Lufenuron (286)

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EXPLANATION

Lufenuron is an insect growth inhibitor that is active against larvae of Lepidoptera and Coleoptera. When ingested, lufenuron interferes with chitin synthesis, and prevents larvae from moulting.

Lufenuron was first evaluated by the 2015 JMPR where an ADI of 0–0.02 mg/kg bw was established. An ARfD was determined to be unnecessary. A residue definition of *lufenuron* was determined for compliance with the MRL and for dietary risk assessment for plant and animal commodities.

Lufenuron was proposed by the Forty-ninth Session of the CCPR for the evaluation of additional uses. The current Meeting received new GAP information and supervised field trials on citrus fruits, pome fruits, peaches, carambola, maize, sweet corn and coffee. In addition, processing studies on oranges and apples were provided.

METHODS OF ANALYSIS

An HPLC-UV method was used to analyse all carambola samples collected from the supervised field trials. Briefly, the method involved extraction using acetonitrile and anhydrous Na_2SO_4. PSA powder and $MgSO_4$ are added to the extract prior to centrifuging. The resulting supernatant is dried prior to reconstituting in acetonitrile and subjecting to HPCL-UV (260 nm) analysis. The LOQ was reported to be 0.05 mg/kg. Concurrent method validation at 0.05 mg/kg and 0.5 mg/kg resulted in acceptable mean recoveries of 83–104% and 92–119%, respectively.

Methods used for analysis of lufenuron residues in citrus fruits, pome fruits, peaches, maize and coffee were reviewed previously by the 2015 JMPR (REM 118.07 citrus, apple, coffee; POPIT MET.153 maize) with LOQs of 0.01 mg/kg.

STABILITY OF RESIDUES IN STORED ANALYTICAL SAMPLES

The stability of residues of lufenuron on frozen storage (-18 °C) was evaluated by the 2015 JMPR. Lufenuron is stable for at least 24 months in commodities with high water (cabbage), high acid (orange) and high oil (cotton seed) content.

Additionally, information on the stability of lufenuron in samples of dry beans (high protein) and potato (high starch) stored frozen storage (-20 °C) for 12 months was made available to the Meeting. Samples were fortified at 0.1 mg/kg and stored for 1, 3, 6, 9 and 12 months. Triplicate samples were analysed on day 0 and duplicate samples at all other time points. Samples of dry bean and potato were analysed using method POPIT MET.153 (LOQ of 0.01 mg/kg)

Table 1 Storage stability of lufenuron in dry bean and potato

Matrix	Time (month)	Procedural recoveries (%)	%Remaining in fortified storage sample	Mean %remaining (% of day 0)
Dry bean	0	98, 103	96, 95, 104 (98)	-
	1	105, 107	91, 90 (91)	92
	3	95, 93	83, 88 (86)	87
	6	90, 88	79, 74 (77)	78
	9	76, 89	82, 77 (79)	81
	12	102, 101	90, 88 (89)	90
Potato	0	95, 98	88, 95, 95 (93)	-
	1	93, 93	77, 74 (75)	81
	3	90, 94	68, 71 (70)	75
	6	85, 84	67, 65 (66)	71
	9	89, 90	63, 66 (64)	69
	12	91, 94	67, 68 (67)	73

Lufenuron residues are stable in high protein (dry bean) and high starch (potato) matrices when stored at -20 °C for at least 12 months.

The periods of demonstrated stability cover the frozen storage intervals in the supervised residue trials on crops considered by the current Meeting.

USE PATTERN

The information available to the 2018 JMPR on registered uses of lufenuron relevant to the residue trial data made available is summarised in Table 2.

Table 2 Use of lufenuron (foliar applications EC formulation)

Crop	Country	No (int)	Application rate (g ai/ha)	Spray concentration (g ai/hL)	Spray volume (L/ha)	Interval (days)	PHI (days)
Citrus fruit	Brazil	1		1.25–3.75	10 L/plant (grd) 20 L/ha✈	-	28
Pome fruit	Chile	3		5	>2	NS	18
Fruit trees	Algeria	-	7.5–50			NS	28
Carambola	Malaysia	2	50		1000	NS	3
Maize	Brazil	1	15		150–400 (grd) 20✈	-	35
Coffee	Brazil	2	30–40		400	30	7

grd = application using ground-based equipment

✈ = application by aircraft

NS = not specified

RESULTS OF SUPERVISED RESIDUE TRIALS ON CROPS

The Meeting received information on supervised field trials on the following crops or crop groups:

Commodity	Table
Citrus (oranges, limes)	3
Pome (apples)	4
Peaches	5
Carambola	6
Maize	7
Coffee	8

Residue values from the trials conducted according to critical GAP have been used for the estimation of maximum residue levels. Those results included in the evaluation are underlined.

