

FENBUCONAZOLE (197)

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APPRAISAL

Fenbuconazole was first evaluated for residues and toxicology by the JMPR in 1997, and then evaluated for residues in 2009 and for toxicology in 2012. The 1997 JMPR allocated an ADI of 0–0.03 mg/kg bw. The 2012 JMPR established an ARfD of 0.2 mg/kg bw.

The Meeting recommended a number of maximum residue levels in 1997 and 2009. Those maximum residue levels were adopted by the Codex Alimentarius Commission in 1999, 2000 and 2013 as Codex MRLs.

The 2009 JMPR received the residue trial data on citrus fruits (grapefruit, oranges and lemons). However, it could not estimate a maximum residue level for fenbuconazole in citrus fruits as the residue trials submitted did not match the available GAP.

Fenbuconazole was scheduled by the Fourt-fourth Session of the CCPR for the residue evaluation of citrus fruits. The “Principles and guidance for application of the proportionality concept for estimation of maximum residue limits for pesticides” were adopted by the Codex Alimentarius Commission in 2013.

Results of supervised residue trials on crops

Information on GAP and supervised trial data were submitted to the 2009 JMPR for lemons and oranges and to the 1997 JMPR for grapefruit and oranges.

Citrus fruits

The GAP on citrus fruit in the USA is a maximum of three foliar applications at a rate of 0.14 kg ai/ha with a PHI of 0 day. Nine trials for grapefruit, sixteen trials for oranges and five trials for lemons were conducted in the USA (3×0.28 kg ai/ha, PHI 0 day). As the application rate of those trials submitted to the 1997 and 2009 JMPR was 2 times the GAP rate, the Meeting decided to use the principle of proportionality to select data for estimating a maximum residue level, an STMR value and an HR value for citrus fruit.

The Meeting considered the result from one trial on grapefruit was not appropriate for use in estimating a maximum residue level as the residue concentration in pulp was higher than in the whole fruit.

Scaled residues in the whole fruit of grapefruit were (scaling factor 0.5: 0.28→0.14 kg ai/ha): 0.05, 0.06, 0.07, 0.08 (2), 0.10, 0.17 and 0.24 mg/kg.

Scaled residues in the whole fruit of oranges were (scaling factor 0.5: 0.28→0.14 kg ai/ha): 0.06 (2), 0.07, 0.08, 0.09 (4), 0.10, 0.14, 0.15 (2), 0.17, 0.22, 0.26 and 0.33 mg/kg.

Scaled residues in the whole fruit in lemons were (scaling factor 0.5: 0.28→0.14 kg ai/ha): 0.26, 0.29 (2), 0.35 and 0.42 mg/kg.

To consider a maximum residue level for a crop group, residues in individual crops should be similar (e.g., medians should not differ by more than 5×). The Meeting agreed to estimate a maximum residue level for the group of citrus fruits. In considering whether to combine data to estimate a maximum residue level, the Meeting recognized that the residue populations from trials on grapefruit, oranges and lemons were significantly different according to statistical test (Kruskal-Wallis H-test): the residue population from trials on lemons was different from those on grapefruit and oranges, while the residue populations from trials on grapefruit and oranges were not different according to statistical test (Mann-Whitney U-test). Therefore, the Meeting decided to combine the grapefruit and oranges data sets to estimate a maximum residue level for citrus fruits (except lemons and limes).

The combined residues in the whole fruit of grapefruit and oranges, in rank order, were (n=24): 0.05, 0.06 (3), 0.07 (2), 0.08 (3), 0.09 (4), 0.10 (2), 0.14, 0.15 (2), 0.17 (2), 0.22, 0.24, 0.26 and 0.33 mg/kg.

Scaled residues in pulp of grapefruit were (scaling factor 0.5): < 0.01 (4) and 0.01 mg/kg.

Scaled residues in pulp of orange were (scaling factor 0.5): < 0.01 (5) mg/kg.

The combined residues in pulp of grapefruit and orange were in rank order (n=10): < 0.01 (9) and 0.01 mg/kg.

Based on the scaled residues in the whole fruit of grapefruit and oranges, the Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR value for processing of 0.09 mg/kg for fenbuconazole in citrus fruit (except lemons and limes). Based on the scaled residues in pulp of grapefruit and orange, the Meeting estimated an STMR value of 0.01 mg/kg and an HR value of 0.01 mg/kg for fenbuconazole in citrus fruit (except lemons and limes).

Scaled residues in pulp of lemon were (scaling factor 0.5): < 0.01, 0.016, 0.018, 0.033 and 0.085 mg/kg.

