5.29 PROPICONAZOLE (160)

RESIDUE AND ANALYTICAL ASPECTS

Propiconazole was last evaluated by the JMPR in 2015 for residues. The JMPR established an ADI of 0–0.07 mg/kg bw and an ARfD of 0.3 mg/kg bw for propiconazole in 2004. The residue is defined for plant and animal commodities as propiconazole for compliance with the MRL and propiconazole plus all metabolites convertible to 2,4-dichlorobenzoic acid, expressed as propiconazole for the estimation of the dietary intakes.

This compound was scheduled at the 48th Session of the CCPR (2016) for the evaluation of additional MRLs at the 2017 JMPR. The Meeting received residue information on citrus fruits, stone fruits and pineapple following post-harvest treatment from the manufacturer. India provided pre-harvest trial information on tea.

Methods of analysis

Analysis of parent propiconazole in citrus fruits, stone fruits and pineapple was performed using method REM 130.11 and method Meth-180 (REM 130.11, modified), which were considered valid by the 2007 JMPR. These methods were fully validated for analysis of propiconazole in citrus fruits, stone fruits and pineapple samples (LOQ, 0.01 mg/kg).

Total residues, convertible to 2,4-DCBA, in stone fruits and pineapple, were analysed based on method AG-626 with the modification: determination of 2,4-DCBA by LC-MS/MS. The modified method used was fully validated for analysis of total residues in stone fruits and pineapple samples (LOQ, 0.05 mg/kg as parent equivalents). For citrus fruit trials, total residues were not analysed.

In tea trials only the parent compound was analysed in dry black tea. The three methods used involved extraction with different organic solvents or by QuEChERS, and determination by GC-ECD, HPLC-DAD or LC-MS/MS (LOQ, 0.05 mg/kg). The parent compound in tea brew was analysed by partitioning with organic solvent and determination by GC-ECD. Recoveries of parent in the analysis of dry black tea and tea brew were satisfactory.

Stability of residues in stored analytical samples

New storage stability data on pineapple fruit, juice and process residues demonstrated that the total residues were stable for at least 760 days, 734 days and 741 days, respectively when stored at -20 °C. Based on information previously submitted to the JMPR (parent and total residues), and the new information (total residues in pineapple matrices), the stability of the parent and total residues in the residue trial and processing samples (except one trial sample of tart cherry) was demonstrated for the period of frozen storage. In one trial sample of tart cherry, the integrity of parent was not assured as the storage period (849 days) was not covered by the verified period (189 days).

Results of supervised residue trials on crops

Residue trials for post-harvest treatments on citrus fruits, stone fruits and pineapple and pre-harvest treatment on tea were provided. In stone fruits and pineapple trials, both parent and total residues were analysed. In citrus fruit trials, only the parent compound was analysed. The total residues were estimated using a conversion factor of 1.2, which was based on the ratios of parent and total residue values in stone fruit trials provided for evaluation by this Meeting. In tea trials, only the parent compound was analysed.

Citrus fruits

Propiconazole is registered for post-harvest treatment on citrus fruits in the USA. The USA critical GAP is for two applications at a rate of 52.7 g ai/100 L by dip/drench. Residue trials from the USA, matching the GAP, were submitted. The previously submitted residue information on citrus fruits that was evaluated by the 2013 JMPR was also considered.

Residue values of parent in whole orange were (n=8): 2.2 (old), 2.3, 2.5 (old), 2.5, 3.4 (old), 3.6, 3.7 (old) and 3.7 mg/kg. Total residues (measured parent×1.2) in orange pulp were (n=4): 0.11, 0.16, 0.17 and 0.35 mg/kg.

Residue values of parent in whole mandarin were (n=4): 3.1, 3.6, 4.8, and 5.9 mg/kg. Total residues (measured parent×1.2) in mandarin pulp were (n=4): 0.070, 0.19, 0.34 and 0.38 mg/kg.

Residue values of parent in whole lemon were (n=4): 3.1, 3.2, 5.6 and 6.6 mg/kg. Total residues (measured parent×1.2) in lemon pulp were (n=4): 0.20, 0.23, 0.36 and 0.43 mg/kg.