Citrus fruit

Table 3 Residues of lufenuron (mg/kg) in citrus (Ito 2017 S16-04237) (mean of duplicate samples) following a single foliar application of lufenuron in an EC-formulation

Location, year, variety CITRUS	N (interval, days)	Rate (g ai/hL)	Spray volume (L/ha)	Growth Stage	DALA	Sample	lufenuron (mg/kg)
Oranges							
Bairro do Porto, Limeira – SP, Brazil, 2016 Valência	1	3.76	10 L/plant	86	14	Fruit	0.09 0.09 (0.09)
					21		0.09 0.10 (0.10)
					28		0.08 0.08 (0.08)
					35		0.07 0.09 (0.08)
					42		0.08 0.09 (<u>0.09</u>)
					14	Juice	<0.01 <0.01 (<0.01)
					21		<0.01 <0.01 (<0.01)
					28		<0.01 <0.01 (<0.01)
					35		<0.01 <0.01 (<0.01)
					42		<0.01 <0.01 (<0.01)

Location, year, variety CITRUS	N (interval, days)	Rate (g ai/hL)	Spray volume (L/ha)	Growth Stage	DALA	Sample	lufenuron (mg/kg)
Bairro Imbiriçu, Aguai – SP, Brazil 2016 Pêra-rio	1	3.76	10 L/plant	86	14 21 28 35 42	Fruit	0.07 0.07 (0.07) 0.08 0.07 (0.08) 0.07 0.06 (0.07) 0.07 0.06 (0.07) 0.06 0.08 (0.07)
					14 21 28 35 42	Juice	<0.01 <0.01 (<0.01) <0.01 <0.01 (<0.01) <0.01 <0.01 (<0.01) <0.01 <0.01 (<0.01) <0.01 <0.01 (<0.01)
Bairro Terra Queimada, Conchal – SP, Brazil 2016 Pêra-rio	1	3.76		86	14 21 28 35 42	Fruit	0.08 0.07 (0.08) 0.09 0.08 (0.09) 0.12 0.10 (0.11) 0.07 0.08 (0.08) 0.09 0.10 (0.10)
					14 21 28 35 42	Juice	<0.01 <0.01 (<0.01) <0.01 <0.01 (<0.01) <0.01 <0.01 (<0.01) <0.01 <0.01 (<0.01) <0.01 <0.01 (<0.01)
Brazil Vila Formosa, Potirendaba – SP Brazil 2016 Valência	1	3.76	11 L/plant	86	14 21 28 35 42	Fruit	0.08; 0.08 (0.08) 0.10; 0.10 (0.10) 0.09; 0.08 (0.09) 0.06; 0.05 (0.06) 0.07; 0.08 (0.08)
					14 21 28 35 42	Juice	<0.01 <0.01 (<0.01) <0.01 <0.01 (<0.01) <0.01 <0.01 (<0.01) <0.01 <0.01 (<0.01) <0.01 <0.01 (<0.01)
Bairro Baguaçu, Olimpia – SP, Brazil 2016 Pêra-rio	1	3.76	10 L/plant	85	28	Fruit	0.10 0.08 (0.09)
					28	Juice	<0.01 <0.01 (<0.01)
Bairro Rio Claro, Monte Alto – SP, Brazil 2016 Pêra-rio	1	3.76	10 L/plant	84	28	Fruit	0.05 0.05 (0.05)
					28	Juice	<0.01 <0.01 (<0.01)
Bairro Barrero Farto, Arthur Nogueira – SP Brazil 2016 Valência	1	3.76	10 L/plant	86	28	Fruit	0.15 0.14 (0.15)
					28	Juice	<0.01 <0.01 (<0.01)
Bairro São João, Ibitinga – SP, Brazil 2016 Valência	1	3.76	10 L/plant	86	28	Fruit	0.05 0.04 (0.05)
					28	Juice	<0.01 <0.01 (<0.01)
Lime							
Fernando Prestes a Olaria, Fernando Prestes – SPBrazil 2016 Quebra - galho	1	3.76	10 L/plant	86	14 21 28 35 42	Fruit	0.11 0.12 (0.12) 0.07 0.06 (0.07) 0.10 0.07 (0.09) 0.05 0.05 (0.05) 0.05 0.06 (0.06)

Location, year, variety CITRUS	N (interval, days)	Rate (g ai/hL)	Spray volume (L/ha)	Growth Stage	DALA	Sample	lufenuron (mg/kg)
					14	Juice	<0.01 <0.01 (<0.01)
					21		<0.01 <0.01 (<0.01)
					28		<0.01 <0.01 (<0.01)
					35		<0.01 <0.01 (<0.01)
					42		<0.01 <0.01 (<0.01)
Bairro Boa Vista, Itápolis – SP, Brazil 2016 Fly dragon	1	3.76	10 L/plant	79	14	Fruit	0.15 0.15 (0.15)
					21		0.18 0.15 (0.17)
					28		0.18 0.15 (0.17)
					35		0.12 0.13 (0.13)
					42		0.11 0.13 (0.12)
					14	Juice	<0.01 <0.01 (<0.01)
					21		<0.01 <0.01 (<0.01)
					28		<0.01 <0.01 (<0.01)
					35		<0.01 <0.01 (<0.01)
					42		<0.01 <0.01 (<0.01)
Bairro São João de Itaguaçu, Urupês – SP, Brazil 2016 Quebra -galho	1	3.76	10 L/plant	78	28	Fruit	0.09 0.10 (0.10)
					28	Juice	<0.01 <0.01 (<0.01)
Bairro da Estrela, Tabapuã – SP Brazil 2016 Quebra -galho	1	3.76	10 L/plant	78	28	Fruit	0.10 0.08 (0.09)
					28	Juice	<0.01 <0.01 (<0.01)

