Isofetamid (290)

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EXPLANATION

Isofetamid, with chemical name of (N-[1,1-dimethyl-2-(4-isopropoxy-o-tolyl)-2-oxoethyl]-3-methylthiophene-2-carboxamide) was first evaluated for toxicology and residues by the JMPR in 2016, where an ADI of 0–0.05 mg/kg bw and an ARfD of 3 mg/kg bw were established. The 2016 JMPR concluded that the residue definition for compliance with the MRL and dietary risk assessment for plant commodities was parent isofetamid. The residue definition for compliance with the MRL and dietary risk assessment for animal commodities was the sum of isofetamid and 2-[3-methyl-4-[2-methyl-2-(3-methylthiophene-2-carboxamido) propanoyl] phenoxy] propanoic acid (PPA), expressed as isofetamid. The residue is fat-soluble.

Isofetamid was scheduled at the Forty-ninth Session of the CCPR for the evaluation of additional uses by the 2018 JMPR. The Meeting received information on use patterns, supervised residue trials (in pome fruits, stone fruits, berries and other small fruits, kiwi fruit, legume vegetables and pulses) and processing studies. A dairy cow feeding study was also provided to the Meeting along with an analytical method for isofetamid and PPA residues in milk and liver matrices.

METHODS OF RESIDUE ANALYSIS

Analytical methods for residues of isofetamid in various plant and animal matrices were previously evaluated by the 2016 JMPR. The current Meeting received concurrent recoveries on methods for pome fruits and stone fruits matrices, blueberry, raspberry, kiwi fruit, snap bean, lima bean, green bean, dry bean, dry pea, and for animal commodities of liver and milk on isofetamid and PPA. The independent validation of methods submitted for the current Meeting are summarized below.

Analytical methods for plant matrices

For matrices of plant origin, samples are mainly extracted with acetonitrile/water, except for pulse samples which are extracted with acetone. After the clean-up procedure, isofetamid and its metabolite the glucoside of 4-HP residues (GPTC) are analysed by LC-MS/MS.

Commodity (References)	Apple, Apple juice, Apple Pomace (IB-2011-JLW-003-01-01) Pear (IB-2014-JAM-004-01-01) Cherry, Peach and Plum (IB-2014-JLW-005-01-01) Blueberry, Raspberry and Kiwi (IB-2014-JLW-004-01-01) Snap bean, Lima bean, Green Pea, Dry bean and Dry Pea (IB-2014-JLW-006-01-0, IB-2012-JLW-006-01-01, IB-2015-JAM-007-01-01)
Analyte:	Isofetamid
Determination:	LC-MS/MS
LOQ:	0.01 mg/kg for the determination of isofetamid and GPTC in all matrices
Accuracy:	The mean recoveries in the validation data were in the range of 78.5–103%.
Repeatability:	The RSDs of isofetamid at each fortification level and overall during method validation were in the range of 0.6–6.0%.
Linearity:	The linearity of detector response was confirmed by analysis of six concentrations of standard solutions in the range 0.02 to 1 ng/mL of isofetamid with two injections for each concentration. Linearity of response for isofetamid was demonstrated with a coefficient of determination (r^2) of 0.9998 and 0.9993.
Specificity:	No interfering peaks were detected in control samples above the LOD.
Description:	Residues of isofetamid were extracted with acetonitrile:water (80:20, v/v). An aliquot of the sample extract was filtered through a 0.45 µm PTFE filter and diluted with acetonitrile:water (20:80, v/v). Isofetamid residues were determined by LC-MS/MS with positive-ion electrospray ionisation (ESI). Quantification of the analytes was achieved by comparison with mixed external standards of isofetamid (reflected as trade name ikf-5411 in the report) and GPTC.

Average recoveries at two fortification levels in the above trials generally fell within the 70–120% range. Information on the validaition recovery rates in the submitted supervised field trials are summarised below.

Table 1 Summary of recovery data for isofetamid, fortified in plant matrices

Matrix	Method	Fortification level (mg/kg)	Recovery (%) （Average）	RSD (%)	Reference
Apple	JSM0119	0.01	89.9, 84.7, 85.7 (86.7)	3.2	Report IB-2011-JLW-003-01-01
		0.1	95.9, 92.5, 92.3 (93.6)	2.2	
Apple juice	JSM0119	0.01	101, 97.8, 103 (101)	2.6	
		0.1	103, 103, 104 (103)	0.6	
Apple wet pomace	JSM0119	0.01	89.5, 86.9, 89.6 (88.7)	1.7	
		0.1	84.2, 84.8, 83.3 (86.4)	3.2	
Pear	JSM0119	0.01	90.4, 93.9, 92.0 (92.1)	1.9	Report IB-2014-JAM-004-01-01
		0.1	92.9, 90.0, 90.8 (91.2)	1.6	
Cherry	JSM0119	0.01	92.7, 91.0, 88.1 (90.6)	2.6	IB-2014-JLW-005-01-01
		0.1	89.5, 89.5, 92.3(90.4)	1.8	
		4.0	102, 100, 100 (100)	1.5	
Peach	JSM0119	0.01	98.5, 93.7, 96.2 (96.1)	2.5	
		0.1	91.0, 87.5, 93.8 (90.8)	3.5	
Plum	JSM0119	0.01	92.0, 91.2, 92.6 (91.9)	0.8	
		0.1	95.8, 93.4, 94.0 (94.4)	1.8	
Blueberry	JSM0119	0.01	89.5, 91.6, 95.1 (92.1)	3.1	IB-2014-JLW-004-01-01
		0.1	93.9, 93.3, 92.2 (93.1)	2.1	
Raspberry	JSM0119	0.01	87.7, 83.1, 85.3 (85.4)	2.7	
		0.1	93.5, 95.6, 92.5 (94.0)	1.5	
		4.0	92.1, 88.1, 93.1 (90.2)	2.9	
Kiwi	JSM0119	0.01	83.0, 86.9, 83.5 (84.5)	2.5	
		0.1	88.6, 86.9, 83.5 (87.3)	1.4	
		4.0	99.5, 94.3, 94.6 (96.1)	3.0	
Bean Pods	JSM0119	0.01	89.0, 88.3, 92.5 (89.9)	2.5	IB-2012-JLW-006-01-01
		1.0	91.2, 93.6, 93.8 (92.9)	1.6	
Bean Seeds	JSM0119	0.01	83.2, 78.4, 73.8 (78.5)	6.0	
		1.0	88.9, 95.0, 91.6 (91.8)	3.3	
Lima Beans	JSM0119	0.01	83.4, 81.3, 84.3 (83.0)	1.9	IB-2014-JLW-006-01-01
		0.1	82.8, 84.8, 82.6 (83.4)	1.5	
Shelled Green Peas	JSM0119	0.01	84.9, 84.7, 87.1 (85.6)	1.6	
		0.1	85.8, 83.5, 82.9 (84.1)	1.8	
Edible Pod Peas	JSM0119	0.01	85.0, 85.1, 87.2 (85.8)	1.5	
		0.1	93.5, 91.6, 93.3 (92.8)	1.1	
		2.0	98.5, 95.0, 94.0 (95.8)	2.5	
Dry Peas	JSM0119	0.01	81.6, 81.1, 79.9 (80.9)	1.1	
		0.10	84.6, 83.4, 85.0 (84.3)	1.0	

Analytical methods for animal matrices

The Meeting received data on independent laboratory validation for the analysis isofetamid and its metabolites (4HP, PPA, 5-HPPA) in commodities of animal origin. Two methods were validated, analytical procedure SMV 8256542-03V for 5-HPPA and analytical procedure SMV 8256542-04V for isofetamid, 4HP and PPA.

Commodity(references):	Liver and milk (JSM0690)
Analyte:	Isofetamid, PPA
Determination:	LC-MS/MS
LOQ:	0.01 mg/kg for the determination of isofetamid and metabolites in all matrices
Accuracy:	The mean recoveries for each fortification level were within the acceptable range of 70 to 120%, demonstrating accuracy (recovery) of the method.
Repeatability:	The coefficient of variance (CV) obtained at each fortification level and overall was within the acceptable range of ≤ 20%, demonstrating precision (repeatability) of the method.
Linearity:	The response of the LC-MS/MS system to matrix matched standard solutions of isofetamid and PPA were linear over the range 0.1 to 10 ng/mL (equivalent to 0.003 to 0.3 mg/kg in sample

matrix). Linearity of response for isofetamid was demonstrated with a coefficient of determination (r^2) from 0.9967 and 0.9999.

Specificity: No interfering peaks were detected in control samples above the LOD.

Description: Residues of isofetamid were extracted with acetonitrile:water (80:20, v/v). An aliquot of the sample extract was filtered through a 0.45 µm PTFE filter and diluted with acetonitrile:water (20:80, v/v). Isofetamid residues were determined by LC-MS/MS with positive-ion electrospray ionisation (ESI). Quantification of the analytes was achieved by comparison with mixed external standards of isofetamid and GPTC.

Information on the validaition data in animal matrices are summarised in Tables 2–3.

