew the previously recommended maximum residue level of 0.2 mg/kg for cucumbers.

The value derived from use of the NAFTA calculator was 0.60 mg/kg (95/99 Rule). However, in order to cover all crops in the group of Fruiting vegetables, Cucurbits, the Meeting agreed a higher maximum residue level was necessary.

Fruiting vegetables, other than Cucurbits

The Meeting received information on supervised trials conducted on tomatoes and peppers in the USA with two applications at 0.41–0.47 kg ai/ha. The GAP in the USA for fruiting vegetables other than cucurbits requires a maximum application rate of 0.43 kg ai/ha, with a maximum of two applications and PHI of 1 day.

Supervised trials were conducted on tomatoes in the USA with two applications at 0.41–0.47 kg ai/ha with the application interval of 24–30 days (GAP: minimum of 5 days). No trial matched the maximum US GAP. The Meeting, therefore, did not revise the previous recommendation of 1 mg/kg for tomatoes.

Supervised trials were conducted on peppers in the USA with two applications at 0.42–0.45 kg ai/ha. The residues of buprofezin in bell peppers from trials in accordance with the maximum

US GAP for fruiting vegetables other than cucurbits were: 0.12, 0.16, 0.19, 0.31, 0.33, 0.34, 0.52 and 0.96 mg/kg. The residues of buprofezin in non-bell peppers from trials in accordance with the maximum US GAP for fruiting vegetables other than cucurbits were: 0.17, 0.54 and 1.1 mg/kg. The residue populations from trials on bell pepper and non-bell pepper were not significantly different (Mann-Whitney U-test); the Meeting decided to merge these results for the estimation of a maximum residue level. Combined residues were in rank order: 0.12, 0.16, 0.17, 0.19, 0.31, 0.33, 0.34, 0.52, 0.54, 0.96 and 1.1 mg/kg (n=11).

The Meeting estimated a maximum residue level for peppers to be 2 mg/kg.

The Meeting estimated an STMR and HR of 0.33 and 1.1 mg/kg respectively for peppers.

The value derived from use of the NAFTA calculator was 1.9 mg/kg (95/99 Rule). The common practice of JMPR is to use one significant figure for maximum residue levels below 10 mg/kg. Rounding up of the value to one significant figure resulted in 2 mg/kg which was in agreement with the recommendation of the present Meeting.

Legume vegetables

Supervised trials were conducted on common beans (pods and immature seeds) in the USA with two applications at 0.42–0.44 kg ai/ha. The residues of buprofezin from trials, in accordance with the maximum US GAP for snap beans (0.43 kg ai/ha × 2, PHI 14 days) were: < 0.02 mg/kg (3). The Meeting concluded that the data was insufficient to recommend a maximum residue level.

Tree nuts

Supervised trials were conducted on almonds in the USA with one application at 2.24 kg ai/ha. The residues of buprofezin in nutmeat from trials in accordance with the maximum US GAP for almond (2.26 kg ai/ha × 1, PHI 60 days) were: < 0.05 mg/kg (6).

The Meeting estimated a maximum residue level, STMR and HR of 0.05(*), 0.05 and 0.05 mg/kg respectively for almonds.

As the residues from all the trials matching GAP were below the LOQs, the NAFTA calculator was not used.

Coffee

Supervised trials were conducted on coffee in Hawaii in the USA with four applications at 1.12–1.23 kg ai/ha. The residues of buprofezin in green coffee beans from trials, in accordance with the maximum US GAP for coffee (1.12 kg ai/ha × 4, PHI 0 day) were: 0.10, 0.12, 0.16 and 0.24 mg/kg. The Meeting concluded that data were insufficient to recommend a maximum residue level.

Almond hulls

The residues of buprofezin in hulls from trials, in accordance with the maximum US GAP for almonds (2.26 kg ai/ha × 1, PHI 60 days) were: 0.07, 0.09, 0.15, 0.23, 0.25, 0.55 and 1.76 mg/kg (n=7).

The Meeting estimated a maximum residue level, STMR and highest residue of 2, 0.23 and 1.76 mg/kg respectively, for almond hulls.

The value derived from use of the NAFTA calculator was 1.7 mg/kg (UCLMedian95th). The common practice of JMPR is to use one significant figure for maximum residue levels below 10 mg/kg. Rounding up the NAFTA calculator derived value to one significant figure results in 2 mg/kg, which was in agreement with the recommendation of the Meeting.

Fate of residues during processing

The Meeting received information on the fate of incurred residues of buprofezin in apples, plums, cherries, olives and coffee under simulated processing conditions.

Processing factors were calculated for apple (juice and wet pomace), plums (prunes), cherries (juice and jam), grapes, olives (olive oil) and coffee (roasted coffee and freeze-dried coffee) and are shown in the table below. STMR-Ps were calculated for commodities for which maximum residue levels were estimated by the current Meeting using the respective STMR and processing factor and are shown in the following table together with processing factors.