Table 4 Residues of lufenuron (mg/kg) in apples (Woodard 2017 TK0163986) (mean of duplicate samples) following applications of lufenuron in an EC-formulation

Location, year, variety APPLE	N (interval, days)	Rate (g ai/hL)	Spray volume (L/ha)	Growth Stage	DALA	Sample	lufenuron (mg/kg)
Morza Chile (2016) Fuji	3 (10, 9)	5	4504	81	0	Fruit	0.25 0.22 (0.24)
		5	4560	85	7		0.25 0.24 (0.25)
		5	4489	85	14		0.26 0.25 (0.26)
					21		0.22 0.35 (0.29)
					28		0.18 0.26 (0.22)
Curico Chile (2016) Fuji	3 (10, 11)	5	4525	81	0	Fruit	0.37 0.39 (0.38)
		5	4436	85	7		0.32 0.37 (0.34)
		5	4506	87	14		0.38 0.46 (0.42)
					21		0.42 0.44 (0.43)
					28		0.35 0.27 (0.31)
Molina Chile (2016) Pink Lady	3 (11, 10)	5	4527	81	0	Fruit	0.24 0.29 (0.27)
		5	4524	82	7		0.38 0.42 (0.40)
		5	4519	85	14		0.34 0.43 (0.38)
					21		0.28 0.42 (0.35)
					28		0.37 0.34 (0.36)
Chimbarongo Chile (2016) Brookfield	3 (10, 11)	5	4479	81	0	Fruit	0.32 0.39 (0.36)
		5	4459	85	7		0.39 0.38 (0.39)
		5	4502	87	14		0.32 0.25 (0.29)
					21		0.37 0.22 (0.30)
					28		0.24 0.24 (0.24)
Rengo Chile (2016) Brookfield	3 (10, 10)	5	4554	81	0	Fruit	0.28 0.30 (0.29)
		5	4491	83	7		0.31 0.32 (0.32)
		5	4516	85	14		0.30 0.26 (0.28)
					21		0.28 0.26 (0.27)
					28		0.26 0.26 (0.26)

Location, year, variety APPLE	N (interval, days)	Rate (g ai/hL)	Spray volume (L/ha)	Growth Stage	DALA	Sample	lufenuron (mg/kg)
Malloa Chile (2016) Galaxy	3 (10, 10)	5 5 5	4607 4494 4537	81 83 85	0 7 14 21 28	Fruit	0.30 0.35 (0.32) 0.29 0.27 (0.28) 0.33 0.28 (0.31) 0.31 0.29 (0.30) 0.33 0.21 (0.27)
Rancagua Chile (2016) Granny Smith	3 (10, 10)	5 5 5	4528 4460 4501	85 85 87	0 7 14 21 28	Fruit	0.23 0.23 (0.23) 0.23 0.19 (0.21) 0.16 0.19 (0.18) 0.16 0.24 (0.20) 0.11 0.13 (0.12)
Doñihue Chile (2016) Pink Lady	3 (10, 11)	5 5 5	4510 4501 4506	81 83 85	0 7 14 21 28	Fruit	0.22 0.28 (0.25) 0.29 0.17 (0.23) 0.34 0.23 (0.28) 0.30; 0.24 (0.27) 0.22; 0.21 (0.22)

Peaches

Table 5 Residues of lufenuron (mg/kg) in peaches (Gasser 2003a 02-1073, Gasser 2003b 02-1074, Clarke 2004a 03-5056, Clarke 2004b 03-5057, Mason 2006 04-5012, Mason 2005 04-5022) (mean of duplicate samples) following applications of lufenuron in an EC-formulation