Table 2 Validation data for isofetamid in animal matrices

Matrix	Analyte (quantification or confirmation ion transition)	Fortification level (mg/kg)	Recovery (%) (Average)	RSD (%)	Reference
Liver	Isofetamid Quantification (m/z 360.2>210.0)	0.01 0.1	109, 108, 95, 95, 88 (99) 82, 102, 107, 97, 107 (99)	9.2 10.5	Report JSM0690
Milk		0.01 0.1	80, 104, 101, 115, 95 (99) 101, 95, 95, 110, 105 (101)	13.0 6.4	
Liver	Isofetamid Confirmation (m/z 360.2>210.0)	0.01 0.1	98, 103, 88, 88, 84 (92) 95, 102, 106, 99, 104 (101)	8.6 4.3	
Milk		0.01 0.1	84, 112, 109, 125, 107 (107) 100, 95, 94, 105, 102 (99)	13.8 4.7	

Table 3 Validation data for PPA in animal matrices

Matrix	Analyte (quantification or confirmation ion transition)	Fortification level (mg/kg)	Recovery (%) (Average)	RSD (%)	Reference
Liver	PPA Quantification (m/z 390.1>210.0)	0.01 0.1	110, 110, 100, 102, 98 (102) 91, 105, 103, 105, 96 (100)	4.6 6.2	Report JSM0690
Milk		0.01 0.1	110, 71, 102, 100, 97 (96) 87, 101, 103, 71, 105 (93)	15.4 15.4	
Liver	PPA Confirmation (m/z 390.1>182.0)	0.01 0.1	83, 90, 85, 98, 92 (90) 89, 99, 98, 96, 90 (94)	6.6 4.9	
Milk		0.01 0.1	104, 78, 97, 96, 98 (95) 71, 102, 107, 71, 102 (91)	10.3 19.9	

Stability of pesticide residues in stored analytical samples

The 2016 JMPR indicated that isofetamid residues were stable at freezer conditions in the following crop commodities for the intervals tested, most for 12 months: almond, oilseed rape seed, grape, lettuce, potato and dry bean. The current Meeting received additional data on storage stability.

The current Meeting received residue storage stability data of isofetamid in almonds, oilseed rape seed, grapes, lettuce, potatoes and dry beans, when stored in the dark at approximately -20 °C (i.e. freezer storage) and assessed after 24 months. Samples (from previous study JSM0212) were extracted and analysed in accordance with the validated residue analytical method, JSM0119.

Isofetamid was shown to be stable in almonds, dry beans, oilseed rape seeds, grapes, lettuce and potatoes when stored at approximately -20 ºC for a period of 24 months. Detailed results are summarized in Table 4.

Table 4 Storage stability of isofetamid in various plant matrices when stored at approximately -20 ºC

Commodity (fortification)	Storage interval (months)	Residues remaining in stored samples		Procedure recovery	
		mg/kg	% [mean]	mg/kg	%
Almonds	24	0.096, 0.097	96.0, 97.0 [97]	0.097	97.0
Dry beans	24	0.083, 0.082	83.0, 82.0 [83]	0.085	85.0
Oilseed rape seed	24	0.084, 0.083	84.0, 83.0 [84.0]	0.077	77.0
Grape	24	0.096, 0.093	96.0, 93.0 [95.0]	0.092	92.0

Commodity (fortification)	Storage interval (months)	Residues remaining in stored samples		Procedure recovery	
		mg/kg	% [mean]	mg/kg	%
Lettuce	24	0.096, 0.085	96.0, 85.0 [91.0]	0.088	88.0
Potato	24	0.085, 0.083	85.0, 83.0 [84.0]	0.084	84.0

The Meeting received a residue study on the stability of isofetamid, 4HP and PPA in milk, liver, kidney, muscle and fat and the stability of 5-HPPA in liver when stored in the dark at approximately -20 °C. Isofetamid, 4HP and PPA were all found to be stable for at least 68 days in milk, muscle, fat, kidney and liver. 5-HPPA was shown to be unstable in homogenized liver at 18 and 63 days.

Table 5 Storage stability of isofetamid in various animal matrices when stored at approximately

-20 ºC

Commodity (fortification)	Storage interval (months)	Residues remaining in stored samples		Procedure recovery	
		mg/kg	% [mean]	mg/kg	%
Milk	0	0.108, 0.106, 0.108, 0.103, 0.101, 0.102	109, 106, 108, 103, 102, 102[105]		
	68	0.901, 0.0831, 0.0911	90.1, 83.3, 91.1 [88.2]	0.0989, 0.0918, 0.0891	98.9, 91.8, 89.5 [93.4]
Liver	0	0.109, 0.110, 0.109, 0.104, 0.108, 0.107	109, 110, 109, 105, 108, 107 [108]		
	68	0.107, 0.107, 0.107	107, 107, 107 [107]	0.110, 0.107, 0.107	110, 107, 107 [108]
Kidney	0	0.110, 0.112, 0.109, 0.111, 0.108, 0.110	110, 112, 110, 111, 109, 110 [110]		
	68	0.103, 0.104, 0.104	103, 104, 104 [104]	0.104, 0.105, 0.105	104, 105, 105 [105]
Muscle	0	0.114, 0.114, 0.114, 0.111, 0.111, 0.111	114, 115, 114, 111, 112, 111 [113]		
	68	0.105, 0.104, 0.102	106, 104, 102 [104]	0.107, 0.109, 0.109	107, 109, 110 [109]
Fat	0	0.109, 0.106, 0.110, 0.109, 0.108, 0.109	109, 106, 110, 109, 108, 109 [109]		
	68	0.0978, 0.0975, 0.0993	98.6, 97.9, 99.3 [98.6]	0.0962, 0.0986, 0.0985	96.2, 98.6, 98.9 [97.9]

Milk and Cow tissues (reference IB-2014-JLW-012-01-01)

Table 6 Storage stability of PPA in various animal matrices when stored at approximately -20 ºC

Commodity (fortification)	Storage interval (months)	Residues remaining in stored samples		Procedure recovery	
		mg/kg	% [mean]	mg/kg	%
Milk	0	0.110, 0.113, 0.110, 0.111, 0.109, 0.112	110, 112, 109, 110, 109, 111[110]		
	68	0.116, 0.110, 0.117	115, 109, 116 [113]	0.115, 0.114, 0.112	114, 113, 111 [113]
Liver	0	0.104, 0.105, 0.102, 0.100, 0.106, 0.103	103, 104, 101, 100, 105, 102 [103]		
	68	0.108, 0.107, 0.107	107, 106, 106 [106]	0.112, 0.115, 0.113	111, 114, 112 [112]
Kidney	0	0.106, 0.108, 0.111, 0.108, 0.19, 0.107	105, 107, 111, 107, 109, 106 [108]		
	68	0.108, 109, 0.110	107, 108, 109 [108]	0.110, 0.111,0.109	109, 110, 109 [109]
Muscle	0	0.109, 0.110, 0.110, 0.106, 0.108, 0.108	108, 110, 109, 105, 108, 107 [108]		
	68	0.103, 0.103, 0.100	103,102, 99.0 [101]	0.105, 0.106, 0.108	104, 105, 108 [106]
Fat	0	0.106, 0.113, 0.114, 0.118, 0.112, 0.112	105, 112, 113, 117, 111, 111 [112]		
	68	0.113, 0.112, 0.111	113, 111, 110 [111]	0.108, 0.107, 0.114	107, 106, 113 [109]

USE PATTERNS

The Meeting received additional information on recently authorized uses on pome fruits (including apple, pear), stone fruits (including peach, plum and cherries), berries, kiwi, grape, legume vegetables and pulses. The national GAPs for these crops are summarized in the following table. The national GAPs for these crops are summarized in Table 7.

Table 7 Registered uses of isofetamid (400 g/L SC formulations)

Crop	Country	Form	Application				Max applications		PHI (days)	Remarks:
			kg ai/ha	kg ai/hL	water L/ha	RTI (days)	no	kg ai/ha		
Apple	Canada	SC	0.365		No more than 1000	10–14	6		20	
Stone Fruit，Crop Group 12-09	Canada	SC	0.365		No more than 1000	7–14	3		1	
Berry and Small Fruit Crop Group 13-07[a] except Subgroup 13-07C, 13-07F, 13-07G (Blueberry, Raspberry, Kiwi)	Canada	SC	0.395-0.496			7–14	3		7	Do not apply more than 3 applications /year.
Edible-podded Legume Vegetables, (Crop Subgroup 6A[b]) except pigeon pea and pea (Pisum spp, which includes dwarf pea, edible-podded pea, snow pea, sugar snap pea) Succulent shelled pea and bean (Crop Subgroup 6B[b]) Dried shelled pea and bean except soya bean (Crop Subgroup 6C[d])	Canada	SC	0.5			7–14	2	1.0	edible-podded snap beans:7 days. succulent shelled peas and beans: 14 days. dried shelled peas and beans: 30 days.	
Pome Fruit, Crop Group 11-10	USA	SC	0.365		935–1870	10–14	6		20	
Stone Fruit, Crop Group 12-12	USA	SC	0.365		935–1870	7–14	3		1	
Caneberry Subgroup 13-07A Bushberry Subgroup 13-07B Fruit, Small Vine Climbing Fruit Except Grapes Subgroup 13-07E[e]	USA	SC	0.393-0.448		50 to 100 gallons per acre for dilute sprays and 5 to 10 gallons per acre for aerial sprays	14	4		7	
Legume vegetables Edible podded, Subgroup 6A[f] Pea and Bean, succulent shelled subgroup 6B[g] Pea and Bean, dried shelled, except soya bean, subgroup 6C[h]	USA	SC	0.5			7–14	2	1.0	edible-podded peas and snap beans: 7 days. succulent shelled beans, lima and shelled green peas: 14 days. dried beans and dried peas: 30 days	

[a] Includes all members of the Berry and Small Fruit group except Subgroups 13-07C, 13-07F and 13-07G

[b] Includes all members of Edible-podded Legume Vegetables Subgroup 6A

[c] Includes all members of Succulent Shelled Pea and Bean Subgroup 6B

[d] Includes all members of Dry Shelled Pea and Bean except Soya bean Subgroup 6C

[e] Includes all members of the Berry and Small Fruit group included in Subgroups 13-07A, 13-07B and 13-07E

[f] Includes all members of the Legume Vegetables, Edible podded, Subgroup 6A

[g] Includes all members of the Pea and Bean, succulent shelled, Subgroup 6B

[h] Includes all members of the Pea and Bean, dried shelled, except soya bean, Subgroup 6C

RESIDUES RESULTING FROM SUPERVISED TRIALS

The Meeting received information on supervised field trials involving foliar treatments of isofetamid to pome fruits (including apple, pear), stone fruits (including peach, plum, cherry), berries, kiwi, grape, legume vegetables and pulses.

