KRESOXIM-METHYL (199)

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EXPLANATION

Kresoxim-methyl is a strobilurin fungicide, acting by inhibiting mitochondrial respiration.

Kresoxim-methyl was first evaluated for toxicology and residues by JMPR in 1998 and a periodic evaluation was conducted by the 2018 JMPR. An ADI of 0-0.3 mg/kg bw was established and an ARfD was not considered necessary.

For plant commodities, the definition of the residue for compliance with the MRL is: kresoxim-methyl and for dietary risk assessment is: Sum of kresoxim-methyl and metabolites (2E)-(methoxyimino){2-[(2-methylphenoxy)methyl]phenyl}acetic acid (490M1), and (2E)-{2-[(4-hydroxy-2-methylphenoxy)methyl]phenyl}(methoxyimino)acetic acid (490M9) including their conjugates, expressed as kresoxim-methyl

For animal commodities, the definition of the residue for compliance with the MRL and for dietary risk assessment is: Sum of metabolites (2E)-(methoxyimino){2-[(2-methylphenoxy)methyl]phenyl}acetic acid (490M1), and (2E)-{2-[(4-hydroxy-2-methylphenoxy)methyl]phenyl}(methoxyimino)acetic acid (490M9), expressed as kresoxim-methyl

The residue is not fat-soluble.

The 2018 JMPR also noted that if future uses of kresoxim-methyl result in an increase of the dietary exposure to metabolite 490M2, to more than the threshhold of toxicological concern (TTC) for a Cramer Class III compound, a reconsideration of the residue definition for dietary exposure may be necessary.

Kresoxim-methyl was scheduled at the Fiftieth Session of the CCPR for evaluation of additional uses by the 2019 JMPR. The Meeting received new GAP information and new supporting residue information for pome fruit.

METHODS OF RESIDUE ANALYSIS

Analytical methods

The 2018 JMPR reviewed and summarized analytical method descriptions and validation data for kresoxim-methyl and metabolites 490M1, 490M2 and 490M9 in plant matrices and for metabolites 490M1, 490M2 and 490M9 in animal matrices.

These methods (including BASF Methods 350/3 and 351/1 used in the pome fruit field trials) employed extraction with methanol or methanol/water, liquid-liquid partitioning (isooctane or dichloromethane), SPE (silica gel, C18 or NH₂ cartridge) clean-up and LC-MS/MS, GC-ECD or GC-MS analysis for kresoxim-methyl. The LOQ for kresoxim-methyl is 0.05 mg/kg.

Method 350/3 (LC-LC-UV) also included an alkaline hydrolysis step (10 M KOH, 1 hour) to measure residues of kresoxim-methyl as kresoxim acid (490M1) and an additional enzymatic hydrolysis step (hesperidinase and β -glucosidase) to measure metabolites 490M2 and 490M9 (free and conjugated). The LOQs for kresoxim-methyl plus 490M2 and for metabolite 490M2 are both 0.05 mg/kg.

STABILITY OF PESTICIDE RESIDUES IN STORED ANALYTICAL SAMPLES

The 2018 JMPR concluded that in frozen stored analytical samples, residues of kresoxim-methyl and metabolites 490M2 and 490M9 were stable in high starch and high protein matrices for at least 24 months. In high water and high acid content matrices, residues of kresoxim-methyl and the 490M2 and 490M9 glucosides were stable for at least 12 months in high water and acid content matrices.

USE PATTERNS

New information on GAP in Australia, China, Europe, Japan, South America, and the USA was provided to the Meeting for foliar applications of WG formulations of kresoxim-methyl on pome fruit. The relevent GAP information from the available labels is summarized in following table.

Table 1 Registered uses of kresoxim-methyl on pome fruit – foliar applications (WG formulations).