Location, year, variety PEACH	N (interval, days)	Rate (g ai/ha)	Spray volume (L/ha)	Growth Stage	DALA	Sample	lufenuron (mg/kg)
Huesca Spain (2002) Babygold 9	2 (14)	48.7 48.4	1012 1006	75 75–77	0 0 14 14 21 21 28 28	Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit	0.16 0.12 0.07 0.09 (0.08) 0.06 0.07 (0.07) 0.05 0.04 (0.05) 0.05 0.04 (0.05) 0.02 0.02 (0.02) 0.02 0.02 (0.02)
Lleida Spain (2002) Tardibelle	2 (13)	48.7 48.2	1013 1022	74–75 77–81	0 0 14 14 21 21 28 28	Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit	0.32 0.30 0.08 0.12 (0.10) 0.08 0.12 (0.10) 0.14 0.10 (0.12) 0.14 0.10 (0.12) 0.13 0.14 (0.14) 0.13 0.14 (0.14)
Monestirolo Italy 2003 Padana	2 (25)	49.7 49.6	994 992	76–77 78–79	0- 0- 0 0 14 14 28 28	Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit	0.02 0.02 0.06 0.06 0.05 0.04 0.03 0.03
Rignano Scalo Italy 2003 Star Red Gold	2 (28)	50.1 50.1	1001 1002	74–75 78–81	0- 0- 0 0 14 14 28 28	Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit	0.03 0.02 0.06 0.06 0.06 0.05 0.03 0.03

Location, year, variety PEACH	N (interval, days)	Rate (g ai/ha)	Spray volume (L/ha)	Growth Stage	DALA	Sample	lufenuron (mg/kg)
Aitona Spain (2004) Landros	2 (14)	51 51	1021 1021	73–74 74	0 0 7 7 13 13 20 21 26 26	Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit	0.08 0.07 0.04 0.04 0.03 0.03 0.03 0.03 0.03 0.03
	2 (14)	51.6 51.4	1031 1028	73–74 74	0 0 7 7 13 13 20 21 26 26	Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit	0.10 0.09 0.03 0.03 0.02 0.02 0.02 0.02 0.03 0.03
Menarguens Spain (2004) Roig D'Albesa	2 (14)	51 49.9	1020 998	78 79	0 0 7 7 14 14 21 21 29 29	Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit	0.08 0.08 0.07 0.07 0.10 0.10 0.06 0.06 0.07 0.07
	2 (14)	51.2 49.8	1025 997	78 79	0 0 7 7 14 14 21 21 29 29	Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit	0.10 0.09 0.06 0.06 0.08 0.08 0.06 0.06 0.05 0.05
Chulilla Spain (2004) Federica	2 (14)	50.8 49.6	1015 992	75 76	0 0 7 7 14 14 21 21 27 27	Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit	0.16 0.13 0.08 0.07 0.05 0.05 0.04 0.04 0.05 0.05
	2 (14)	49 50.2	979 1005	75 76	0 0 7 7 14 14 21 21 27 27	Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit	0.16 0.14 0.07 0.06 0.06 0.05 0.04 0.04 0.04 0.04

Location, year, variety PEACH	N (interval, days)	Rate (g ai/ha)	Spray volume (L/ha)	Growth Stage	DALA	Sample	lufenuron (mg/kg)
Borgo d'Ale Italy (2004) Red Moon	2 (14)	48.8 48.2	976 963	75 81	0 0 7 7 14 14 21 21 28 28	Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit	0.18 0.15 0.06 0.05 0.05 0.05 0.03 0.03 0.02 0.02
	2 (14)	50.3 51.6	1006 1032	75 81	0 0 7 7 14 14 21 21 28 28	Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit	0.21 0.18 0.09 0.08 0.03 0.03 0.03 0.03 0.02 0.02
Badia Polesine Italy (2004) Big Top	2 (14)	49.7 50.3	994 1007	73–75 83–85	0 0 7 7 14 14 21 21 28 28	Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit	0.05 0.04 0.03 0.03 0.02 0.02 0.02 0.02 0.01 0.01
	2 (14)	49.5 49.5	990 990	73–75 83–85	0 0 7 7 14 14 21 21 28 28	Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit	0.03 0.03 0.03 0.03 0.02 0.02 0.02 0.02 0.01 0.01
Via Madrara Italy (2004) Amiga	2 (14)	49.9 49.8	999 995	75 83–84	0 0 7 7 14 14 21 21 28 28	Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit	0.09 0.08 0.10 0.09 0.06 0.05 0.04 0.04 0.05 0.05
	2 (14)	50.1 49.7	1002 994	75 83–84	0 0 7 7 14 14 21 21 28 28	Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit Pulp Fruit	0.09 0.07 0.07 0.06 0.08 0.07 0.06 0.05 0.04 0.04

Table 6 Residues of lufenuron (mg/kg) in carambola (Kwong, 2005, MYF 012005A; Bin Shahrun, 2014, 240-C-1 to 240-C-4) (mean of duplicate samples) following a two foliar applications of lufenuron in an EC-formulation