Processing factors and STMR-Ps for apples, plums, cherries, grapes, olives and their processed commodities.

Commodity	Median or best estimate of processing factor	STMR/ STMR-P, mg/kg
Apple		0.28
Apple juice	0.57	0.16
Apple wet pomace	2.0	0.56
Plums		0.155
Prunes	3.0	0.465
Cherries		0.73
Cherry juice	< 0.17	0.12
Cherry jam	< 0.17	0.12
Grape		0.17
Grape juice (pasteurized)	0.58	0.098
White wine	0.88	0.15
Red wine	0.60	0.10
Dried grapes	2.2	0.37

Apple pomace (wet), prunes, dried grapes and olive oil are expected to contain higher residues than the respective raw agricultural commodities.

Multiplying the STMR of apple found in the supervised trials by the processing factor of 2.0 and adjusting for a dry weight basis, resulted in an STMR-P estimate of 1.4 mg/kg for apple pomace (dry basis). Since the recommended maximum residue level for apple was 3 mg/kg, no maximum residue level was necessary for apple pomace.

Multiplying the HR of plums found in the supervised trials (0.55 mg/kg) by the processing factor of 3.0 resulted in an HR estimate of 1.65 mg/kg for prunes. Since the recommended maximum residue level for plums was 2 mg/kg, no maximum residue level was necessary for prunes.

Multiplying the HR of grapes found in the supervised trials (0.74 mg/kg) by the processing factor of 2.2 resulted in an HR estimate of 1.63 mg/kg for dried grapes. The Meeting estimated a maximum residue level of 2 mg/kg for dried grapes.

Since the calculated STMR-P for olive oil was 3.49 mg/kg and the recommended maximum residue level for olives was 5 mg/kg, the residues of buprofezin in olive oil is covered by the maximum residue level for olives.

On the basis of the STMR and HR for peppers and the default dehydration factor of 7, an STMR and HR for chilli peppers (dry) were calculated to be 2.31 and 7.7 mg/kg, respectively. Based on the HR, the Meeting recommended a maximum residue level for chilli peppers (dry) at 10 mg/kg.

Residues of animal commodities

The Meeting estimated the dietary burden of buprofezin residues in farm animals from the diets listed in Annex 6 of the 2006 JMPR Report. Among commodities reviewed by the 2008 and current JMPR, almond hulls (STMR-P, 0.24 mg/kg), apple pomace (wet) (STMR-P, 0.56 mg/kg) and citrus pulp, dry

(STMR-P, 1.2 mg/kg) can be fed to beef and dairy cattle. Poultry dietary burdens, through exposure to treated feed items were evaluated by the 2008 JMPR or the current Meeting.

The 2008 JMPR estimated a maximum and mean dietary burden of 0.40 ppm of dry matter diet for beef and dairy cattle in Australia. The current Meeting re-calculated animal dietary burden using almond hulls, apple wet pomace and citrus pulp, dry as shown in the table below.

Summary of livestock dietary burdens (ppm of dry matter diet)

	US-Canada		EU		Australia	
	max	mean	max	mean	max	mean
Beef cattle	0.28	0.28	0.28	0.28	0.40 ^a	0.40 ^a
Dairy cattle	0.14	0.14	0.26	0.26	0.40 ^b	0.40 ^b

^a Suitable for estimating maximum residue levels and STMRs for meat and edible offal.

^b Suitable for estimating a maximum residue level and STMRs for milk.

Since the maximum and mean animal dietary burdens calculated by the current Meeting were the same as those by the 2008 JMPR, the Meeting confirmed the maximum residue levels recommended by the 2008 JMPR for meat (from mammals other than marine mammals, edible offal (mammalian) and milks at 0.05(*), 0.05(*) and 0.01(*) mg/kg respectively. It also confirmed that STMRs and HRs for these commodities were 0 mg/kg.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of buprofezin were calculated for the 13 GEMS/Food Consumption Cluster Diets using STMRs and STMRPs estimated by the 2008 and current Meeting (Annex 3). The ADI is 0–0.009 mg/kg bw and the calculated IEDIs were 1–50% of the maximum ADI. The Meeting concluded that the long-term intake of residues of buprofezin resulting from the uses considered by the current JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-Term Intakes (IESTI) of buprofezin were calculated for food commodities and their processed commodities using HRs/HR-Ps or STMRs/STMR-Ps estimated by the current Meeting (see Annex 4). The ARfD is 0.5 mg/kg and the calculated IESTIs were 0–30% of the ARfD for the general population and 0–50% of the ARfD for children. The Meeting concluded that the short-term intake of residues of buprofezin, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