Based on the scaled residues in the whole fruit of lemon, the Meeting estimated a maximum residue level of 1 mg/kg and an STMR for processing of 0.29 mg/kg for fenbuconazole in lemons and limes. Based on the scaled residues in pulp of lemon, the Meeting estimated an STMR value of 0.018 mg/kg and an HR value of 0.085 mg/kg for fenbuconazole in lemons and limes.

Fate of residues during processing

The Meeting received information on the fate of incurred residues of fenbuconazole during the processing of citrus whole fruit (grapefruit and oranges) to juice, dried pulp and cold press oil conducted in the USA in 2009. Based on processing factors for grapefruit and oranges, in combination with STMR for processing estimated for citrus fruits (except lemons and limes) and lemons and limes, the STMR-Ps for juice, dried pulp and oil were calculated as follows.

Processing factors, STMR-P and HR-P for food and feed

Processed commodity	Calculated processing factors*	PF (Mean or best estimate)	Raw agricultural commodity (RAC) STMR		STMR-P (mg/kg)
			mg/kg	RAC	
Juice	< 0.204, < 0.256	< 0.23	0.09	Citrus fruit (except lemons and limes)	0.021
			0.29	Lemons and limes	0.067
Cold press oil	49.0, 66.7	58	0.09	Citrus fruit (except lemons and limes)	5.2
			0.29	Lemons and limes	17
Dried pulp	6.31, 7.74	7.0	0.09	Citrus fruit (except lemons and limes)	0.63

* Processing factors were derived from the two processing studies each on grapefruit or orange. The factor is the ratio of the residue in processed commodity divided by the residue in the RAC.

The Meeting estimated the maximum residue levels of 4 mg/kg ($0.5 \text{ mg/kg} \times 7.0 = 3.5 \text{ mg/kg}$) for deried citrus pulp, 30 mg/kg ($0.5 \text{ mg/kg} \times 58 = 29 \text{ mg/kg}$) mg/kg for citrus oil (except lemons and limes) and 60 mg/kg ($1 \text{ mg/kg} \times 58 = 58 \text{ mg/kg}$) for oil of lemons and limes based on the maximum residue levels of citrus fruit (except lemons and limes) and of lemons and limes.

Residues in animal commodities

Farm animal feeding studies

A lactating dairy cattle feeding study and a laying hen feeding study were submitted to the 1997 JMPR.

Animal commodity maximum residue levels

Dried citrus pulp may be fed to beef cattle, dairy cattle, broilers and layers. But the STMP-P of dried citrus pulp was low at 0.63 mg/kg not contributing significantly to animal dietary burden. The calculated maximum and mean dietary burdens, with addition of dried citrus pulp, to be used for estimating maximum residue levels for commodities of animal origin (both mammals and poultry) were identical to those calculated by the 2009 JMPR.

The Meeting, therefore, confirmed the previous recommendations of the maximum residue levels for fenbuconazole in 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 dietary intake assessment.

Definition of the residue (for compliance with the MRL and for estimation of dietary intake, for plant and animal commodities): *fenbuconazole*

The residue is not fat soluble.

Commodity		Recommended MRL, mg/kg		STMR or STMR-P, mg/kg	HR or HR-P, mg/kg
CCN	Name	New	Previous		
FC 0001	Citrus fruit (except Lemons and Limes)	0.5	-	0.01	0.01
OR 0001	Citrus oil, edible (except Lemons and Limes)	30	-	5.2	-
AB 0001	Citrus pulp, dry	4	-	0.63	-
FC 0002	Lemons and Limes (including Citron)	1	-	0.018	0.085
	Oil of Lemons and Limes	60	-	17	-

Commodity name	STMR or STMR-P, mg/kg	HR or HR-P, mg/kg
Citrus juice (except lemons and limes)	0.021	-
Juice of lemons and limes	0.067	-

DIETARY RISK ASSESSMENT***Long-term intake***

In the current evaluation STMRs were estimated for 7 food commodities. Where consumption data were available these STMRs were used in the estimates of dietary intake together with previous MRL recommendations for other food commodities. The results are shown in Annex 3 of the 2013 JMPR Report.

The ADI is 0–0.03 mg/kg bw and the calculated IEDIs were 0–2% of the maximum ADI (0.03 mg/kg bw). The Meeting concluded that the long-term intake of residues of fenbuconazole, resulting from the uses considered by current JMPR, is unlikely to present a public health concern.

Short-term intake

The International Estimated Short Term Intake (IESTI) for fenbuconazole was calculated for 7 food commodities (including processed fractions) for which maximum residue levels were estimated at the present meeting and for which consumption data were available. The results are shown in Annex 4 of the 2013 JMPR Report.

The ARfD is 0.2 mg/kg bw and the calculated IESTI were a maximum of 0% of the ARfD for all population groups. The Meeting concluded that the short-term intake of residues of fenbuconazole, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.