Group	Crop	Countries	Table No.
Pome Fruit	Apple	Canada, USA	8
	Pear	Canada, USA	9
Stone Fruit	Peach	Canada, USA	10
	Plum	Canada, USA	11
	Cherry	Canada, USA	12
Berries and other small fruits	Blueberry	Canada, USA	13
	Raspberry		14
Assorted tropical and subtropical fruits-inedible peel	Kiwi	USA	15
Legume vegetables	Snap bean	Canada, USA	16
	Lima bean	USA	17
	Green pea	Canada, USA	18
	Peas with pods	USA	19
Pulses	Dry beans	Canada, USA	20
	Dry peas	Canada, USA	21

Results from replicated field plots are listed and mean values are caculated. If higher residue values were observed at longer PHIs than GAP these were selected for estimating maximum residue levels and for dietary intake assessment.

Pome Fruits

The results from 30 supervised trials on pome fruit in Canada and the USA were provided to the Meeting.

Apple

In the 20 apple trials, six foliar applications of 0.365 kg ai/ha isofetamid (SC) were applied in 945–1450 L water/ha to single replicate plots.

Table 8 Residues in apple from supervised trials in Canada and the USA involving six foliar applications of isofetamid (400 g/L SC formulation).

Apple Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			isofetamid	mean	
GAP: USA	6	0.365		935–1870		PHI: 20			
USA, 2011 North Rose, NY (Cortland)	6	0.363		1169	fruit	19	0.016,0.030	0.023	Report:IB-2011-JLW-003-01-01 Trial:IB-2011-JLW-003-01

Apple Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			isofetamid	mean	
USA, 2011 North Rose, NY (Ida Red)	6	0.363		1169	fruit	20	0.165,0.198	0.182	Report:IB-2011-JLW-003-01-01 Trial:IB-2011-JLW-003-02
USA, 2011 Hereford, PA (Red delicious, Starkrimson)	6	0.362		982	fruit	20	0.043,0.049	0.046	Report:IB-2011-JLW-003-01-01 Trial:IB-2011-JLW-003-03
USA, 2011 Hereford, PA (Rome, Law Strain)	6	0.365		1253	fruit	20	0.088,0.137	0.113	Report:IB-2011-JLW-003-01-01 Trial:IB-2011-JLW-003-04
USA, 2011 Blairsville, GA (Rome Beauty)	6	0.361		1169	fruit	20	0.044,0.039	0.042	Report:IB-2011-JLW-003-01-01 Trial:IB-2011-JLW-003-05
USA, 2011 Cana, VA (Rome)	6	0.364		1431	fruit	21	0.034,0.064	0.049	Report:IB-2011-JLW-003-01-01 Trial:IB-2011-JLW-003-06
Canada, 2011 Branchton, Out. Can. (McIntosh)	6	0.390		1076	fruit	21	0.065,0.084	0.075	Report:IB-2011-JLW-003-01-01 Trial:IB-2011-JLW-003-07
Canada, 2011 St. George, Ont. Can. (Empire)	6	0.395		1337	fruit	18	0.088,0.078	0.083	Report:IB-2011-JLW-003-01-01 Trial:IB-2011-JLW-003-08
USA, 2011 Conklin, MI (Idared)	6	0.365		1450	fruit	20	0.047,0.084	0.066	Report:IB-2011-JLW-003-01-01 Trial:IB-2011-JLW-003-09
USA, 2011 Tecumseh, MI (Red Delicious)	6	0.605 (1-3app) 0.361 (4-6app)		1356	fruit	20	ND,ND	ND	Report:IB-2011-JLW-003-01-01 Trial:IB-2011-JLW-003-10
USA, 2011 Tecumseh, MI (Red Delicious)	6	0.607 (1-3app) 0.360 (4-6app)		1356	fruit	10 20 30 40	0.118,0.110 0.030,0.030 0.014,0.011 ND,ND	0.114 0.030 0.013 ND	Report:IB-2011-JLW-003-01-01 Trial:IB-2011-JLW-003-11
USA, 2011 Oregon, WI (Macintosh)	6	0.364		1048	fruit	20	0.183,0.184	0.184	Report:IB-2011-JLW-003-01-01 Trial:IB-2011-JLW-003-12
USA, 2011 Oregon, WI (Paula Reds)	6	0.366		1016	fruit	20	0.025,0.015	0.020	Report:IB-2011-JLW-003-01-01 Trial:IB-2011-JLW-003-13
USA, 2011 Canon City, CO (Red Delicious, Red Chief M26 Root Stalk)	6	0.317		1094	fruit	19	0.281,0.253	0.267	Report:IB-2011-JLW-003-01-01 Trial:IB-2011-JLW-003-14
USA, 2011 Los Molinos, CA (Summerfield)	6	0.375		1038	fruit	19	0.362,0.287	0.325	Report:IB-2011-JLW-003-01-01 Trial:IB-2011-JLW-003-15
USA, 2011 Ephrata, WA (Red Delicious)	6	0.378		945	fruit	20	0.159,0.187	0.173	Report:IB-2011-JLW-003-01-01 Trial:IB-2011-JLW-003-16
USA, 2011 Wapato, WA (Red Delicious)	6	0.354		1365	fruit	10 20 30 40	0.345,0.385 0.248,0.249 0.242,0.306 0.141,0.169	0.365 0.249 0.274 0.155	Report:IB-2011-JLW-003-01-01 Trial:IB-2011-JLW-003-17
USA, 2011 Weiser, ID (Red Delicious)	6	0.372		1150	fruit	20	0.136,0.151	0.144	Report:IB-2011-JLW-003-01-01 Trial:IB-2011-JLW-003-18
USA, 2011 Payette, ID (Law Rome)	6	0.367		1132	fruit	19	0.170,0.166	0.168	Report:IB-2011-JLW-003-01-01 Trial:IB-2011-JLW-003-19

Apple Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			isofetamid	mean	
USA, 2011 Altamont, OR (Red Flesh)	6	0.367		1094	fruit	21	0.336,0.424	0.380	Report:IB-2011-JLW-003-01-01 Trial:IB-2011-JLW-003-20

Pear

In the 10 pear trials, six foliar applications of 0.365 kg ai/ha isofetamid (SC) were applied in 1005–1640 L water/ha to single replicate plots.

Table 9 Residues in pear from supervised trials in Canada and the USA involving six foliar applications of isofetamid (400 g/L SC formulation).

Pear Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			isofetamid	mean	
GAP: USA	6	0.365		935-1870		PHI: 20			
USA, 2014 Wayne County, NY (Bartlett)	6	0.361		1183	fruit	20	0.0412,0.0438	0.043	Report:IB-2014-JAM-004-01-01 Trial:IB-2014-JAM-004-01
Canada, 2014 Branchton, Ontario. (Bosc)	6	0.363		1196	fruit	20	0.115,0.141	0.128	Report:IB-2014-JAM-004-01-01 Trial:IB-2014-JAM-004-02
Canada, 2014 Branchton, Ontario. (Bartlett)	6	0.365		1203	fruit	20	0.0847,0.0879	0.0863	Report:IB-2014-JAM-004-01-01 Trial:IB-2014-JAM-004-03
Canada, 2014 Simcoe, Ontario. (Harrow Sweet)	6	0.364		1005	fruit	15	0.128,0.148	0.138	Report:IB-2014-JAM-004-01-01 Trial:IB-2014-JAM-004-04
USA, 2014 Oceana County, MI (Bartlett)	6	0.363		1173	fruit	20	0.0206,0.0606	0.041	Report:IB-2014-JAM-004-01-01 Trial:IB-2014-JAM-004-05
USA, 2014 Madera, CA (Hosui)	6	0.359		1415	fruit	21	0.126,0.131	0.129	Report:IB-2014-JAM-004-01-01 Trial:IB-2014-JAM-004-06
USA, 2014 Tulare County, CA (Olympic)	6	0.359		1640	fruit	20	0.279,0.294	0.287	Report:IB-2014-JAM-004-01-01 Trial:IB-2014-JAM-004-07
USA, 2014 Ephrata, WA (D'Anjou)	6	0.364		1033	fruit	20	0.156,0.146	0.151	Report:IB-2014-JAM-004-01-01 Trial:IB-2014-JAM-004-08

Pear Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			isofetamid	mean	
USA, 2014 Hood River, OR (Red Anjou)	6	0.365		1173	fruit	20	0.126,0.132	0.129	Report:IB-2014-JAM-004-01-01 Trial:IB-2014-JAM-004-09
USA, 2014 Hood River, OR (Starkrimson)	6	0.356		1232	fruit	5 10 15 19	0.115,0.198 0.118,0.108 0.0561,0.0645 0.0626, 0.556	0.157 0.113 0.0603 0.059	Report:IB-2014-JAM-004-01-01 Trial:IB-2014-JAM-004-10

Stone Fruits

Supervised trials on cherries, plum, apricot and peach in Europe were reviewed by the 2016 JMPR. As no GAP for stone fruits was available to the 2016 JMPR, the 2016 Meeting did not recommend any maximum residue levels for stone fruits. It was noted in the Sponsor's data package, that formal registration labels in EU countries were not available.