Crop	Country	A	Applicatio	n	Ma	ax/season	PHI (days)	Remarks
		kg ai/ha	g	water L/ha	no	kg ai/ha		
		(max)	ai/100L	(min)				
				Pome fru	ıits			
Pome fruit a	USA	0.22		2800	4	0.9	30	7-14 day RTI
Apples	Australia		5		3		42	7-10 day RTI
	Belgium	0.1	6.5	1500	4		35	10-14 day RTI
	Canada	0.225			4	0.9	30	10-14 day RTI
	France	0.1			2		28	10 day minimum RTI
	Netherlands	0.1			4		28	7 day minimum RTI
	Spain	0.1		200	4		28	7-14 day RTI
	UK	0.1		150	4		28	10-14 day RTI
Pears	Australia		5		3		42	7-10 day RTI
	Belgium	0.1	6.5	1500	4		35	10-14 day RTI
	Canada	0.18			4	0.72	30	7-14 day RTI
	France	0.1			2		28	10 day minimum RTI
	Netherlands	0.1	10		4		28	7 day minimum RTI
	Spain	0.1		200	4		28	7-14 day RTI
Medlar	France	0.1			2		28	10 day RTI
Crabapple	France	0.1			2		28	10 day minimum RTI
Nashi pear	France	0.1			2		14	10 day minimum RTI
Quince	France	0.1			2		14	10 day minimum RTI
	Spain	0.1		200	4		28	7-14 day RTI

^a USA: **Pome fruit**: Includes apple; crabapple; loquat; mayhaw; pear; pear, oriental; quince.

RESULTS OF SUPERVISED RESIDUE TRIALS ON CROPS

The Meeting evaluated new pome fruit information from North America and Europe.

The supervised trials were well documented with laboratory and field reports. Laboratory reports included procedural recoveries with spiking at residue levels similar to those occurring in samples from the supervised trials. Intervals of freezer storage between sampling and analysis were recorded for all trials and were covered by the conditions of the freezer storage stability studies.

Results from replicated field plots are presented as average values and have not been corrected for concurrent method recoveries. Residues and application rates have been rounded to two significant digits and the results from trials conducted according to the maximum GAP and used for the estimation of maximum residue levels have been (underlined).

Control (untreated) plots were sampled and analysed in all trials, and if residues in these control samples exceeded the LOQ, this is reported as (c=nn mg/kg).

Where results from separate plots with distinguishing characteristics such as different formulations, varieties or treatment schedules were reported, results are listed for each plot, and the highest value has been used in calculations of maximum residue levels and STMRs. Trials that are not considered to be independent have their location information surrounded by a heavy border (Tables 4 and 5).

In the following tables, 'total residues' refers to the sum of kresoxim-methyl and metabolite 490M1 (expressed as kresoxim-methyl – conversion factor: 1.047) plus metabolite 490M9 (expressed as kresoxim-methyl-conversion factor: 0.994).

Pome fruit

Apples, pears

In field trials on apples and pears, conducted in Europe in 1995, eight foliar applications of kresoximmethyl (WG formulations) were applied, about 10 days apart, made using tractor-mounted airblast sprayers or a vertical boom sprayer to apply about 300 litres spray mix/ha, increasing to about 600 litres/ha later in the season. Plot sizes ranged from 28-200 square metres.

Samples of at least 2 kg (or 24 units) whole fruit were frozen and stored for up to 4 months before GC-ECD analysis using Method BASF No. 351/1 to measure residues of kresoxim-methyl. The average recovery rate was 88% and the limit of quantitation (LOQ) was 0.05 mg/kg.

Table 2 Residues of kresoxim-methyl in apples following eight foliar treatments of kresoxim-methyl (WG formulations)

