

5.9 FLONICAMID (282)

RESIDUE AND ANALYTICAL ASPECTS

Flonicamid is the ISO approved common name for N-cyanomethyl-4-(trifluoromethyl)nicotinamide (IUPAC). Flonicamid (CAS No. 158062-67-0) is systemic pyridine carboxamide insecticide with selective activity against Hemipterous pests.

Flonicamid was first evaluated for residues and toxicological aspects by the 2015 JMPR. The 2015 JMPR established an ADI for flonicamid of 0–0.07 mg/kg bw and concluded that an ARfD was unnecessary.

The 2015 JMPR also recommended the following residue definition for flonicamid:

Definition of the residue for compliance with the MRL and dietary risk assessment in plant commodities: *Flonicamid*

Definition of the residue for compliance with the MRL and dietary risk assessment in animal commodities: *Flonicamid and the metabolite TFNA-AM, expressed as parent*

The residue is not fat-soluble.

Flonicamid was last evaluated in 2017 for additional maximum residue levels. At the Fiftieth Session of the CCPR (2017), flonicamid was listed for consideration of additional uses by the 2019 Extra JMPR. The Meeting received information on registered use patterns, analytical method information, storage stability data and supervised residue trials on citrus fruits with product labels from the USA

Methods of analysis

The current Meeting received additional concurrent recovery information for the analysis of flonicamid in plant matrices.

Methods H13-87 and 09604 were used in the investigation of the storage stability in high acid matrices. In H13-87 method, methanol was used as extraction solvent. Residues were determined by GC-MS and individual LOQs of 0.01 mg/kg were validated for parent flonicamid and each of its metabolites TFNA, and TFNG in orange pulp. In orange peel, individual LOQs of 0.04 mg/kg were validated for parent flonicamid and each of its metabolites TFNA, and TFNG. The 09604 method involves extraction of the residue with acetonitrile:water (1:1). Determination was performed by LC-MS/MS. Based on concurrent recovery data, individual LOQs of 0.01 mg/kg were validated for parent flonicamid and each of its metabolites TFNA, TFNA-AM and TFNG.

Method IB-2014-JLW-002-01-01 was used for residue determination of field crop samples from the supervised trials. The method involves extraction of residues with acetonitrile:water (1:1; v/v). Determination was performed by LC-MS/MS and supported with concurrent recovery data suggesting individual LOQs of 0.01 mg/kg for parent flonicamid and each of its metabolites TFNA, TFNA-AM and TFNG.

Stability of residues in stored analytical samples

The Meeting received information on the storage stability of parent flonicamid and its metabolites TFNA, TFNA-AM and TFNG in high acidic matrices (citrus fruits and strawberries).

Flonicamid, TFNA and TFNG in orange peel and orange pulp were found to be stable in storage at -20 °C for at least 16 months (480–486 days). Flonicamid, TFNA, TFNA-AM and TFNG in strawberry were found to be stable in storage at -20 °C for at least 15 months (460 days).

Among all the samples from supervised trials in storage, the longest storage duration before analysis was 268 days. The Meeting concluded that all the residue results from supervised trials were analysed within acceptable storage intervals.

Results of supervised residue trials on crops

Flonicamid is registered for use on citrus fruits in the USA with a maximum GAP involving three foliar sprays of 0.1 kg ai/ha each (7 day interval), a maximum seasonal rate of 0.3 kg ai/ha and a PHI of 0 days. The Meeting received supervised trial data for applications of flonicamid on citrus fruits conducted in the USA.

Lemons and Limes

Corresponding supervised field trials conducted in the USA on lemons matching the GAP were submitted.

Residues of flonicamid in lemon fruits were (n=5): 0.13(2), 0.22 0.25 and 0.71 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg and a STMR value of 0.22 mg/kg for flonicamid in the subgroup lemons and limes.

Oranges, Sweet, Sour

Corresponding supervised field trials conducted in the USA on oranges matching the GAP were submitted.

Residues of flonicamid in orange fruits were (n=14): 0.051, 0.061, 0.064, 0.083, 0.088, 0.10, 0.11, 0.12, 0.15, 0.18, 0.22(2), 0.23 and 0.24 mg/kg.

The Meeting noted that the US GAP involves treatment of all citrus fruit and decided to use oranges as representative commodity for the subgroup of oranges, sweet, sour.

The Meeting estimated a maximum residue level of 0.4 mg/kg and a STMR value of 0.115 mg/kg for flonicamid in the subgroup oranges, sweet, sour.

Pummelos and Grapefruits

Corresponding supervised field trials conducted in the USA on grapefruits matching the GAP were submitted.

Residues of flonicamid in grapefruits were (n=6): 0.019, 0.034, 0.057, 0.070, 0.079 and 0.13 mg/kg.

The Meeting noted that the US GAP involves treatment of all citrus fruit and decided to use grapefruits as representative commodity for the subgroup of pummelos and grapefruit.

The Meeting estimated a maximum residue level of 0.3 mg/kg and a STMR value of 0.0635 mg/kg for flonicamid in the subgroup pummelos and grapefruit.

The Meeting noted that data from mandarins were not available therefore the Meeting did not consider a recommendation for the citrus group.

Fate of residues during processing

The fate of flonicamid residues has been examined simulating commercial processing of orange fruits.

Estimated processing factors for the commodities considered at this Meeting are summarised below.

Raw commodity	Processed commodity	Flonicamid			
		Individual processing factors	Mean or best estimate processing factor	STMR or STMR-P (mg/kg)	Maximum residue level (mg/kg)
Citrus fruits	Lemon (RAC)			0.22	1.5
	Juice	0.02 (from orange)	0.02	0.0044	-
	Dried pulp	1.8 (from orange)	1.8	0.396	3
	Oil	0.01 (from orange)	0.01	0.0022	-

The Meeting estimated a maximum residue level of 3 mg/kg for citrus pulp, dry on the basis of the processing factor of 1.8 for orange pulp, dry and the maximum residue level for lemon of 1.5 mg/kg.

Residues in animal commodities

The Meeting recalculated the livestock dietary burden based on the uses considered by the current and previous Meeting on the basis of diets listed in the 2016 edition of FAO Manual Appendix IX (OECD Feedstuff Table). The addition of citrus pulp, dry does not add significantly to the maximum and mean dietary burdens of up to 27.7 ppm and 15.3 ppm calculated by the 2016 JMPR. The Meeting confirmed its previous recommendations for flonicamid in 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 assessment.

Definition of the residue for compliance with the MRL and dietary risk assessment for plant commodities: *Flonicamid*

Definition of the residue for compliance with the MRL and dietary risk assessment for animal commodities: *Flonicamid and the metabolite TFNA-AM, expressed as parent*

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for flonicamid is 0–0.07 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for flonicamid were 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 1–10% of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of flonicamid from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The 2015 JMPR decided that an ARfD for flonicamid was unnecessary. The Meeting therefore concluded that the acute dietary exposure to residues of flonicamid from the uses considered is unlikely to present a public health concern.