Supervised trials on peach, plum and cherry in Canada and the USA were provided to the current Meeting.

Peach

In the 12 peach trials, three foliar applications of 0.365 kg ai/ha isofetamid (SC) were applied, at a 6–8 day interval in water volumes of 947–1437 L/ha to single replicate plots.

Table 10 Residues in peach from supervised trials in Canada and the USA involving three foliar applications of isofetamid (400 g/L SC formulation).

Peach Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			isofetamid	mean	
GAP: USA	3	0.365		935-1870		PHI: 1			
GAP: Canada	3	0.365		No more than 1000		PHI: 1			
USA, 2014 Alton NY (Baby Gold #5)	3	0.360		1180		1	0.49,0.58	0.54	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-01
USA, 2014 Chula, GA (June Prince)	3	0.361		1425		1	0.45,0.44	0.45	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-02
USA, 2014 Monetta, SC (Big Red)	3	0.365		1437		1	0.71,0.84	0.78	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-03
USA, 2014 Cana, VA (O'Henry)	3	0.358		1344		1	0.93,1.56	1.25	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-04
Canada, 2014 Lincoln, Ontario (PF11)	3	0.371		1019		1	0.47,0.49	0.48	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-05

Peach Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			isofetamid	mean	
Canada, 2014 Lincoln, Ontario (PF11)	3	0.367		1006		1	0.61,0.75	0.68	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-06
Canada, 2014 Renton, Ontario (Red Haven)	3	0.377		1033		1	1.65,1.74	1.70	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-07
USA, 2014 Hart, MI (Baby Gold #5)	3	0.365		1407		1	0.34,0.29	0.32	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-08
USA, 2014 Hondo, TX (Tex Prince)	3	0.362		1412		1	0.23,0.25	0.24	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-09
USA, 2014 Madera, CA (Spring Crest)	3	0.360		947		1	0.68,0.97	0.83	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-010
USA, 2014 Kingsburg, CA (Late Ross)	3	0.364		1415		1	0.67,0.84	0.76	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-012
USA, 2014 Ephrata, WA (Glowing Star)	3	0.365		1408		1	0.87,0.89	0.88	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-013

Plum

In the 12 peach trials, three foliar applications of 0.365 kg ai/ha isofetamid (SC) were applied, at a 6–8 day interval in water volumes of 758–1873 L/ha to single replicate plots.

Table 11 Residues in plum from supervised trials in Canada and the USA involving three foliar applications of isofetamid (400 g/L SC formulation).

Peach Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			isofetamid	mean	
GAP: USA	3	0.365		935-1870		PHI: 1			
USA, 2014 Hart, MI (Stanley)	3	0.369		1417	fruit	1	0.07,0.02	0.05	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-014
Canada, 2014 Branchton, Ontario (German)	3	0.366		1204	fruit	1	0.29,0.36	0.33	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-015

Peach Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			isofetamid	mean	
USA, 2014 Madera, CA (Apple Dandy)	3	0.364		1177	fruit	1 3 5 7	0.03,0.05 0.02, 0.02 0.03,0.02 0.03,0.01	0.04 0.02 0.03 0.02	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-016
USA, 2014 Madera, CA (Fortune)	3	0.366		940	fruit	1	0.05,0.05	0.05	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-018
USA, 2014 Orland, CA (French)	3	0.360		1404	fruit	1	0.30,0.39	0.35	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-017
USA, 2014 Terra Bella, CA (Yummy Beaut)	3	0.364		1372	fruit	1	0.03,0.03	0.03	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-019
USA, 2014 Payette, ID (Empress)	3	0.364		758	fruit	1	0.22,0.20	0.21	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-020
USA, 2014 Ephrata, WA (Italian)	3	0.365		1873	fruit	1	0.13,0.15	0.14	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-021
USA, 2014 Newberg, OR (Italian)	3	0.364		1263	fruit	1	0.34,0.38	0.36	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-022

Cherry

In the 15 cherry trials, three foliar applications of 0.365 kg ai/ha isofetamid (SC) were applied, at a 6–8 day interval in water volumes of 779–2054 L/ha to single replicate plots.

Table 12 Residues in cherry from supervised trials in Canada and the USA involving three foliar applications of isofetamid (400 g/L SC formulation).

Cherry Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			isofetamid	mean	
GAP: USA	3	0.365		935-1870	fruit	PHI: 1			
GAP: Canada	3	0.365		No more than 1000		PHI: 1			
USA, 2014 Hart, MI (Sweet Dark Cherry, Rynbrandt)	3	0.367		943	fruit	1	0.66,0.66	0.66	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-023

Cherry Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			isofetamid	mean	
USA, 2014 Perry UT (Sweet Cherry, Bing)	3	0.360		2054	fruit	3hr	0.99,1.04	1.02	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-025
USA, 2014 Tulare, CA (cherry, Rainier)	3	0.360		1400	fruit	1	1.01,0.70	0.86	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-026
USA, 2014 Westley, CA (Sweet cherry, Royal Hazel)	3	0.360		935	fruit	1	3.42,1.62	2.52	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-027
USA, 2014 Ephrata, WA (Sweet cherry, Bing)	3	0.362		1026	fruit	1	1.11,1.16	1.14	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-028
USA, 2014 Ephrata, WA (Sweet cherry, Skeena)	3	0.356		1865	fruit	1	1.45,1.18	1.32	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-029
USA, 2014 Mosier, OR (Sweet cherry, Bing)	3	0.367		1398	fruit	1 3 5 7	0.40,0.40 0.36,0.36 0.28,0.24 0.29,0.24	0.40 0.36 0.26 0.27	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-030
USA, 2014 Hereford, PA (Tart Cherry, Montmorency)	3	0.364		1338	fruit	6	0.78,0.73	0.76	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-031
Canada, 2014 Branchton, Ontario(Tart Cherry, Meteor)	3	0.362		1196	fruit	1	1.17,1.12	1.15	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-032
Canada, 2014 St. Catharines, Ontario (Tart Cherry, Montmorency)	3	0.354		779	fruit	1	1.33,1.47	1.4	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-033
USA, 2014 Hart, MI. (Tart Cherry, Montmorency)	3	0.361		944	fruit	1	2.36,1.96	2.16	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-034
Canada, 2014 Arkona, Ontario (Tart Cherry, Montmorency)	3	0.363		1005	fruit	4hr	0.31	0.31	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-035

Cherry Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			isofetamid	mean	
USA, 2014 Perry UT (Tart Cherry, Montmorency)	3	0.362		2002	fruit	2hr	1.74,1.67	1.71	Report:IB-2014-JAM-005-01-01 Trial:IB-2014-JLW-005-036

Berries and other small fruits

Blueberry (Subgroup 004B Bush berries)

The results from 10 trials on blueberry conducted in Canada and the USA were provided to the Meeting.

Table 13 Residues in Blueberry from supervised trials in Canada and the USA involving three foliar applications of isofetamid (400 g/L SC formulation).

Blueberry Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			isofetamid	Mean	
GAP: Canada	3	0.395-0.496				PHI: 7			
USA, 2014 Dundee, NY (Blue Ray) c	3	0.639		281	fruit	7	0.263,0.239	0.251	Report:IB-2014-JLW-004-01-01 Trial:IB-2014-JLW-004-01; 1st application date: July 16th; Approximately 19 miles from Branchport
USA, 2014 Branchport, NY (Duke) d	3	0.651		286	fruit	6	0.237,0.301	0.269	Report:IB-2014-JLW-004-01-01 Trial:IB-2014-JLW-004-02; 1st application date: June 14th
USA, 2014 New Tripoli, PA (Weymouth) a	3	0.652		858	fruit	6	0.298,0.299	0.299	Report:IB-2014-JLW-004-01-01 Trial:IB-2014-JLW-004-03; 1st application date: June 10th
USA, 2014 New Tripoli, PA (Dixie) b	3	0.637		747	fruit	7	0.338,0.352	0.345	Report:IB-2014-JLW-004-01-01 Trial:IB-2014-JLW-004-04; 1st application date: July 14th
USA, 2014 Chula, GA (Brightwell (highbush))	3	0.648		734	fruit	7	0.450,0.473	0.462	Report:IB-2014- Report:IB-2014-JLW-004-01-01 Trial:IB-2014-JLW-004-05
USA, 2014 Seven Springs, NC (O'Neal (highbush))	3	0.635		842	fruit	4 8 11 15	4.58,3.88 0.926,0.750 0.959,1.02 0.218,0.189	4.23 0.838 0.990 0.204	Report:IB-2014-JLW-004-01-01 Trial:IB-2014-JLW-004-06
USA, 2014 Bethany, IL (Dukes, Patriots, Blue Ray, Blue gold)	3	0.591		435	fruit	7	3.59	3.59	Report:IB-2014-JLW-004-01-01 Trial:IB-2014-JLW-004-07

Blueberry Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			isofetamid	Mean	
Canada, 2014 Ste-Madeleine, QC (Patriot)	3	0.636		249	fruit	7	0.185,0.183	0.184	Report:IB-2014-JLW-004-01-01 Trial:IB-2014-JLW-004-08
USA, 2014 Fennville, MI (Jersey (Felker))	3	0.638		944	fruit	8	0.950,0.598	0.774	Report:IB-2014-JLW-004-01-01 Trial:IB-2014-JLW-004-09
USA, 2014 Hillsboro, OR (Blue Crop)	3	0.651		571	fruit	7	0.945,0.827	0.886	Report:IB-2014-JLW-004-01-01 Trial:IB-2014-JLW-004-10

[a] The Weymouth variety is an early season, upright variety. Date of the first application: June 10th.

