

## 5.16 METRAFENONE (278)

### RESIDUE AND ANALYTICAL ASPECTS

Metrafenone, a benzophenone fungicide, was evaluated for the first time by the 2014 JMPR, where an ADI of 0–0.3 mg/kg bw was established, an ARfD was not considered necessary and a residue definition of *metrafenone* (parent only) was established for plant and animal commodities, for both compliance with MRLs and for dietary intake assessment.

It was scheduled by the 47<sup>th</sup> Session of the CCPR for the evaluation of additional uses by the 2016 JMPR and the Meeting received new GAP and residue information on pome fruit, stone fruit and hops from the manufacturer.

New GAP information on grapes and fruiting vegetables was also provided by the manufacturer, together with an ambient temperature metrafenone residue stability study in homogenised melons.

#### *Methods of analysis*

The 2014 JMPR reviewed and summarised analytical method descriptions and validation data for metrafenone in crop and animal matrices. These included The QuEChERS 1 method and Method 535/3 used to measure metrafenone in the new supervised residue trials. Method validation data for pome fruit, stone fruit and hops were provided to the Meeting. LOQs for all matrices were 0.01 mg/kg.

#### *Stability of pesticide residues in stored analytical samples*

##### *Plant matrices–fresh analytical sub-samples*

The Meeting received an ambient storage residue stability study on melons where homogenised samples were spiked with 0.1 mg/kg metrafenone and stored at 19 °C±1 °C for up to 16 hours before analysis for metrafenone. Residues were stable (more than 79% residues remaining) for up to 16 hours at room temperature.

The Meeting concluded that if samples from supervised residue field trials were sub-sampled (quartered or sliced) in the field, and frozen within 16 hours of sampling, the results from those trials were suitable for estimating maximum residue levels.

##### *Plant matrices–stored analytical samples*

The 2014 JMPR concluded that metrafenone residues were stable for up to 24 months in analytical frozen samples of a range of representative substrates (at least 31 months in high starch and high water content matrices). In general, residues in the stored samples were greater than 80% of the spiked levels. Frozen sample storage times in the new trials were within the storage intervals considered acceptable by the 2014 JMPR

#### *Results of supervised residue trials on crops*

The Meeting received new supervised trial data for foliar applications of metrafenone on pome fruit, stone fruit and hops. Trials on grapes and fruiting vegetables evaluated by the 2014 JMPR were re-assessed in light of new GAP information provided to the Meeting.

The results from these new trials and those previously reported by the 2014 JMPR and matching critical GAP were used to estimate maximum residue levels, STMRs and HRs for a number of commodities for which GAP information was available.

#### *Pome fruit*

Results from supervised trials on apples and pears conducted in USA were provided to the Meeting.

The critical GAP for metrafenone on pome fruit in Canada and USA is for up to 3 foliar applications of 0.336 kg ai/ha applied at least 7–14 days apart with a PHI of 7 days, applying a total of 1.01 kg ai/ha/season.

In 11 independent trials on apples in USA matching this GAP, residues were: 0.08, 0.2, 0.22, 0.22, 0.22, 0.23, 0.31, 0.45, 0.49, 0.54 and 0.76 mg/kg.

In six independent trials on pears in USA matching this GAP, residues were: 0.14, 0.16, 0.19, 0.39, 0.41 and 0.48 mg/kg.

The Meeting noted that the data sets for apples and pears were not statistically different (Mann-Whitney) and agreed to combine the data sets for apples and pears to estimate a pome fruit group maximum residue level.

The combined data set for metrafenone residues in apples and pears from trials matching the GAP for pome fruit in Canada and USA is: 0.08, 0.14, 0.16, 0.19, 0.2, 0.22, 0.22, 0.22, 0.23, 0.31, 0.39, 0.41, 0.45, 0.48, 0.49, 0.54 and 0.76 mg/kg.

The Meeting estimated an STMR of 0.23 mg/kg and a group maximum residue level of 1 mg/kg for metrafenone on pome fruit.