Location Year Trial ID (variety)	Application					DALA (days)	lufenuron (mg/kg)
	Spray Volume (L/ha)	Rate (g ai/ha)	No.	RTI (days)	Max Rate/ season (g ai/ha)		
Ladang Belimbing, Ulu Mantin, 71700 Mantin, Negeri Sembilan 2005, MYF 012005A (B17)	1000	54	2	7	108	0 1 3 7 14	0.09 0.07 <0.05 0.08 <0.05
	1000	107	2	7	214	0 1 3 7 14	0.08 0.07 0.06 0.09 <0.05
Ladang Belimbing, Ulu Mantin, 71700 Mantin, Negeri Sembilan[1], 2014, 240-C-1 (B10)	1000	54	2	7	108	0	<0.05
						3	<0.05
MARDI Kluang, KM 15, Jalan Kluang-Kota Tinggi, 86009 Kluang, Johor 240-C-2 (B10)	1000	54	2	7	108	0	<0.05
						1	<0.05
						3	0.05
Ladang Belimbing, Batu 8, 71700 Mantin, Negeri Sembilan[1] 240-C-3 (B10)	1000	54	2	7	108	0	<0.05
						1	<0.05
						3	<0.05
MARDI Jelebu, Simpang Durian, 72400 Jelebu, Negeri Sembilan 240-C-4 (B10)	1000	54	2	7	108	0	<0.05
						1	<0.05
						3	0.05

Maize

Table 7 Residues of lufenuron (mg/kg) in maize (JMPR 2015; Iwai 2017 TK0313741) (mean of duplicate samples) following applications of lufenuron in an EC-formulation

Location, year, variety MAIZE	N (interval, days)	Rate (g ai/ha)	Spray volume (L/ha)	Growth Stage	DALA	Sample	lufenuron (mg/kg)
JMPR 2015							
Engenheiro Coelho – SP Brazil 2009 Bandeirante	2	15 15		33–34 51–53	35 82	Immature (=sweetcorn) Grain	<0.01 <0.01
Palmeira – PR Brazil 2009 30 R 50	2	15 15		41–43 49–51	35 66	Immature (=sweetcorn) Grain	<0.01 <0.01
Goiânia – GO Brazil 2009 Impacto	2	15 15		39 51	35 78	Immature (=sweetcorn) Grain	<0.01 <0.01

Location, year, variety MAIZE	N (interval, days)	Rate (g ai/ha)	Spray volume (L/ha)	Growth Stage	DALA	Sample	lufenuron (mg/kg)
Uberlândia – MG Brazil 2009 Master	2	15 15		60 69	35 56	Immature (=sweetcorn) Grain	<0.01 <0.01
Current Meeting							
Primavera do Leste – MT Brazil 2017 30F53	1	15	400	75	35	Grain	<0.01
Araguari – MG Brazil 2017 Supremo vip	1	15	400	85	35	Grain	<0.01
Bandeirantes – PR Brazil 2017 XB 7116	1	15	400	75	35	Grain	<0.01
Cabeceiras – GO Brazil 2017 Supremo viptera	1	15	400	89	35	Grain	<0.01

Table 8 Residues of lufenuron (mg/kg) in green coffee beans (JMPR 2015; Draetta 2017 TK0313740) (mean of duplicate samples) following applications of lufenuron in an EC-formulation

Location, year, variety COFFEE	N (interval, days)	Rate (g ai/ha)	Spray volume (L/ha)	Growth Stage	DALA	Sample	lufenuron (mg/kg)
JMPR 2015							
Holambra – SP Brazil 2006 Mundo Nova	2 (30)	40 40		73–77 85–87	3 7 10	Beans Beans Beans	<0.01 <0.01 <0.01
Santa Amélia – PR Brazil 2006 Obatá	2 (30)	40 40		73–77 85–87	3 7 10	Beans Beans Beans	<0.01 <0.01 <0.01
Monte Carmelo - MG Brazil 2006 Mundo Nova	2 (30)	40 40		85 89	3 7 10	Beans Beans Beans	<0.01 <0.01 <0.01
Indianópolis - MG Brazil 2006 Mundo Nova	2 (30)	40 40		85 89	3 7 10	Beans Beans Beans	<0.01 <0.01 <0.01
Current Meeting							
Sooretama - ES Brazil 2017 Conilon	2 (30)	42.8 41.7	429 418	81 85	3 7 10	Beans Beans Beans	0.02 0.03 0.02
São Mateus - ES Brazil 2017 Conilon	2 (30)	41.1 41.1	412 412	81 89	3 7 10	Beans Beans Beans	0.01 0.01 0.01
Poços de Calda - MG Brazil 2017 Catuai	2 (30)	40 40	401 401	83 88	3 7 10	Beans Beans Beans	0.03 0.03 <0.01
Campinas - SP Brazil 2017 Catuai amarelo	2 (30)	38.9 40.9	390 410	77 88	3 7 10	Beans Beans Beans	<0.01 0.04 <0.01

FATE OF RESIDUES IN PROCESSING

Oranges

The effect of processing on residues of oranges was made available to the Meeting (Ito 2017 S16-04237).