[b] The Dixie variety is a late season, very spreading variety with large berries. Date of the first application: July 14th.

[c] The Blue Ray variety is a mid-season, spreading plant with extra-large berries. Date of the first application: June 14th.

[d] The Duke variety is an early season, upright plant with medium-large, light blue berries. Date of the first application: July 16th.

Raspberry (Subgroup 004A Cane berries)

The results from five supervised trials (one decline curve trial and four at harvest trials) on raspberries in Canada and the USA were provided to the Meeting.

Raspberries were fortified over the range of 0.01–4.1 mg/kg for isofetamid and GPTC. The averages and standard deviations for isofetamid and GPTC in raspberries (n=13) were 90 ± 4.4 and 95 ± 5.0%, respectively.

Table 14 Residues in raspberries from supervised trials in Canada and the USA involving 3 foliar applications of isofetamid (SC formulation)

Raspberry Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha (mean)	kg ai/hL	water (L/ha)			isofetamid	Mean	
Canada GAP	3	0.395-0.496				PHI 7			
USA, 2014, Tripoli/PA (Boyne)	3	0.647 0.633 0.639 (0.640)	0.136 0.136 0.136	474 464 468	fruit	0 2 6 13	3.53,3.59 2.18,2.28 0.448, 0.620 0.152,0.158	3.56 2.23 0.534 0.155	Report: IB-2014-JLW-004-01-01 Trial: IB-2014-JLW-004-11
USA, 2014, Oregon/WI (Autumn Bliss)	3	0.655 0.650 0.649 (0.651)	0.053 0.054 0.053	1231 1201 1227	fruit	6	0.181,0.222	0.205	Report: IB-2014-JLW-004-01-01 Trial: IB-2014-JLW-004-12
USA, 2014, Hillsboro/OR (Willamette) a	3	0.651 0.627 0.626 (0.635)	0.113 0.113 0.114	574 554 562	fruit	7	1.32,1.38	1.35	Report: IB-2014-JLW-004-01-01 Trial: IB-2014-JLW-004-13
USA, 2014, Sherwood/OR (Meeker) b	3	0.647 0.633 0.630 (0.637)	0.113 0.113 0.113	573 560 558	fruit	7	1.47,1.70	1.59	Report: IB-2014-JLW-004-01-01 Trial: IB-2014-JLW-004-14
Canada, 2014, Abbotsford/BC (Meeker)	3	0.650 0.628 0.638 (0.639)	0.117 0.117 0.117	557 537 547	fruit	7	0.941,0.810	0.876	Report: IB-2014-JLW-004-01-01 Trial: IB-2014-JLW-004-15

[a] The Willamette variety is an extremely large, nearly round berry that ripens early.

[b] The Meeker variety is a large, thimble-shaped berry with a long, willowy growth habitat and a long harvest season.

Assorted tropical and subtropical fruits - inedible peel

Kiwi fruit (Subgroup 006E Assorted tropical and subtropical fruits - inedible peel -vines)

The results from three supervised on kiwis in the USA were provided to the Meeting.

Kiwi fruit were fortified over the range of 0.01–4.0 ppm for isofetamid and 0.01–0.10 ppm for GPTC. The averages and standard deviations for isofetamid (n=11) and GPTC (n=8) were 89 ± 5.7 and 94 ± 3.6%, respectively.

Table 15 Residues in kiwi fruit from supervised trials in the USA involving 3 foliar applications of isofetamid (SC formulation).

Raspberry Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha (mean)	kg ai/hL	water (L/ha)			isofetamid	Mean	
Canada GAP	3	0.395- 0.496				PHI 7			
USA, 2014, Porterville/CA (Hayward)	3	0.637 0.644 0.643 (0.641)	0.041 0.042 0.042	1545 1564 1545	fruit	7	1.09,0.688	0.889	Report: IB-2014-JLW-004-01-01 Trial: IB-2014-JLW-004-13
USA, 2014, Gridley/CA (Chico)	3	0.653 0.651 0.652 (0.652)	0.070 0.070 0.070	936 936 936	fruit	7	<0.01,<0.01	<0.01	Report: IB-2014-JLW-004-01-01 Trial: IB-2014-JLW-004-14
USA, 2014, Sanger/CA (Hayward)	3	0.644 0.639 0.638 (0.640)	0.135 0.135 0.135	478 468 468	fruit	7	4.26,3.34	3.80	Report: IB-2014-JLW-004-01-01 Trial: IB-2014-JLW-004-15

Legume Vegetables

Beans with pods (Subgroup 14A)

The Meeting received data from eight supervised residue trials (at harvest trials/end-point) on snap beans which were conducted in Canada and the USA.

Table 16 Residues in snap beans from supervised trials in Canada and the USA involving 2 foliar applications of isofetamid (SC formulation).

Snap beans Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			isofetamid	mean	
USA GAP	2	0.5				PHI 7			
USA, 2012, North Rose/NY [a] (CA Red Kidney)	2	0.502 0.508	0.117 0.117	430 435	Whole pods (dry)	51	0.020,0.016	0.018	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-01
USA, 2012, Seven Springs/NC (Contender)	2	0.487 0.487	0.217 0.212	224 229	Whole pods	3 5 7 9	0.167,0.192 0.187,0.241 0.082,0.072 0.069,0.060	0.180 0.214 0.077 0.065	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-02
USA, 2012, Bradenton/FL (Roma II Bush Bean)	2	0.503 0.499	0.283 0.263	178 190	Whole pods	5	0.143,0.175	0.159	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-03

Snap beans Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			isofetamid	mean	
USA, 2012, Geneva/MN (Great Northern)	2	0.499 0.498	0.189 0.191	264 260	Whole pods	6	0.355,0.295	0.325	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-04
USA, 2012, Bagley/IA (Cow Peas-CA Buckeye #5)	2	0.509 0.525	0.261 0.261	195 201	Whole pods	7	0.087,0.104	0.096	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-05
USA, 2012, Sharon/ND, (Navy Ensign)	2	0.511 0.504	0.214 0.214	238 235	Whole pods	7	0.191,0.123	0.157	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-07
USA, 2012, Hillsboro/OR (Snap)	2	0.501 0.493	0.254 0.254	197 194	Whole pods	7	0.055,0.059	0.057	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-17
Canada, 2012, Ehn Creek, Manitoba (Pinto-Windbreaker)	2	0.508 0.508	0.250 0.250	203 203	Whole pods	7	0.036,0.025	0.031	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-08

[a] analysis sample was dried pods.

Succulent beans without pods (Subgroup 14C)

The Meeting received data from six supervised residue trials which were conducted 2014 in USA (one decline curve trial and five at harvest trials).

Table 17 Residues in lima beans from supervised trials in the USA involving 2 foliar applications of isofetamid (SC formulation).

Lima beans Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			isofetamid	mean	
USA GAP	2	0.5				PHI 14			
USA, 2014, Smithfiled/VA (Early Thorogreen)	2	0.508 0.501	0.177 0.138	286 362	Lima bean seeds	14	0.006,0.007	0.007	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-01
USA, 2014, Seven Springs/NC (Jackson Wonder bush)	2	0.490 0.491	0.150 0.142	331 343	Lima bean seeds	30	ND,ND	ND	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-02
USA, 2014, Chula/GA (Jackson Wonder)	2	0.495 0.491	0.182 0.181	272 276	Lima bean seeds	14	ND,ND	ND	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-03
USA, 2014, Bagley/IA (Fordhook 242)	2	0.490 0.490	0.173 0.157	283 311	Lima bean seeds	23	ND,ND	ND	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-04
USA, 2014, Madera/CA (Fordhook 242)	2	0.495 0.500	0.151 0.153	326 329	Lima bean seeds	34 41 48 55	ND,ND ND,ND ND,ND ND,ND	ND ND ND ND	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-05
USA, 2014, Payette/ID, (Fordhook 242)	2	0.506 0.506	0.180 0.180	284 284	Lima bean seeds	28	ND,ND	ND	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-06

ND=not detected (<0.005 ppm)

Succulent peas without pods (Subgroup 14D)

The Meeting received residue trials in green pea conducted 2014 in Canada and the USA (1 decline curve trial and 10 at harvest trials).

Table 18 Residues in peas (green) from supervised trials in Canada and the USA involving 2 foliar applications of isofetamid (SC formulation).