#### *Stone fruit*

Results from supervised trials on cherries and peaches conducted in USA were provided to the Meeting.

##### *Cherries*

The critical GAP for metrafenone on cherries in Canada and USA is for up to 2 foliar applications of 0.336 kg ai/ha applied at least 7–14 days apart with a PHI of 7 days, applying a total of 0.67 kg ai/ha/season.

In 12 independent trials in USA matching this GAP, residues in cherries (without stones) were: 0.32, 0.37, 0.39, 0.43, 0.44, 0.49, 0.55, 0.6, 0.65, 0.7, 0.97 and 1.2 mg/kg.

The Meeting noted that the GAP in USA and Canada covered the Codex Cherries sub-group and based on the data for cherries (without stones), estimated an STMR for metrafenone of 0.52 mg/kg for cherries (sub-group).

The Meeting also noted that cherry stones do not contribute significantly to the total fruit weight and agreed to use the above data set to estimate a maximum residue level of 2 mg/kg for metrafenone for cherries (sub-group).

##### *Peaches (including Nectarine and Apricots)*

The critical GAP for metrafenone on peaches (including nectarines) in Canada and USA is for up to 2 foliar applications of 0.336 kg ai/ha applied at least 7–14 days apart with a PHI of 7 days, applying a total of 0.67 kg ai/ha/season.

In 14 independent trials on peaches in USA matching this GAP, residues in peaches (without stones) were: 0.05, 0.14, 0.17, 0.19, 0.2, 0.21, 0.21, 0.21, 0.22, 0.23, 0.25, 0.28, 0.29 and 0.49 mg/kg.

The Meeting noted that the GAP in USA for apricots was the same as for peaches, and thus covered the Codex Peaches sub-group (i.e. including apricots) and estimated an STMR for metrafenone of 0.21 mg/kg for peaches sub-group.

The Meeting also noted that peach (and nectarine) stones do not contribute significantly to the total fruit weight and agreed to use the above data set to estimate a maximum residue level of 0.7 mg/kg for metrafenone for peaches (sub-group).

#### *Small fruit vine climbing*

##### *Grapes*

The Meeting received new GAP information for grapes in USA, up to 3 foliar applications of 0.336 kg ai/ha, 14–21 day retreatment interval and a PHI of 14 days.

In eight independent trials from the USA, evaluated by the 2014 JMPR and matching the new USA GAP, residues in grapes were: 0.22, 0.34, 0.35, 0.45, 0.46, 0.47, 0.48 and 1.0 mg/kg.

Noting that the 2014 JMPR had estimated an STMR of 0.76 mg/kg and a maximum residue level of 5 mg/kg for metrafenone on grapes based on data matching the Canadian GAP (up to 6 foliar applications of 0.225 kg ai/ha, PHI 14 days), the Meeting agreed that the new GAP in USA would be accommodated by the existing STMR and maximum residue level.

#### *Fruiting vegetables, Cucurbits*

The Meeting received new GAP information for cucurbits in Canada and USA, up to 3 foliar applications of 0.336 kg ai/ha, 7–14 day retreatment interval and a PHI of 0 days.

##### *Cucumber*

The Meeting agreed to review the data on cucumbers provided to the 2014 JMPR in light of the new GAP for fruiting vegetables, cucurbits in Canada and USA.

In six independent trials from USA on cucumbers matching the new GAP in Canada and USA, residues were: 0.05, 0.08, 0.1, 0.1, 0.14 and 0.16 mg/kg.

##### *Squash, Summer*

The Meeting agreed to review the data on summer squash provided to the 2014 JMPR in light of the new GAP for fruiting vegetables, cucurbits in Canada and USA.

In 14 independent trials from North America on summer squash matching this new GAP, residues in summer squash were: 0.07, 0.1, 0.1, 0.11, 0.11, 0.12, 0.13, 0.13, 0.14, 0.17, 0.22, 0.28, 0.29 and 0.31 mg/kg.