Fruit samples from two trials conducted at an exaggerated rate (bulk samples) were processed using procedures designed to simulate commercial practices. Samples of fruit were washed with water using an extraction machine (Citrus Extractor – JBT, Model 391) separated into peel, dry pulp, juice and emulsion. Each sample was homogenised. The emulsion samples were

filtered through a sieve and juice sample were filtered using the Finisher JBT, model UCF 35. For analysis, the emulsion was centrifuged to separate the oil.

Table 9. Residues of lufenuron (mg/kg) in orange commodities after processing oranges (Ito 2017 S16-04237) (mean of duplicate samples)

Location, year, variety ORANGES	N	Rate (g ai/hL)	DALA	Sample	Lufenuron (mg/kg)	Processing factor (PF)
Arthur Nogueria – SP Brazil 2016 Valencia	1	18.8	28	RAC	0.53	-
				Peel	0.76	1.4
				Juice	<0.01	<0.02
				Pulp dry	0.06	0.11
				Oil	9.8	19
Ibitinga – SP Brazil 2016 Valencia	1	18.8	28	RAC	0.28	
				Peel	0.57	2
				Juice	<0.01	<0.04
				Pulp dry	0.05	0.18
				Oil	8.2	29

Apple

One field trial was conducted on pome fruits in the EU (France) in 2003, where two applications of 5 g ai/hL were applied (Clarke 2003 03-5072). Approximately 77 kg of fruit were harvested for further processing.

Fruit samples were washed with water and sampled for analysis. Unwashed fruit were crushed and pressed. Wet pomace samples were taken and the pomace dried in an oven at 60 °C. To the juice, pectolytic enzymes were added and after storage for 12 hours the juice was filtered and raw juice samples taken. Pasteurisation was conducted at 85 °C and pasteurised juice samples taken. Unwashed fruit were blanched, crushed and sieved into puree. Wet pomace samples were taken. Sugar was added to the purée and heated. Samples of purée were taken. Residues determined in whole apple fruit (RAC) and its associated processed fractions (wet pomace, dry pomace, juice and purée) are shown in Table 10.

Table 10 Residues of lufenuron (mg/kg) in apple commodities after processing apples (Clarke 2003 03-5072) (mean of duplicate samples)

Location, year, variety APPLE	N (interval, days)	Rate (g ai/hL)	DALA	Sample	Lufenuron (mg/kg)	Processing factor (PF)
Beaucaire France 2003 Golden	2 (13)	5 5	28	RAC	0.05	
				Pomace wet	0.24	4.8
				Pomace dry	0.88	17.6
				Juice	<0.01	<0.2
				Juice pasteurised	<0.01	<0.2
				Purée	<0.01	<0.2

In summary, residues of lufenuron concentrated in orange peel, orange oil and apple pomace. (Table 11).

Table 11 Summary of lufenuron processing factors

Commodity	Processing fraction	Processing factor (PF)	Best estimate PF
Orange	Peel	1.4, 2.0	1.7
	Juice	<0.02, <0.04	<0.02
	Dried pulp	0.11, 0.18	0.145
	Oil	19, 29	24
Apple	Pomace, wet	4.8	4.8
	Pomace, dry	17.6	17.6
	Juice	<0.2	<0.2
	Pureé	<0.2	<0.2

APPRAISAL

Lufenuron is an insect growth inhibitor that is active against larvae of Lepidoptera and Coleoptera. When ingested, lufenuron interferes with chitin synthesis, and prevents larvae from moulting.

Lufenuron was first evaluated by the 2015 JMPR where an ADI of 0–0.02 mg/kg bw was established. An ARfD was determined to be unnecessary.

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

The residue is fat-soluble.

Lufenuron was scheduled by the Forty-ninth Session of the CCPR for the evaluation of additional use patterns by the 2018 JMPR. The current Meeting received new GAP information and supervised field trials on citrus fruit, pome fruit, peaches, carambola, maize, sweet corn, and coffee along with processing studies on oranges and apples.

Methods of analysis

An HPLC-UV method, used to analyse all carambola samples collected from the supervised field trials, with a validated LOQ of 0.05 mg/kg, was determined to be acceptable.

Methods used for analysis of residues in citrus fruit, pome fruit, peaches, maize, sweet corn and coffee were previously reviewed by the 2015 JMPR (REM 118.07 citrus, apple, coffee; POPIT MET.153 maize) with LOQs of 0.01 mg/kg.

Storage Stability of residues in stored analytical samples

The stability of lufenuron residues during frozen storage (-18 °C) was evaluated by the 2015 JMPR. Lufenuron is stable for at least 24 months in commodities with high water (cabbage), high acid (orange) and high oil (cotton seed) content.

The current Meeting received frozen storage stability data for dry beans and potatoes. Lufenuron was determined to be stable for at least 12 months in commodities with high protein (dry beans) and high starch (potato) content.

The periods of demonstrated stability cover the frozen storage intervals used in the supervised field trials considered by the current Meeting.

Results of supervised residue trials on crops

Citrus fruits

The critical GAP in Brazil for citrus fruit is one application at 3.75 g ai/hL with a 28-day PHI.