Residue values of parent in whole grapefruit were (n=4): 1.6, 1.6, 2.2, and 2.3 mg/kg. Total residues (measured parent×1.2) in grapefruit pulp were (n=4); 0.07, 0.080, 0.13 and 0.16 mg/kg.

The residue distributions among the citrus fruits were considered similar by Kruskal-Wallis test, except for grapefruit. Therefore, the Meeting decided to combine the residue values for orange, mandarin and lemon.

The combined data set for parent in whole orange, mandarin and lemon was (n=16): 2.2 (old), 2.3, 2.5 (old), 2.5, 3.1, 3.1, 3.2, 3.4 (old), 3.6, 3.6, 3.7 (old), 3.7, 4.8, 5.6, 5.9 and 6.6 mg/kg.

The combined data set for total residues (measured parent×1.2) in whole orange, mandarin and lemon was (n=16): 2.6, 2.8, 3.0, 3.0, 3.7, 3.7, 3.8, 4.1, 4.3, 4.3, 4.4, 4.5, 5.7, 6.8, 7.1 and 8.0 mg/kg

The combined data set for total residues (measured parent×1.2) in pulp of orange, mandarin and lemon was (n=12); 0.070, 0.11, 0.16, 0.17, 0.19, 0.20, 0.23, 0.34, 0.35, 0.36, 0.38, 0.43 mg/kg.

The Meeting estimated a maximum residue level of 15 mg/kg (Po), an STMR of 0.22 mg/kg and an HR of 0.43 mg/kg for orange (Subgroup), mandarin (Subgroup) and lemon (Subgroup) based on a post-harvest treatment thus replacing its previous recommendation of 9 mg/kg (Po) for oranges.

The Meeting estimated a maximum residue level of 6 mg/kg (Po), an STMR of 0.11 mg/kg and an HR of 0.16 mg/kg for pummelo and grapefruits (Subgroup) based on a post-harvest treatment.

Stone fruits

Propiconazole is registered for post-harvest treatment on stone fruits in the USA. The USA critical GAP on cherry and nectarine is a single application at a rate of 12.9 g ai/100 L by in-line dip/drench method. Residue trials on cherry and nectarine conducted in the USA matching the GAP were submitted. The previously submitted residue information on cherry evaluated by the 2013 JMPR was also considered.

Residue values of parent in cherry were (n=5): 0.67 (old), 0.73, 0.85 (old), 1.3 and 1.4 mg/kg. The total residues in cherry were (n=5): 0.77, 0.80 (old), 1.0 (old), 1.6 and 1.8 mg/kg.

Residue values of parent in nectarine were (n=2): 0.77 and 0.82 mg/kg. The total residues in nectarine were (n=2): 0.60 and 0.94 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg (Po), an STMR of 1.0 mg/kg and an HR of 1.8 mg/kg for cherries (Subgroup) with post-harvest treatment. The Meeting did not estimate a maximum residue level for nectarine as the number of trials was not sufficient.

The USA critical GAP on peach and plum is a single application at a rate of 0.54 g ai/1000 kg by in-line aqueous or fruit coating spray method. Residue trials on peach and plum conducted in the USA, matching the GAP, were submitted. The previously submitted residue information on peach and plum evaluated by the 2013 JMPR was also considered.

Residue values of parent in peach were (n=3): 0.44, 0.49 (old) and 0.50 (old) mg/kg. The total residues in peach were (n=3): 0.58, 0.59 and 0.60 mg/kg.

The Meeting replaces its previous recommendations with a maximum residue level of 1.5 mg/kg (Po), an STMR of 0.59 mg/kg and an HR of 0.60 mg/kg for peach.

Residue values of parent in plum were (n=5): 0.06, 0.12, 0.12, 0.16 (old), and 0.19 (old) mg/kg. The total residues in plum were (n=5): 0.09, 0.14, 0.15, 0.19 (old) and 0.23 (old) mg/kg.