##### *Melons (except watermelon)*

The Meeting noted that the 2014 JMPR had reviewed the data from melon trials but was unable to estimate a maximum residue level because the melon samples had been quartered in the field and no information was available on residue stability in chopped or sliced samples.

Based on new information showing that metrafenone residues were stable for up to 16 hours in homogenised samples at room temperatures, the Meeting reviewed the data on melons provided to the 2014 JMPR in light of the new critical GAP in Canada and USA.

In 12 independent trials on melons (cantaloupes) in North America matching the new GAP in Canada and USA, residues were: 0.04, 0.08, 0.09, 0.13, 0.13, 0.13, 0.15, 0.18, 0.18, 0.21, 0.23 and 0.28 mg/kg.

The Meeting noted that the GAP in Canada and USA was for the cucurbit group, that median residues in cucumber, summer squash and melons were within a 5-fold range (0.1 – 0.14 mg/kg) and that the data sets were not from different populations (Kruskal-Wallis). The Meeting therefore agreed to combine these data sets to recommend a group maximum residue level for fruiting vegetables, cucurbits.

Residues in cucumber, summer squash and melons from trials matching the GAP in Canada and USA for fruiting vegetables, cucurbits were: 0.04, 0.05, 0.07, 0.08, 0.08, 0.09, 0.1 (4), 0.11, 0.12, 0.13 (5), 0.14, 0.14, 0.15, 0.16, 0.17, 0.18, 0.18, 0.21, 0.22, 0.23, 0.28, 0.28, 0.29 and 0.31 mg/kg.

The Meeting estimated an STMR of 0.13 mg/kg and a group maximum residue level of 0.5 mg/kg for metrafenone on fruiting vegetables, cucurbits and to withdraw the previous recommendations for cucumber, summer squash and gherkin.

#### *Fruiting vegetables, other than Cucurbits*

The Meeting received new GAP information for fruiting vegetables (other than cucurbits) in Canada and USA, up to 3 foliar applications of 0.336 kg ai/ha, 7–14 day retreatment interval and a PHI of 0 days.

#### *Peppers*

In nine independent trials from USA on peppers matching this new GAP, residues were: 0.08, 0.15, 0.25, 0.27, 0.35, 0.4, 0.41, 0.43 and 0.5 mg/kg.

The Meeting noted that the 2014 JMPR had estimated STMRs of 0.115 mg/kg and maximum residue levels of 2.0 mg/kg for metrafenone on sweet pepper and on Chili pepper based on glasshouse sweet pepper trials conducted in Europe matching the GAP in France (up to 2 foliar applications of 0.15 kg ai/ha, PHI 3 days).

The Meeting agreed that the new GAP in Canada and USA would be accommodated by the existing maximum residue level but that since the STMR from the USA trials was higher than that estimated by the 2014 JMPR, the Meeting agreed to use the 0.35 mg/kg STMR from the trials matching the USA GAP for dietary intake estimation for peppers, sweet and peppers, Chili.

#### *Tomato*

The Meeting agreed to review the data on tomatoes provided to the 2014 JMPR in light of the new GAP in Canada and USA.

In 19 independent trials from North America on tomatoes matching this new GAP, residues were: 0.08, 0.09, 0.09, 0.1 (3), 0.11 (3), 0.17, 0.18, 0.2, 0.22, 0.23, 0.25, 0.26, 0.29, and 0.43 mg/kg.

The Meeting estimated an STMR of 0.11 mg/kg and a maximum residue level of 0.6 mg/kg for metrafenone on tomato to replace the previous recommendation and noting that the GAP in Canada and USA included use on eggplants, agreed to extrapolate the above estimations to eggplants.

#### *Dried herbs*

Results from supervised trials on hops conducted in Europe and North America were provided to the Meeting.

*Hops*

The GAP for metrafenone on hops in USA is for up to 2 foliar applications of 0.336 kg ai/ha with a PHI of 3 days. In trials in North America matching this GAP, metrafenone residues in dried hop cones were: 13, 17, 21 and 24 mg/kg. In trials conducted in Europe and matching the GAP in USA, residues were 13, 20, 21, 23, 33 and 34 mg/kg.