Peas without pods Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			isofetamid	mean	
USA GAP	2	0.5				PHI 14			
USA, 2014, Germansville/PA (Maestro)	2	0.501 0.503	0.164 0.163	306 307	Peas	9	ND,ND	ND	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-07
USA, 2014, Seven Geneva/MN (Sugar Ann)	2	0.494 0.492	0.172 0.173	288 283	Peas	5	ND,ND	ND	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-08
USA, 2014, Bagley/IA (Sugar Sprint)	2	0.493 0.488	0.135 0.174	365 278	Peas	34 37 40 43	ND ND ND,ND ND	<0.01 <0.01 <0.01 <0.01	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-09
USA, 2014, Northwood/ND (Oregon Trail)	2	0.486 0.492	0.130 0.175	371 281	Peas	3	0.012,0.020	0.016	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-10
USA, 2014, Sharon/ND (Oregon Trail)	2	0.494 0.489	0.132 0.131	376 372	Peas	2	0.017,0.012	0.015	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-11
USA, 2014, Brookings/SD, (Sugar Snap)	2	0.488 0.501	0.168 0.170	291 294	Peas	17	ND,ND	ND	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-13
USA, 2014, Fitchburg/WI (Jumpstart)	2	0.494 0.499	0.152 0.142	325 352	Peas	11	0.025,0.020	0.023	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-14
USA, 2014, Parkdale/OR (Progress 9)	2	0.498 0.473	0.164 0.147	303 322	Peas	7	<0.01, <0.01	<0.01	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-16
USA, 2014, Hillsboro/OR (Columbia)	2	0.478 0,506	0.150 0.180	318 281	Peas	7	ND,ND	ND	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-17
Canada, 2014, St-Marc-sur- Richelieu/QC (Alexandra)	2	0.495 0.492	0.165 0.164	300 300	Peas	13	ND,ND	ND	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-12
Canada, 2014, Taber/AB (Carbee)	2	0.501 0.502	0.165 0.166	303 303	Peas	3	0.017,0.010	0.014	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-15

ND=Not Detected (<0.005 ppm), LOQ=0.01 ppm

Peas with pods (Subgroup 14B)

The Meeting received residue trials in edible-podded pea (green pea pods) conducted in the USA (3 at harvest trials) in 2014.

Table 19 Residues in peas with pods from supervised trials in the USA involving 2 foliar applications of isofetamid (SC formulation).

Peas with pods Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			isofetamid	mean	
USA GAP	2	0.5				PHI 7			
USA, 2014, Seven Geneva/MN (Sugar Ann)	2	0.494 0.492	0.172 0.173	288 283	whole pods	3	0.97,0.77	0.87	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-08
USA, 2014, Bagley/IA (Sugar Sprint)	2	0.493 0.488	0.135 0.174	365 278	whole pods	40	<0.01,ND	<0.01	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-09
USA, 2014, Northwood/ND (Oregon Trail)	2	0.486 0.492	0.130 0.175	371 281	whole pods	3	0.27,0.27	0.27	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-10

ND=Non Detected (<0.005 ppm), LOQ=0.01 ppm

Pulses

Dry beans

The Meeting received the results of 15 supervised trials (1 decline curve trial and 14 at harvest trials) on dry beans conducted in Canada and the USA.

Table 20 Residues in dry beans from supervised trials in Canada and the USA involving 2 foliar applications of isofetamid (SC formulation).

Dry beans Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			isofetamid	mean	
USA GAP	2	0.5				PHI 30			
USA, 2012, North Rose/NY (CA Red Kidney)	2	0.502 0.508	0.117 0.117	430 435	Seeds	51	ND,ND	ND	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-01
USA, 2012, Geneva/MN (Great Northern)	2	0.499 0.498	0.189 0.191	264 260	Seeds	30	ND,ND	ND	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-04
USA, 2012, Bagley/IA (Cow Peas-CA Buckeye #5)	2	0.509 0.525	0.261 0.261	195 201	Seeds	32	<0.01,<0.01	<0.01	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-05
USA, 2012, Northwood/ND, (Navy Ensign)	2	0.306 0.505	0.215 0.215	142 235	Seeds	20 25 30 35	ND,ND ND,ND ND,ND ND,ND	ND ND ND ND	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-06
USA, 2012, Sharon/ND, (Navy Ensign)	2	0.511 0.504	0.214 0.214	238 235	Seeds	30	ND,ND	ND	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-07
USA, 2012, Carrington City/ND (Navy Ensign)	2	0.497 0.513	0.214 0.214	232 239	Seeds	29	ND,ND	ND	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-09
USA, 2012, Velva/ND, (Pinto Windbreaker)	2	0.493 0.502	0.253 0.254	195 197	Seeds	46	ND,ND	ND	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-10
USA, 2012, Loveland/TX, (Black Eye Pea)	2	0.507 0.493	0.212 0.212	238 232	Seeds	30	ND,<0.01	<0.01	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-13
USA, 2012, Jerome,/ID (Tendergreen)	2	0.490 0.511	0.187 0.198	262 258	Seeds	40	ND,ND	ND	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-14

Dry beans Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			isofetamid	mean	
USA, 2012, Orland/CA, (Lima Baby Green)	2	0.497 0.497	0.212 0.212	234 234	Seeds	42	ND,ND	ND	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-15
USA, 2012, Jerome/ID, (Small Reds)	2	0.505 0.500	0.171 0.180	296 277	Seeds	39	ND,ND	ND	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-16
Canada, 2012, Ehn Creek, Manitoba (Pinto-Windbreaker)	2	0.508 0.508	0.250 0.250	203 203	Seeds	39	ND,<0.01	<0.01	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-08
Canada, 2012, Dundurn,/SK (White Envoy)	2	0.492 0.416	0.250 0.224	197 185	Seeds	33	0.043,0.029	0.036	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-11
Canada, 2012, Broderick/SK (White Envoy)	2	0.493 0.444	0.250 0.237	197 187	Seeds	36	ND,ND	ND	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-12
Canada, 2012, Minto/MB (Pinto Windbreaker)	2	0.501 0.499	0.249 0.250	201 199	Seeds	46	ND,ND	ND	Report: IB-2012-JLW-006-01-01 Trial: IB-2012-JLW-006-18

ND: <0.005mg/kg

Dry Peas

The Meeting received residue trials in dry peas conducted in Canada and the USA in 2014 and 2015 (one decline curve and 12 at harvest trials).

Table 21 Residues in dry peas from supervised trials in Canada and the USA involving 2 foliar applications of isofetamid (SC formulation).

Dry Peas Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			isofetamid	mean	
USA GAP	2	0.5				PHI 30			
USA, 2014, Carrington/ND (Oregon Trail)	2	0.491 0.488	0.131 0.131	375 372	Seeds	36	ND,ND	ND	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-18
USA, 2014, Velva/ND (Agassiz)	2	0.488 0.497	0.169 0.168	289 295	Seeds	25	<0.01,ND	<0.01	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-19
USA, 2014, Hastings/NE (Midas)	2	0.492 0.485	0.175 0.173	282 281	Seeds	30	0.02,0.02	0.02	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-20
USA, 2014, St. Lawrence/SD (Sugar Snap)	2	0.495 0.498	0.170 0.169	292 294	Seeds	42 45 48 51	0.02,0.03 ND,ND 0.11,0.05 ND,ND	0.025 ND 0.08 ND	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-21
USA, 2014, Payette/ID (Austrian Winter)	2	0.510 0.500	0.178 0.178	286 281	Seeds	31	ND,ND	ND	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-22
USA, 2014, Parkdale/OR (Progress 9)	2	0.498 0.473	0.135 0.124	369 380	Seeds	26	ND,ND	ND	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-23
USA, 2014, Jerome/ID (Carousel)	2	0.490 0.499	0.164 0.162	299 308	Seeds	30	ND,ND	ND	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-24

Dry Peas Country, year Location (Variety)	Application				Matrix	DAT	Residues (mg/kg)		Reference & Comments
	N	kg ai/ha	kg ai/hL	water (L/ha)			isofetamid	mean	
USA, 2014, Hermiston/OR (Columbia)	2	0.476 0.491	0.163 0.168	292 292	Seeds	21	ND,ND	ND	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-25
USA, 2014, Rupert/ID (Cascadia)	2	0.498 0.496	0.174 0.164	287 303	Seeds	21	ND,ND	ND	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-26
Canada, 2014, Minto/MB (CDC Meadow)	2	0.505 0.492	0.166 0.161	304 306	Seeds	29	<0.01,ND	<0.01	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-27
Canada, 2014, Boissevain/MB, (Agassiz)	2	0.503 0.503	0.152 0.152	332 332	Seeds	28	ND,ND	ND	Report: IB-2014-JLW-006-01-01 Trial: IB-2014-JLW-006-28
Canada, 2015, Alvena/SK, (CDC Amarillo)	2	0.507 0.511	0.164 0.164	310 312	Seeds	34	ND,ND	ND	Report: IB-2015-JAM-007-01-01 Trial: IB-2015-JLW-007-01
Canada, 2015, Wakaw/SK (Treasure)	2	0.487 0.500	0.164 0.164	297 305	Seeds	35	ND,ND	ND	Report: IB-2015-JAM-007-01-01 Trial: IB-2015-JLW-007-02

FATE OF RESIDUES IN STORAGE AND PROCESSING

Processing

One processing study on apple was conducted in the USA during 2011. Six foliar applications of isofetamid were made at 1.8 kg/ha (5 times the maximum label rate of 5 × 0.365 kg ai/ha), with a PHI of 20 days. Treated and untreated field samples of apple (RAC) were placed in frozen storage (-16 °C) and shipped via freezer trucks to Golden Pacific Labs. The bulk apple samples were batch processed to simulate, as closely as possible, commercial practice.