APPLE		Application	on	DALA		Resid			References &
Country, year		I 4				(mg/			Comments
Location	no	kg ai/ha	water		Kresoxim-	490M2	490M9	Total	
(Variety)			(L/ha)		methyl				
GAP: Netherlands	4	0.1	-	28		7-day min	imum retrea	tment into	
Germany, 1994	8	0.099-0.1	310-590	0	0.09				1995/10418
Schleswig-Holstein				21	< 0.05				DO5/02/94
(James Grieve)				28	< 0.05				
				35	< 0.05				
				42	< 0.05				
Germany, 1994	8	0.097-0.11	310-590	0	< 0.05				1995/10418
Baden-Württemberg				21	< 0.05				DU2/02/94
(James Grieve)				29	< 0.05				
				35	< 0.05				
				42	< 0.05				
Germany, 1994	8	0.1	300-610	0	0.12				1995/10418
Rheinland-Pfalz				21	0.07				DU3/03/94
(Melrose)				28	< 0.05				
				35	< 0.05				
				42	< 0.05				
France, 1994	8	0.098-0.11	290-610	0	0.22				1995/10418
31330 Merville				21	0.09				FR8/09/94
Garonne				28	< 0.05				
(Golden)				35	< 0.05				
				42	< 0.05				
France, 1994	8	0.097-0.12	340-640	0	0.19				1995/10418
31340 Sayrac				21	< 0.05				FR8/10/94
Garonne				28	< 0.05				
(Reine d.Reineltes)				35	< 0.05				
D 1 1 1001		0.00=.01	200 (00	42	< 0.05				4007/40440
Belgium, 1994	8	0.097-0.1	290-600	0	0.10				1995/10418
3800 St-Truiden				21	< 0.05				AGR/03/94
Limburg				29	< 0.05				
(Elstar)				35	< 0.05				
NT 1 1 1 1004	0	0.12.0.12	240.710	43	< 0.05				1005/10410
Netherlands, 1994	8	0.12-0.13	340-710	0	0.20				1995/10418
47559 Wykler-				21	< 0.05				AGR/04/94
Groesbeek				28	< 0.05				
Limburg				35	< 0.05				
(Jonagold)		0.006.012	260.650	42	< 0.05				1005/10410
UK, 1994	8	0.086-0.12	260-650	0	0.41				1995/10418
East Malling				20	0.11				OAT/01/94
Kent				27	0.14				
(Cox)				34	0.06				
	1			41	0.06			I	

APPLE		Application	on	DALA		Resid			References &
Country, year						(mg/			Comments
Location	no	kg ai/ha	water		Kresoxim-	490M2	490M9	Total	
(Variety)			(L/ha)		methyl				
UK, 1994	8	0.094-0.11	280-650	0	0.25				1995/10418
Holly Farm, Otham				21	< 0.05				OAT/04/94
Kent				29	0.05				
(Bramley)				36	< 0.05				
				42	< 0.05				
UK, 1994	8	0.096-0.11	310-620	0	0.24				1995/10418
Brenchley				21	< 0.05				OAT/05/94
Kent				29	< 0.05				
(Bramley)				36	< 0.05				
				42	< 0.05				
UK, 1994	8	0.1-0.12	360-600	0	0.99				1995/10418
Gloucestershire				22	0.23				OAT/02/94
(Cox)				28	0.18				
				36	< 0.05				
				42	0.11				
UK, 1994	8	0.08-0.11	240-640	0	0.41				1995/10418
Worcestershire				22	0.22				OAT/03/94
(Cox)				28	0.09				
				36	< 0.05				
				42	0.05				
UK, 1994	8	0.098-0.11	290-620	0	0.43				1995/10418
Cambridgeshire				20	0.15				OAT/06/94
(Bramley)				28	0.06				
				34	0.05				
				42	< 0.05				

Table 3 Residues of kresoxim-methyl in pears following eight foliar treatments of kresoxim-methyl (WG formulations)

PEAR		Application	on	DALA		Resid			References &
Country, year					(mg/kg)				Comments
Location	no	kg ai/ha	water		Kresoxim-	490M2	490M9	Total	
(Variety)			(L/ha)		methyl				
GAP: Netherlands	4	0.1	-	28		7-day min	imum retrea	tment inte	erval
Spain, 1994	8	0.078-0.11	280-660	0	0.11				1995/10418
Sevilla				20	< 0.05				AC/01/94
41800 Sanlucar la				29	< 0.05				
mayor				36	< 0.05				
(Ercolini)				42	< 0.05				
Spain, 1994	8	0.093-0.13	350-620	0	0.05				1995/10418
Huelva				21	< 0.05				AC/02/94
(Blanquilla)				29	< 0.05				
				36	< 0.05				
				42	< 0.05				
Spain, 1994	8	0.088-0.12	275-560	0	0.11				1995/10418
Sevilla				22	< 0.05				AC/03/94
41849 Aznalcazar				28	< 0.05				
(Pasacrasana)				35	< 0.05				
				42	< 0.05				

In field trials on apples and pears, conducted in North America in 1997, four foliar applications of kresoxim-methyl (WG formulations) were applied, about 7 days apart, using tractor-mounted airblast sprayers to apply about 470 litres ('concentrate') or about 2300 litres/ha ('dilute') spray mix/ha. Plot sizes ranged from 48-640 square metres.