Residues in trials from Brazil on oranges conducted according to the critical GAP were (n = 8): 0.05 (2), 0.07, 0.09 (3), 0.11 and 0.15 mg/kg.

The Meeting estimated a maximum residue level and STMR for the subgroup of oranges sweet, sour of 0.3 mg/kg and 0.09 mg/kg, respectively

In trials from Brazil on limes matching the critical GAP, residues were (n = 4): 0.09 (2), 0.10 and 0.17 mg/kg.

The Meeting estimated a maximum residue level and STMR for limes of 0.4 mg/kg and 0.10 mg/kg, respectively.

Pome fruit

The critical GAP in Chile for pome fruit is three applications at 5 g ai/hL with an 18-day PHI.

Residue trials were reported from Chile where three applications were made at 5 g ai/hL with sampling at 0, 7, 14, 21 and 28 days after application.

The Meeting noted there was little decline in residues and agreed that residues in samples collected at 14 or 21 days reflect critical GAP. Residues in 8 trials approximating critical GAP in Chile were: 0.20, 0.28 (2), 0.29, 0.30, 0.31, 0.38 and 0.43 mg/kg.

The Meeting estimated a maximum residue level and STMR for apples of 1 mg/kg and 0.29 mg/kg, respectively. Noting the use in Chile is for pome fruit, the Meeting agreed to extrapolate the recommendation to the pome fruit crop group.

Peaches

In Algeria, the critical GAP for lufenuron on tree fruit is for foliar application at 50 g ai/ha and a 28-day PHI with a maximum number of applications not specified.

Trials were available from Italy and Spain where trees received two foliar applications at 50 g ai/ha. As lufenuron is a persistent residue (t ½ 28 days), the Meeting was unable to determine whether additional sprays or shorter intervals between sprays would make a significant contribution to the terminal residues, therefore, a maximum residue level was not estimated.

Carambola

In Malaysia, the critical GAP for lufenuron on carambola is a maximum of 2 foliar spray applications at 50 g ai/ha and a PHI of 3 days.

In the supervised field trials, fruits were wrapped with papers during the growing stage to protect against fruit flies. As the Malaysian GAP does not specify the requirement to wrap/cover the fruit, the Meeting concluded that a maximum residue level could not be estimated in the absence of trials conducted in accordance with the critical GAP (unwrapped fruit).

Maize

The critical GAP for lufenuron on maize is in Brazil with a single foliar application at 15 g ai/ha and a 35-day PHI.

In trials from Brazil matching the critical GAP, residues were (n = 4) : < 0.01 (4) mg/kg. In addition, four trials were reported by the 2015 JMPR on maize, where two foliar applications were made with harvest at 35 days (immature corn=sweet corn) and at approximately 50 days after the last application (maize), residues were < 0.01 mg/kg for both immature and mature maize.

The Meeting concluded there is no expectation of residues above the LOQ of 0.01 mg/kg and estimated a maximum residue level and STMR of 0.01 mg/kg and 0.01 mg/kg, respectively, for maize.

Coffee beans

The critical GAP in Brazil for lufenuron on coffee is two foliar applications at 40 g ai/ha at an interval of 30 days with a 7-day PHI.

In trials from Brazil matching the critical GAP, residues in green coffee beans were (n = 8) < 0.01 (4), 0.01 (1), 0.03 (2) and 0.04 mg/kg.

The Meeting estimated a maximum residue level and STMR of 0.07 mg/kg and 0.01 mg/kg, respectively, for coffee beans.

Fate of residues during processing

Residues in processed commodities

Processing studies on oranges were reviewed by the Meeting. A summary of relevant lufenuron processing factors is provided below.

	Processed Fraction	Processing Factor (PF)[a]	Best estimate PF	RAC STMR or median	STMR×PF= STMR-P (mg/kg)	Highest residue-P (mg/kg)
Orange	Peel	1.4, 2.0	1.7	0.09	0.153	0.51
MRL 0.3	Juice	< 0.02, < 0.04	< 0.02		0.01*	
	Dried pulp	0.11, 0.18	0.145		0.013	
	Oil	19, 29	24		2.16	7.2
Apple	Pomace, wet	4.8	4.8	0.29	1.42	
MRL 1	Pomace, dry	17.6	17.6		5.19	17.6
	Juice	< 0.2	< 0.2		0.06	
	Purée	< 0.2	< 0.2		0.06	

[a] PF = residues lufenuron in processed commodity divided by lufenuron in RAC

STMR-P for juice is from actual supervised trials where residues were measured.

Residues of lufenuron concentrated in orange peel, orange oil and apple dry pomace.

The Meeting recommended a maximum residue level of 8 mg/kg for orange oil.

Residues in animal commodities

Estimation of livestock dietary burdens

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the JMPR. The dietary burdens, estimated using the OECD diets listed in Appendix IX of the 2016 edition of the FAO manual, are presented in Annex 6 and summarised below.