One processing study on plum was conducted in the USA during 2014. Three foliar applications of isofetamid were made at 1.8 kg/ha (5 times the maximum label rate of 5 × 0.365 kg ai/ha), with a PHI of 1 day. For the prune processing phase, plums at harvest were dried in the field, bagged and otherwise treated the same as RAC samples.

Table 22 Isofetamid residues in apple and processed commodities

Location, Country; Year; (variety)	Process type (Trial application rate)	Commodity	Residue of isofetamid (mg/kg)	Processing Factor (PF) [a]	Trial no.
North Rose, NY USA 2011 (Ida Red)	Apple juice and wet pomace (6×1.8 kg ai/ha)	Apple (RAC)	1.143	--	Trial No: IB-201 I-JLW-003-02
		Apple juice	0.357	0.31	
		Wet pomace	4.638	4.06	

[a] The factor is the ratio of isofetamid residues in the processed item divided by the residue of isofetamid in the RAC.

Table 23 Isofetamid residues in plum and processed commodities

Location, Country; Year; (variety)	Process type (Trial application rate)	Commodity	Residue of isofetamid (mg/kg)	Processing Factor (PF) [a)]	Trial no.
Madera, CA USA 2014 (Fortune)	Dried prune (3×1.8 kg ai/ha)	Plum (RAC)	0.340, 0.372	--	Trial No: IB-2014-JLW-005-18
		Dried prune	1.47, 1.34	4.1, 3.8 [3.95]	

[a] The factor is the ratio of isofetamid residues in the processed item divided by the residue of isofetamid in the RAC.

Animal Feeding Study

The Meeting received a dairy cow feeding study.

An isofetamid feeding study in diary cows was conducted in the USA in 2015. Isofetamid was administered orally once daily in the diet to dairy cows for 28 days at levels of 0.5 (low), 1.5 (mid) and 5.0 (high) ppm diet dry wt/day. The cows in the control group received placebos (empty capsules) concurrently with the treated animals. Three additional cows from the high-dose group were maintained for up to 7 days after the 28-day dosing-period to provide depuration information. Cows were milked twice daily. Milk samples were collected beginning on study day -1 and then daily throughout test-week 1 and every 3 days throughout the remaining 28-day dosing-period. Milk samples were collected daily during the depuration phase. On days 13 and 28 pooled milk from the control, low-dose and high-dose groups were separated into skim milk and cream. Cows were humanely terminated on day 29. Tissues were collected within 24 hours of administration of the last dose of isofetamid. For the depuration phase, one cow was humanely terminated on days 30, 32 and 36. Approximately 1 kg each, when available, of loin and leg muscle, subcutaneous, abdominal and perirenal fat, liver and kidney was collected from each animal. Samples were analysed using a validated method SMV 8256542, see study 8256542 (Richardson, M. and Heslop, D. 2013).

Method validation at 0.01 mg/kg (LOQ) and 0.05 mg/kg was performed within the study. The limit of quantitation (LOQ) was set at 0.01 mg/kg based on the lowest fortification level. The limit of detection (LOD) was set at 0.0034 mg/kg based on the lowest standard in the calibration curve.

The metabolite PPA was not detected (below the limit of detection, <0.0034 mg/kg) in any of the samples of milk, muscle, fat, kidney or liver. Isofetamid residues were below the LOQ (0.01 mg/kg) in all matrices from all dose groups.

APPRAISAL

Isofetamid is a succinate dehydrogenase inhibitor (SDHI) fungicide with a single site of action that inhibits cellular respiration. Isofetamid was first evaluated for toxicology and residues by the JMPR in 2016. The 2016 JMPR set an ADI of 0–0.05 mg/kg bw and an ARfD of 3 mg/kg bw for isofetamid. The 2016 Meeting also concluded that the residue definition for plant commodities for compliance with the MRL and for dietary risk assessment was parent isofetamid. The residue definition for compliance with the MRL and dietary risk assessment for animal commodities was, the sum of isofetamid and 2-[3-methyl-4-[2-methyl-2-(3-methylthiophene-2-carboxamido) propanoyl] phenoxy] propanoic acid (PPA), expressed as isofetamid. The residue is fat-soluble.

Isofetamid was scheduled at the Forty-ninth Session of the CCPR for the evaluation of additional uses by the 2018 JMPR. The Meeting received information on use patterns, supervised residue trials and processing studies. A dairy cow feeding study was also provided to the Meeting along with an analytical method for isofetamid and PPA residues in milk and liver matrices.

Methods of analysis

The 2016 JMPR Meeting reviewed analytical methods for isofetamid in plant commodities, and for isofetamid and PPA in animal commodities. All methods were sufficiently validated and acceptable for the consideration of the residue data and enforcement. The methods for determining isofetamid residues in plant commodities including pome fruit, stone fruit, blueberry, raspberry, kiwi fruit, snap bean, lima bean, green bean, dry bean and dry pea were supported with concurrent recovery data from supervised trials submitted to the current Meeting. Analytical methods for determining isofetamid and PPA in cattle milk and liver matrices were independently validated and the methods were considered to be equivalent with the methods for animal commodities reviewed by 2016 JMPR. The methods were considered suitable for the plant and animal commodities evaluated.

Stability of pesticide residues in stored analytical samples

The 2016 JMPR indicated that isofetamid residues are stable at -20 °C for at least 12 months in almonds, rape seeds, grapes, lettuce, potatoes and dry beans.

The current Meeting received residue storage stability data for isofetamid in almonds, rape seed, grapes, lettuce, potatoes and dry beans. Residues of isofetamid in these commodities are stable for at least 24 months when stored frozen at approximately -20 ºC.

The Meeting also received a residue study on the stability of isofetamid and PPA in milk, liver, kidney, muscle and fat. Isofetamid and PPA were found to be stable for at least 68 days in milk, muscle, fat, kidney and liver.

The Meeting agreed that the demonstrated storage stability in various representative plant and animal commodities covered the residue sample storage intervals used in the field trials considered by the current Meeting.

Results of supervised residue trials on crops

The Meeting received information on supervised field trials involving foliar treatments of isofetamid to pome fruits (including apple and pear), stone fruits (including peach, plum and cherry), berries, kiwi fruit, grape, legume vegetables and pulses.

Pome fruits

Results of supervised trials on apple and pear conducted in Canada and the USA were provided to the Meeting.

Apple and Pear

The critical GAP for isofetamid on pome fruits in the USA is for 6 foliar applications of 0.365 kg ai/ha with a re-treatment interval of 7 days and a PHI of 20 days.

In 16 trials on apples conducted in North America matching the GAP in the USA, the residues of isofetamid in apples (whole fruit) were (n = 16): 0.030, 0.042, 0.049, 0.066, 0.075, 0.083, 0.11, 0.14, 0.17(2), 0.18(2), 0.27(2), 0.32 and 0.38 mg/kg.

In eight trials on pears conducted in North America matching the GAP in the USA, the residues of isofetamid in pears (whole fruit) were (n = 8): 0.041, 0.043, 0.13(3), 0.14, 0.15 and 0.29 mg/kg.

The Meeting noted that residues from apples and pears were similar (Mann-Whitney test) and could be combined. The combined residue data set were (n = 24): 0.030, 0.041, 0.042, 0.043, 0.049, 0.066, 0.075, 0.083, 0.11, 0.13(3), 0.14(2), 0.15, 0.17(2), 0.18(2), 0.27(2), 0.29, 0.32 and 0.38 mg/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg, a STMR of 0.135 mg/kg and a HR of 0.42 mg/kg (highest individual value) for isofetamid on the group of pome fruits.

Stone fruits

Results from supervised trials on peach, plum and cherry conducted in Canada and the USA were provided to the Meeting.

The critical GAP for isofetamid on stone fruits in Canada and the USA is for up to 3 foliar applications of 0.365 kg ai/ha with a re-treatment interval of 7 days and a PHI of 1 day.

Peaches

In 11 trials on peach conducted in North America and matching the GAP of the USA, residues of isofetamid were (n = 11): 0.24, 0.32, 0.45, 0.54, 0.68, 0.76, 0.78, 0.83, 0.88, 1.3 and 1.7 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg, a STMR of 0.76 mg/kg and a HR of 1.7 mg/kg for isofetamid on the subgroup of peaches.

Plums

In eight trials on plums conducted in North America and matching the GAP of the USA, the residues of isofetamid were (n = 8): 0.03, 0.05(2), 0.14, 0.21, 0.33, 0.35 and 0.36 mg/kg.

The Meeting estimated a maximum residue level of 0.8 mg/kg, a STMR of 0.175 mg/kg and a HR of 0.39 mg/kg (highest individual) for isofetamid on the subgroup of plums.

Cherries

In 13 trials on cherry conducted in North America and matching the GAP of the USA, the residues of isofetamid were (n = 13): 0.31, 0.40, 0.66, 0.76, 0.86, 1.0, 1.1, 1.2, 1.3, 1.4, 1.7, 2.2 and 2.5 mg/kg.

The Meeting estimated a maximum residue level of 4 mg/kg, a STMR of 1.1 mg/kg and a HR of 3.4 mg/kg (highest individual) for isofetamid on the subgroup of cherries.

Berries and other small fruits

Bush berries

The critical GAP for isofetamid in “Berry and Small Fruit Crop Group” from Canada is for 3 foliar applications at 0.496 kg ai/ha with a re-treatment interval (RTI) of 7 days and a PHI of 7 days.