Duplicate samples of at least 1.8 kg (or 24 units) whole fruit were frozen within 4 hours of collection and stored for up to 3.5 months before LC-LC-UV analysis using Method BASF No. 350/3 to measure residues of kresoxim-methyl (including metabolite 490M1) and metabolites 490M2 and

490M9. Average recoveries were 87-98% for the three analytes and relative standard deviations (RSD) were < 20 %. The limit of quantitation (LOQ) was 0.05 mg/kg for each analyte.

Table 4 Residues of kresoxim-methyl (including metabolite 490M1) and metabolites 490M2 and 490M9 in apples following four foliar treatments of kresoxim-methyl (WG formulations)

APPLE Country, year	T	Applica	tion	DALA	m	Res	sidues nt equival	ents	References & Comments
Location (Variety)	no	kg ai/ha	water (L/ha)		Kresoxim- methyl	490M2	490M9	Total ^a	-
GAP: USA	4	0.22	(L/III)	30	memyr	7 1/	dor, matera	atment interva	.1
USA, 1997	4	0.22	467-473	29	0.081	< 0.05	< 0.05	0.13	1998/5018
Yates County, NY (MacIntosh)	4	0.17-0.28	407-473	29	0.081	< 0.03	< 0.03	0.13	RCN 97045 last application
	+					0.07			0.23 kg ai/ha
USA, 1997 Wayne County, NY (Northern Spy)	4	0.23	2340-2350	30	<u>< 0.05</u>	0.06	< 0.05	< 0.1	1998/5018 RCN 97046
USA, 1997 Lehigh County, PA (Jonamack)	4	0.23	470-480	30	0.06	< 0.05	< 0.05	0.11	1998/5018 RCN 97047
USA, 1997	4	0.22-0.23	2300-2350	10	0.20	< 0.05	< 0.05	0.25	1998/5018
Berks County, PA				20	0.09	< 0.05	< 0.05	0.14	RCN 97048
(Star Krimson)				30	0.05	< 0.05	< 0.05	0.1	
ľ	1			40	0.05	< 0.05	< 0.05	0.1	
				60	< 0.05	< 0.05	< 0.05	< 0.1	
USA, 1997 Stokes County, NC (Red Delicious)	4	0.22-0.23	460-470	30	0.08	< 0.05	0.05	0.13	1998/5018 RCN 97049
USA, 1997	4	0.22-0.23	2330-2360	30	< 0.05	< 0.05	< 0.05	< 0.1	1998/5018
Carroll County, VA Red)	Ĺ	0.22 0.25	2000 2000			0.00	0.00	0.1	RCN 97050
USA, 1997 Kent Count, MI (Empire)	4	0.22	470-480	30	0.06	< 0.05	0.06	0.12	1998/5018 RCN 97051
USA, 1997	4	0.224	2370-2390	30	< 0.05	< 0.05	0.08	0.13	1998/5018
Ottawa County, MI (Golden Delicious)	-	0.224	2370-2370	30	<u> </u>	V 0.05	0.00	0.13	RCN 97052
USA, 1997 Delta County, CO (Red Delicious)	4	0.22-0.23	460-475	31	< 0.05	0.05	< 0.05	< 0.1	1998/5018 RCN 97055
USA, 1997	4	0.22-0.23	2270-2410	30	0.06	< 0.05	< 0.05	0.11	1998/5018
Cache County, UT (Red Delicious)	4	0.22-0.23	2270-2410	30	0.00	< 0.03	< 0.03	0.11	RCN 97056
USA, 1997 Tulare County, CA (Fuji)	4	0.22-0.23	460-480	30	< 0.05	< 0.05	< 0.05	< 0.1	11998/5018 RCN 97057
USA, 1997 Blatte County, CA (Fuji)	4	0.22-0.23	2330-2390	30	< 0.05	0.06	< 0.05	< 0.1	1998/5018 RCN 97058
USA, 1997	4	0.22-0.23	465-475	10	0.21	0.05	0.06	0.27	1998/5018
Ephrata				20	0.13	0.05	0.05	0.18	RCN 97059
Grant County, WA				30 40	< 0.05 <u>0.05</u>	0.06 < 0.05	< 0.05 < 0.05	< 0.1 0.1	
				60	< 0.05	< 0.05	< 0.05	< 0.1	
USA, 1997 Royal City Grant County, WA	4	0.22	2330-2340	30	< 0.05	< 0.05	< 0.05	< 0.1	1998/5018 RCN 97060
(Red Delicious) USA, 1997 Fruitland Payette County, ID	4	0.22-0.23	435-490	30	< 0.05	< 0.05	< 0.05	< 0.1	1998/5018 RCN 97061
(Law Rome)									