Potential cattle feed items include: citrus pulp, apple pomace, potato culls, maize grain, soya beans and tomato pomace.

Summary of livestock dietary burden (ppm)

	US-Canada	EU	Australia	Japan

	Max	mean	Max	Mean	max	Mean	Max	Mean
Beef cattle	0.02	0.02	1.17	1.17	1.17 [a]	1.17 [c]	0.008	0.008
Dairy cattle	0.59	0.59	0.6 [b]	0.6 [d]	0.59	0.59	0.009	0.009
Broilers	0.01	0.01	0.013	0.013	-	-	0.008	0.008
Layers	0.009	0.009	0.013 [e]	0.013 [f]	-	-	0.009	0.009

[a] Highest maximum beef or dairy cattle dietary burden suitable for maximum residue level estimates for mammalian tissues

[b] Highest maximum dairy cattle dietary burden suitable for maximum residue level estimates for mammalian milk

[c] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.

[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

[e] Highest maximum poultry dietary burden suitable for maximum residue level estimates for poultry meat and eggs

[f] Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues and eggs

Animal commodity maximum residue levels

As noted by the 2015 JMPR, two feeding studies on lactating cows and steers were available. Since no accumulation of residues in steers compared to dairy cows was observed, the Meeting decided to base its recommendations for mammalian products on the lactating cow feeding study, generally showing higher residues at identical intake levels.

The calculations used in estimating maximum residue levels and STMR values are shown below.

	Feed level (ppm) for milk residues	Residues (mg/kg) in milk	Feed level (ppm) for tissue residues	Residues (mg/kg) in			
				Muscle	Liver	Kidney	Fat
maximum residue level beef or dairy cattle							
Feeding study [a]	0.82	0.16 (cream 3.1)	4.3	0.26	0.39	0.23	5.3
			0.82	0.04	0.07	0.04	1.2
Dietary burden and high residue	0.6	0.117 (cream 2.29)	1.17	0.06	0.10	0.06	1.61
STMR beef or dairy cattle							
Feeding study [b]	0.82	0.16 (cream 3.1)	4.3	0.125	0.37	0.22	4.1
			0.82	0.03	0.06	0.03	0.73
Dietary burden and median residue estimate	0.6	0.117 (cream 2.29)	1.17	0.04	0.09	0.05	1.07

[a] highest residues for tissues and mean residues for milk

[b] mean residues for tissues and mean residues for milk

The Meeting replaces its previous recommendations of 0.7 mg/kg for mammalian fats and meat (from mammals other than marine mammals), 0.04 mg/kg for edible offal, 0.1 mg/kg for milks and 2 mg/kg for milk fats with the following estimated maximum residue levels: milk, 0.15 mg/kg; milk fat, 5 mg/kg (based on cream assuming it contains 50% fat); meat (mammalian except marine mammals), 2 mg/kg; mammalian fat (except milk fat), 2 mg/kg and edible offal 0.15 mg/kg (based on liver). The Meeting estimated the following STMRs: milk 0.117 mg/kg; milk fat 4.58 mg/kg; meat (mammalian except marine mammals) 0.04 mg/kg; mammalian fat (except milk fat) 1.07 mg/kg; liver 0.09 mg/kg and kidney 0.05 mg/kg.

RECOMMENDATIONS

On the basis of the data from supervised field trials, the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI assessment.

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

The residue is fat soluble.

CCN	Commodity Name	Maximum residue level, mg/kg	STMR, STMR-P or median (mg/kg)

		New	Previous	
SB 0716	Coffee beans	0.07	-	0.01
MO 0105	Edible offal (Mammalian)	0.15	0.04	0.09 liver 0.05 kidney
FC 0205	Lime	0.4	-	0.10
MF 0100	Mammalian fats	2	0.7	1.07
MM 0095	Meat (mammalian except marine mammals)	2 (fat)	0.7	0.04 muscle 1.07 fat
GC 0645	Maize	0.01	-	0.01
ML 0106	Milks	0.15	0.1	0.117
FM 0103	Milk fats	5	2	4.58
FC 0004	Oranges sweet, sour, Subgroup of (includes all commodities in this subgroup)	0.3	-	0.09
OR 0004	Orange oil, edible	8	-	2.16
FP 0009	Pome fruits, Group of (includes all commodities in this group)	1	-	0.29
JF 0004	Orange juice			0.01
	Apple juice			0.06
	Apple puree			0.06
	Citrus pulp, dry			0.01305
	Apple pomace, dry			5.192

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for lufenuron is 0–0.02 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for lufenuron 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 2–10% of the maximum ADI.

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

Acute dietary exposure

The 2015 JMPR decided that an ARfD for lufenuron was unnecessary. The Meeting therefore concluded that the acute dietary exposure to residues of lufenuron resulting from uses that have been considered by the current Meeting is unlikely to present a publich health concern.

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