The Meeting replaces its previous recommendations with a maximum residue level of 0.5 mg/kg (Po), an STMR of 0.15 mg/kg and an HR of 0.23 mg/kg for plums (Subgroup).

Pineapples

Propiconazole is registered for post-harvest treatment on pineapple in the USA. Pineapple is allowed to be treated at rates of 25.8 g ai/100 L, once by drench and once by directed peduncle spray. Residue trials from the USA matching the GAP were submitted.

Residue values of parent in whole pineapple were (n=4): 0.92, 0.97, 1.1 and 1.2 mg/kg.

Total residues of propiconazole in whole pineapple were (n=4): 1.1, 1.1, 1.5 and 1.6 mg/kg.

The Meeting estimated a maximum residue level of 4 mg/kg (Po) for pineapples, an STMR of 0.16 (1.3×P*f*, < 0.12) mg/kg and an HR of 0.19 (1.6×P*f*, < 0.16) mg/kg for pineapple flesh.

Tea, black (pre-harvest treatment)

Propiconazole is registered for foliar use on tea in India at a rate of 1 x 0.1 kg ai/ha with a 7-day PHI. Residue trials from India matching the GAP were submitted.

Residue values of parent in dry black tea were 0.42, 0.64, 1.7 and 3.0 mg/kg.

The Meeting did not estimate a maximum residue level for black tea as the number of trials was not sufficient.

Fate of residues in storage and processing

One separate processing study on pineapple was received. Total residues of propiconazole in pineapple following post-harvest treatment were 0.43 mg/kg in fruit without crown, < 0.05 mg/kg in pulp, < 0.05 mg/kg in juice and 0.67 mg/kg in process residue. Processing factors and STMR-P values were estimated below. For orange, processing factors for juice, dried pulp and oil were estimated by the 2013 JMPR. Based on a processing factor for orange oil, the Meeting estimated a maximum residue level of 2800 mg/kg for citrus oil (15 mg/kg, multiplied by P*f*, 185).

RAC	Product	Pf	RAC, STMR	STMR-P	RAC, HR	HR-P
Orange	Whole fruit		4.2		8.0	
	Juice	< 0.011		0.046		
	Oil	185		777		
	Dried pulp	1.4		5.9		
Pineapple	Whole fruit		1.3		1.6	
	Flesh (raw edible)	< 0.12		0.16		0.19
	Juice	< 0.12		0.16		
	Wet pomace (moisture of 76.25%)	1.6		2.1		

Residue value of parent propiconazole in dry black tea and tea brew was 1.7 mg/kg and 0.22 mg/kg of dry black tea, respectively. The Meeting did not estimate a processing factor for tea brew as the total residue values were not available.

Residues in animal commodities

It is unlikely that post-harvest treated product (dried orange pulp, pineapple process residue) would to be fed to livestock and reference is made to the 2013 JMPR consideration. Therefore, this Meeting did not make new recommendations for animal commodities.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for use in dietary exposure assessment.

For compliance with MRLs for plant and animal commodities: *propiconazole*

For estimation of dietary intake for plant and animal commodities: *propiconazole plus all metabolites convertible to 2,4-dichlorobenzoic acid, expressed as propiconazole*

The residue is fat soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The 2004 JMPR established an ADI of 0–0.07 mg/kg bw for propiconazole. The International Estimated Daily Intakes (IEDIs) of propiconazole were calculated for the 17 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the current and previous Meeting. The results are shown in Annex 3 in the 2017 JMPR Report.

The calculated IEDIs represented 0–6% of the maximum ADI. The Meeting concluded that the long-term dietary exposure to residues of propiconazole from the uses considered by the JMPR is unlikely to present a public health concern.

Short-term dietary exposure

The 2004 JMPR established an ARfD of 0.3 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) of propiconazole were calculated for the food commodity using an HR estimated by the current Meeting. The results are shown in Annex 4 in the 2017 JMPR Report.

The IESTIs represented 0–6% of the ARfD for general population and 0–10% of the ARfD for children. The Meeting concluded that the short-term dietary exposure to propiconazole resulting from uses considered by the current Meeting is unlikely to present a public health concern.