In several trials in similar locations the varietal and management differences were considered likely to result in sufficiently different residue scenarios and thus were considered to be independent.

In 10 independent trials on blueberry conducted in North America and similar to the Canadian GAP but at higher application rates of 0.650 kg ai/ha the residues of isofetamid in blueberry were (n = 10): 0.18, 0.25, 0.27, 0.30, 0.34, 0.46, 0.77, 0.89, 0.99 and 3.6 mg/kg.

Using the proportionality approach, residue weree scaled with factors ranging from 0.761 to 0.839.

Scaled isofetamid residues were (n = 10): 0.14, 0.19, 0.20, 0.23, 0.27, 0.35, 0.59, 0.68, 0.77 (factor 0.781) and 3.0 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg, a STMR of 0.31 mg/kg and a HR of 3.0 mg/kg for isofetamid on the subgroup of bush berries.

Cane berries

The critical GAP for isofetamid on cane berries included in "Berry and Small Fruit Crop Group 13-07" in Canada is for 3 foliar applications at 0.496 kg ai/ha with a re-treatment intervals of 7 days and a PHI of 7 days.

In five independent trials on raspberries conducted in North America, and similar to the Canadian GAP but at higher application rates of 0.650 kg ai/ha, the residues of isofetamid in raspberries were (n = 5): 0.20, 0.53, 0.88, 1.4 and 1.6 mg/kg.

Using the proportionality approach, residues were scaled with factors ranging from 0.762 to 0.781.

Scaled isofetamid residues were (n = 5): 0.16, 0.41, 0.68, 1.1 and 1.2 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg, a STMR of 0.68 mg/kg and a HR of 1.2 mg/kg for isofetamid on subgroup of cane berries.

Assorted tropical and subtropical fruits – inedible peel

Kiwi fruit

The critical GAP for isofetamid on "Fruit, Small Vine Climbing Fruit except Grapes Subgroup 13-07E" in the USA is for 4 foliar applications at 0.448 kg ai/ha (seasonal maximum of 1.794 kg ai/ha) with re-treatment intervals of 14 days and a PHI of 7 days.

In three trials conducted in the USA, 3 foliar applications of 0.65 kg ai/ha with a PHI of 7 days resulted in isofetamid residues in kiwi fruits of (n = 3): < 0.01, 0.89 and 3.8 mg/kg.

The Meeting agreed that there were insufficient data with which to estimate a maximum residue level for kiwi fruit.

Legume vegetables

The critical GAP for isofetamid in legume vegetables in Canada and the USA is for the following foliar applications:

- beans and peas with pods: 2 × 0.5 kg ai/ha, 7-14 days RTI and a PHI of 7 days;
- Succulent beansand peas without pods: 2 × 0.5 kg ai/ha, 7–14 days RTI and a PHI of 14 days.

Beans with pods

In seven trials on snap beans conducted in Canada and the USA, matching the critical GAP the residues of isofetamid were (n = 7): 0.031, 0.057, 0.077, 0.096, 0.16, 0.16 and 0.32 mg/kg.

Peas with pods

None of the submitted trials matched the cGAP. The Meeting noted that as beans with pods is a representative crop for both the subgroup of beans with pods and the subgroup of peas with pods, the maximum residue level recommendation for beans with pods could also be applied to peas with pods.

Based on the data for snap beans the Meeting estimated a maximum residue level of 0.6 mg/kg, a STMR of 0.096 mg/kg and a HR of 0.36 mg/kg (highest individual) for isofetamid on subgroup of beans with pods and for subgroup of peas with pods.

Succulent beans without pods

The critical GAP for isofetamid in "Legume Vegetables, Edible podded" in Canada is for 2 foliar applications at 0.5 kg ai/ha with a re-treatment interval of 7 days and a PHI 14 days.

In two trials on lima beans conducted in the USA and matching the critical GAP the residues of isofetamid were (n = 2): < 0.01 (2) mg/kg.

The Meeting agreed that there was insufficient data to estimate a maximum residue level for succulent beans without pods.

Succulent peas without pods

In three trials on peas conducted in Canada and the USA, and matching the cGAP the residues of isofetamid were (n = 3): < 0.01(2) and 0.023 mg/kg.

The Meeting agreed that there was insufficient data to estimate a maximum residue level for succulent peas without pods.

Pulses

The critical GAP for isofetamid on pulses including dry beans and dry peas in the USA and Canada is for 2 foliar applications of 0.5 kg ai/ha with a 7 day re-treatment interval and a PHI of 30 days.

Dry beans

In eight trials on dry beans conducted in North America and matching the critical GAP the residues of isofetamid were (n = 8): < 0.01 (7), 0.036 mg/kg.

Dry peas

In 11 trials on dry peas conducted in North America and matching the critical GAP the residues of isofetamid were (n = 11): < 0.01 (9), 0.02, 0.08 mg/kg.

The Meeting noted that residues from dry beans and dry peas were similar (Mann-Whitney test) and could be combined. The combined residue data were (n = 19): < 0.01 (16), 0.02, 0.036 and 0.08 mg/kg

The Meeting estimated a maximum residue level of 0.05 mg/kg, and a STMR of 0.01 mg/kg for isofetamid on subgroup of dry beans except soya bean, and subgroup of dry peas.

Fate of residues during processing

The Meeting received studies on the effect of processing on isofetamid residues in apple and plum.

Summary of isofetamid processing factors and STMR-P values in apple and plum processed commodities

Matrix	Isofetamid		RAC STMR (mg/kg)	STMR-P (mg/kg)
	Calculated processing factors	PF		
Apple juice	0.31	0.31	0.13	0.04
Apple wet pomace	4.1	4.1		0.53
Dried prune	4.1, 3.8	4.0 (mean)	0.14	0.56

The Meeting estimated a maximum residue level of 4 × 0.8 = 3 mg/kg for dried prune, along with a STMR-P of 4 × 0.14 = 0.56 mg/kg and a HR of 4 × 0.38 = 1.5 mg/kg.

Residues in animal commodities

Farm animal feeding studies

An isofetamid feeding study in dairy cow was provided to the Meeting. Isofetamid was administered orally once daily in the diet to dairy cows for 28 days at levels of 0.5 (low), 1.5 (mid) and 5.01 (high) ppm diet (dry wt/day). The metabolite PPA was not detected in milk, muscle, fat, kidney or liver. Isofetamid residues were below the LOQ (0.01 mg/kg) in all animal matrices.

Estimation of livestock dietary burdens

The current Meeting noted that residues in apple (pomace), dry beans and dry peas may contribute to the livestock dietary burden. The dietary burdens were estimated using the OECD diets listed in Appendix IX of the 2016 edition of the FAO manual. The dietary burden for dairy cattle and beef cattle remained unchanged. The slight increase in estimated maximum and mean dietary burdens for poultry layers (0.008 ppm) were not expected to add significantly to residues in poultry. The meeting confirmed the previous 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 IEDI and IESTI assessment.

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

Definition of the residue for compliance with the MRL and dietary risk assessment for animal commodities: the sum of isofetamid and 2-[3-methyl-4-[2-methyl-2-(3-methylthiophene-2-carboxamido) propanoyl] phenoxy] propanoic acid (PPA), expressed as isofetamid.

The residue is fat-soluble.

	Commodity	Recommended maximum residue level (mg/kg)		STMR or STMR-P (mg/kg)	HR or HR-P (mg/kg)
CCN	Name	New	Previous		
VP 2060	Beans with pods, subgroup of (includes all commodities in this subgroup)	0.6		0.096	0.36
FB 2006	Bush berries, subgroup of (includes all commodities in this subgroup)	5		0.31	3
FB 2005	Cane berries, subgroup of (includes all commodities in this subgroup)	3		0.68	1.2
FS 0013	Cherries, subgroup of (includes all commodities in this subgroup)	4		1.1	3.4
VD 2065	Dry beans, subgroup of (except soya bean (dry))	0.05		0.01	-
VD 2066	Dry peas, subgroup of (includes all commodities in this subgroup)	0.05		0.01	-
FS 2001	Peaches, subgroup of (including Nectarine and Apricots)(includes all commodities in this subgroup)	3		0.76	1.7
VP 2061	Peas with pods, subgroup of (includes all commodities in this subgroup)	0.6		0.096	0.36
FS 0014	Plums, subgroup of (including fresh Prunes) (includes all commodities in this subgroup)	0.8		0.175	0.39
FP 0009	Pome fruits, group of (includes all commodities in this group)	0.6		0.135	0.42
DF 0014	Prunes, dried	3		0.56	1.5

Table of additional STMR/median and HR/highest residue values for use in dietary exposure and livestock dietary burden estimation.

				STMR, STMR-P or median (mg/kg)	HR, HR-P or highest residue (mg/kg)
	Apple juice			0.04	
	Apple wet pomace			0.53	

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for isofetamid is 0–0.05 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for isofetamid 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 2018 JMPR Report. The IEDIs ranged from 0–6% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of isofetamid from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for isofetamid is 3 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for isofetamid were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present JMPR and for which consumption data were available. The results are shown in Annex 4 of the 2018 JMPR Report. The IESTIs varied from 0–3% of the ARfD for children and 0–1% for the general population.

The Meeting concluded that acute dietary exposure to residues of isofetamid from uses considered by the the present JMPR is unlikely to present a public health concern.

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