Since the European and North American data sets were not from different populations (Mann-Whitney), the Meeting agreed to use the global data set approach and combined these data sets to recommend a maximum residue level for hops, dry.

Residues from trials in North America and Europe matching the USA GAP for hops were: 13, 13, 17, 20, 21, 21, 23, 24, 33 and 34 mg/kg

The Meeting estimated an STMR of 21 mg/kg and a maximum residue level of 70 mg/kg for metrafenone on hops, dry.

***Fate of residues during processing***

Processing studies on apples, tomatoes and hops were among those reviewed by the 2014 JMPR and the processing factors estimated by that Meeting for the commodities considered at this Meeting are summarised below.

Summary of selected processing factors and STMR-P values for metrafenone

RAC	Matrix	Processing Factors <sup>a</sup>	STMR (mg/kg)	STMR-P (mg/kg)
Apple	fruit		0.23	
	canned	0.12		0.028
	juice	0.21		0.048
	wet pomace	1.2		0.28
	dried slices	0.56		0.13
	sauce	4.45		1.0
Tomato	fresh		0.11	
	preserved	< 0.02		< 0.002
	juice (raw)	0.34		0.037
	wet pomace	5.5		0.61
	paste	0.385		0.042
	puree	0.81		0.089
Hops	dried cones		21	
	extracted hops	1.8		38
	brewers yeast	0.01		0.21
	beer	< 0.0005		< 0.01

<sup>a</sup> Each PF value is the median of 2–4 separate studies where residues were above the LOQ in the RAC. The PF in each study was the ratio of the metrafenone residues in the processed item divided by the residues in the RAC.

The Meeting noted that in the above studies, metrafenone residues did not concentrate in food commodities during processing except in tomato sauce and wet tomato pomace and apple pomace.

For dried chili peppers, applying the default processing factor of 10 to the STMR and the maximum residue level estimated for peppers, the Meeting estimated an STMR of 3.1 mg/kg and a maximum residue level of 20 mg/kg for metrafenone on peppers Chili, dried.

### ***Residues in animal commodities***

#### ***Farm animal dietary burden***

The Meeting noted that the 2014 JMPR had calculated beef and dairy cattle maximum dietary burdens of 9.3 ppm (dw) and mean dietary burdens of 4.9 ppm (dw) for beef and dairy cattle based on the Australian livestock diet listed in Appendix IX of the FAO Manual.

Noting that the addition of wet apple pomace would not significantly change the estimated livestock dietary burdens (wet apple pomace not being a component of the Australian beef and dairy cattle livestock diet), the Meeting agreed that the maximum and mean livestock dietary burdens for beef and dairy cattle calculated by the 2014 JMPR did not need to be recalculated.

The Meeting also agreed that the maximum dietary burdens (2.0 ppm dw) and the mean dietary burdens (1.3 ppm dw) for poultry, calculated by the 2014 JMPR did not need to be recalculated as none of the feed items from the commodities considered by the Meeting contributed to any of the poultry diets.

## **RECOMMENDATIONS**

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI assessment.

Definition of the residue (for compliance with the MRL and for dietary risk assessment) for plant and animal commodities: *metrafenone*

*The residue is fat soluble.*

## **DIETARY RISK ASSESSMENT**

### ***Long-term dietary exposure***

The International Estimated Daily Intake (IEDI) for metrafenone was calculated for the food commodities for which STMRs or HRs were estimated and for which consumption data were available. The results are shown in Annex 3.

The International Estimated Daily Intakes of metrafenone for the 17 GEMS/Food cluster diets, based on estimated STMRs were 0–1% of the maximum ADI of 0.3 mg/kg bw (Annex 3). The Meeting concluded that the long-term dietary exposure to residues of metrafenone, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

### ***Short-term dietary exposure***

The 2014 JMPR decided that an ARfD was unnecessary. The Meeting therefore concluded that the short-term exposure to metrafenone residues is unlikely to present a public health concern.