APPLE		Applica	tion	DALA		Res	sidues		References &
Country, year					mg/kg parent equivalents			Comments	
Location	no	kg ai/ha	water		Kresoxim-	490M2	490M9	Total ^a	
(Variety)			(L/ha)		methyl				
USA, 1997	4	0.22-0.23	2285-2330	30	< 0.05	< 0.05	< 0.05	< 0.1	1998/5018
Fruitland									RCN 97062
Payette County, ID									
(Red Delicious)									
USA, 1997 Menomonie	4	0.22	470-480	30	0.08	< 0.05	< 0.05	0.13	1998/5018
Dunn County, WI									RCN 97053
(Paula Red)									
USA, 1997 Menomonie	4	0.23	2300-2370	30	< 0.05	< 0.05	< 0.05	< 0.1	1998/5018
Dunn County, WI									RCN 97054
(MacIntosh)									
USA, 1997	4	0.22-0.23	2210-2360	30	0.07	< 0.05	0.05	0.12	1998/5018
Hood River County, OR									RCN 97064
(Red Delicious)									

Results are average residues from duplicate samples

Table 5 Residues of kresoxim-methyl (including metabolite 490M1) and metabolites 490M2 and 490M9 in pears following four foliar treatments of kresoxim-methyl (WG formulations)

PEAR Country, year		Applica	tion	DALA	mo	Resi	dues t equivale	nta	References & Comments
Location	no	kg ai/ha	water		Kresoxim-	490M2	490M9	Total ^a	Comments
(Variety)			(L/ha)		methyl				
GAP: USA	4	0.22	-	30					
USA, 1997	4	0.22-0.24	460-480	31	< 0.05	< 0.05	0.14	0.19	1998/5040
Lehigh County, PA (Barlet)	4	0.22-0.24	2360-2430	31	< 0.05	< 0.05	0.08	0.13	RCN 97072
USA, 1997	4	0.22	465-495	30	< 0.05	< 0.05	< 0.05	< 0.1	1998/5040
Sacramento County, CA (Bartlet)	4	0.22	2340-2370	30	< 0.05	< 0.05	0.08	0.13	RCN 97073
USA, 1997	4	0.22	415-465	30	< 0.05	< 0.05	< 0.05	< 0.1	1998/5040
Porterville Tulare County, CA (Bosc)	4	0.21-0.22	2445-2640	30	<u>0.06</u>	< 0.05	< 0.05	0.11	RCN 97074
USA, 1997	4	0.22	460-470	30	< 0.05	< 0.05	< 0.05	< 0.1	1998/5040
Porterville	4	0.22	2660-2690	30	< 0.05	< 0.05	0.10	0.15	RCN 97075
Tulare County, CA					*****				
(Tsu-Li)									
USA, 1997	4	0.22	460-475	10	0.12	< 0.05	< 0.05	0.17	1998/5040
Grant County, WA				20	< 0.05	< 0.05	< 0.05	< 0.1	RCN 97076
(D'Anjou)				30	< 0.05	< 0.05	< 0.05	< 0.1	
				40 60	< 0.05 < 0.05	< 0.05 < 0.05	< 0.05 < 0.05	< 0.1 < 0.1	
	4	0.22	2310-2335	10	0.16	< 0.05	0.03	0.23	-
	4	0.22	2310-2333	20	0.16	< 0.05	0.07	0.23	
				30	< 0.05	< 0.05	< 0.07	< 0.13	
				40	< 0.05	< 0.05	< 0.05	< 0.1	
				60	< 0.05	< 0.05	< 0.05	< 0.1	
USA, 1997	4	0.21-0.22	455-465	30	< 0.05	< 0.05	0.16	0.21	1998/5040
Parkdale	4	0.22-0.24	2310-2350	30	< 0.05	< 0.05	0.12	0.17	RCN 97077
Hood River County, OR (Red Bartlet)									
USA, 1997	4	0.22-0.24	460-510	29	< 0.05	< 0.05	0.15	0.2	1998/5040
Hood River Hood River County, OR (Bartlet)									RCN 97184

