

5.18 TEBUCONAZOLE (189)

RESIDUE AND ANALYTICAL ASPECTS

Tebuconazole is a triazole fungicide in the DMI (demethylation inhibitor) class. Tebuconazole was first evaluated by JMPR in 1994 (T, R). The latest residue evaluation was conducted in 2017 (R).

The 2010 JMPR review of tebuconazole reaffirmed an ADI of 0–0.03 mg/kg bw and established an ARfD of 0.3 mg/kg bw. The residue definition for compliance with the MRL and for estimation of dietary exposure for plant and animal commodities is parent tebuconazole. The residue is not fat soluble.

It was scheduled at the Fiftieth Session of the CCPR for the evaluation of additional uses by the 2019 Extra JMPR. The Meeting received additional residue studies to support the additional uses in citrus fruits.

Methods of analysis

One new analytical method (HW-002-P09-01) was submitted that was used in the processing studies and is considered suitable for the determination of tebuconazole residues in orange fruits, dried pulp, oil and juice. The method is based on a simple extraction with 3:1 v/v acetone:water followed by determination with LC-MS/MS. The LOQ of the method is set at 0.01 mg/kg.

Stability of residues in stored analytical samples

Storage stability studies were not provided to the current Meeting. The 2011 Meeting concluded that residues of tebuconazole are stable in high-acid commodities for at least 30 months in frozen storage. Samples considered by the current meeting were stored for up to 273 days (ca. 9 months).

Results of supervised residue trials on crops

In Spain, tebuconazole is registered for post-harvest use on citrus fruits as a drench spray with a concentration of 0.1 kg ai/hL; no withholding period is specified. Four trials each for mandarins and oranges were conducted approximating the Spanish GAP. For post-harvest treatment the variability is expected to be significantly less than that of field trials thus four trials can be considered sufficient.

Mandarins (Subgroup of)

In mandarins (whole fruit), residues of tebuconazole were (n=4): 0.38, 0.40, 0.46 and 0.48 mg/kg. Residues in pulp were < 0.05 (4) mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg (mean + 4SD) in mandarin subgroup. Based on residues in pulp, the Meeting estimated a STMR of 0.05 mg/kg and HR of 0.05 mg/kg in mandarin subgroup.

Oranges, Sweet, Sour (subgroup)

In oranges (whole fruit), residues of tebuconazole were (n=4): 0.25, 0.27 (2), and 0.28 mg/kg. Residues in pulp were < 0.05 (4) mg/kg, and residues in peel were (n=4): 0.83, 0.91, 0.92, and 1.2 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg (mean + 4SD) in orange, sweet, sour (subgroup). Based on residues in pulp and peel, the Meeting estimated a STMR of 0.05 mg/kg and HR of 0.05 mg/kg in orange, sweet, sour (subgroup) pulp and a STMR of 0.915 mg/kg and HR of 1.2 mg/kg in orange peel.

Fate of residues during processing

The Meeting received processing studied for oranges. In one study (RA-3076/96), fruits were peeled prior to processing, which is not reflective of commercial processing, where whole fruits are pressed to obtain juice. Since residues of tebuconazole are on the surface of the fruits, peeling removed a

significant amount of the residue that otherwise could have been transferred to the juice. In a second study (RAHWN001), oranges were scarified prior to juicing. This also removed a significant amount of the surface residue that could otherwise be transferred to juice. Therefore, the Meeting decided not to use either study to estimate a processing factor for citrus juice. The processing factors derived from the processing studies and the resulting recommendations for STMR-Ps, HR-Ps, and/or maximum residue levels are summarized in the table below.

Processing (Transfer) Factors from the Processing of Raw Agricultural Commodities (RACs) with Field-Incurred Residues from Foliar Treatment with tebuconazole

RAC	Processed Commodity	Processing Factors [best estimate]	RAC MRL	Processed Commodity MRL	RAC STMR	Processed Commodity STMR-P
Oranges	marmalade	<0.22, 0.63 [0.63]	0.4	--	0.27	0.17
	oil	24.5	0.4	10	0.27	6.6
	pomace, dried	7.2	0.4	3	0.27	1.9

Estimated maximum and mean dietary burdens of farm animals

The Meeting estimated the contribution from citrus pulp (dry) to the livestock dietary burden and based on the small increase by 0.8 ppm of dry matter diet, in relation to the maximum dietary burden estimate from the 2011 JMPR (54 ppm of dry matter diet), no change to the residue situation in animal commodities is expected. The Meeting confirms its previous recommendations for animal commodities.

RECOMMENDATIONS

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

The residue definition for compliance with the MRL and for dietary risk assessment for plant and animal commodities is parent tebuconazole.

The residue is not fat soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for tebuconazole is 0–0.03 mg/kg bw. The International Estimated Daily Intakes (IEDI) for tebuconazole was estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2019 Extra JMPR Report.

The IEDIs ranged from 1–5% of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of tebuconazole from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for tebuconazole is 0.3 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for tebuconazole were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2019 Extra JMPR Report.

The IESTIs were 0–1% (children) and 0% (general population) of the ARfD. The Meeting concluded that acute dietary exposure to residues of tebuconazole from uses considered by the present Meeting is unlikely to present a public health concern.