 $^{^{\}mathrm{a}}$ Sum of kresoxim-methyl (plus 490M1) and metabolite 490M9, expressed as kresoxim-methyl

PEAR		Application				Residues				
Country, year					mg	nts	Comments			
Location	no	kg ai/ha	water		Kresoxim-	490M2	490M9	Total a		
(Variety)			(L/ha)		methyl					
USA, 1997	4	0.22	465-480	30	< 0.05	< 0.05	0.06	0.11	1998/5040	
Payette County, ID	4	0.21-0.22	2280-2300	30	< 0.05	< 0.05	< 0.05	< 0.1	RCN 97078	
(Bartlet)										
Canada, 1997	4	0.22-0.24	460-475	30	< 0.05	< 0.05	< 0.05	< 0.1	1998/5040	
Kings County, NS	4	0.22	2375-2430	30	< 0.05	< 0.05	< 0.05	< 0.1	RCN 97115	
(Clapps Favorite)										
Canada, 1997	4	0.22-0.24	455-475	29	0.09	< 0.05	< 0.05	0.14	1998/5040	
Brant County, ON	4	0.22	2320-2390	29	0.09	< 0.05	< 0.05	0.14	RCN 97116	
(Bosc)										

^a Sum of kresoxim-methyl (plus 490M1) and metabolite 490M9, expressed as kresoxim-methyl

APPRAISAL

Kresoxim-methyl is a strobilurin fungicide, acting by inhibiting mitochondrial respiration.

Kresoxim-methyl was first evaluated for toxicology and residues by JMPR in 1998 and a periodic evaluation was conducted by the 2018 JMPR. An ADI of 0-0.3 mg/kg bw was established and an ARfD was not considered necessary.

For plant commodities, the definition of the residue for compliance with the MRL is: kresoxim-methyl and for dietary risk assessment is: Sum of kresoxim-methyl and metabolites (2E)-(methoxyimino){2-[(2-methylphenoxy)methyl]phenyl}acetic acid (490M1), and (2E)-{2-[(4-hydroxy-2-methylphenoxy)methyl]phenyl}(methoxyimino)acetic acid (490M9) including their conjugates, expressed as kresoxim-methyl

For animal commodities, the definition of the residue for compliance with the MRL and for dietary risk assessment is: Sum of metabolites (2E)-(methoxyimino){2-[(2-methylphenoxy)methyl]phenyl}acetic acid (490M1), and (2E)-{2-[(4-hydroxy-2-methylphenoxy)methyl]phenyl}(methoxyimino)acetic acid (490M9), expressed as kresoxim-methyl

The residue is not fat-soluble.

The 2018 JMPR also noted that if future uses of kresoxim-methyl result in an increase of the dietary exposure to metabolite 490M2, to more than the threshhold of toxicological concern (TTC) for a Cramer Class III compound, a reconsideration of the residue definition for dietary exposure may be necessary.

Kresoxim-methyl was scheduled at the Fiftieth Session of the CCPR for evaluation of additional uses by the 2019 JMPR. The Meeting received new GAP information and new supporting residue information for pome fruit.

Results of supervised residue trials on crops

New supervised trials from Canada and the USA were available for the use of kresoxim-methyl on pome fruit. The analytical methods used in these trials were reviewed by the 2018 JMPR and the demonstrated stability of residues in frozen samples (12 months) covered the storage intervals in the trials considered by the Meeting.

Product labels were available from Australia, Belgium, Canada, France, the Netherlands, Spain, the UK and the USA.

For dietary risk assessment, 'total residues' refers to the sum of kresoxim-methyl and metabolites 490M1 and 490M9, expressed as kresoxim-methyl. The parent-equivalent conversion factors were 1.047 (409M1) and 0.994 (490M9).

Pome fruit

The critical GAP for kresoxim-methyl on pome fruit is in the USA, with a maximum of 4 foliar applications of 0.22 kg ai/ha, a minimum retreatment interval of 7 days and a pre-harvest interval of 30 days.

In trials from Canada and the USA on apples and pears, matching the GAP in the USA, residues of kresoxim-methyl in apples were: < 0.05 (8), 0.05 (2), 0.06 (3), 0.07 and 0.08 (3) mg/kg (n = 17) and in pears were: < 0.05 (6), 0.06 and 0.09 mg/kg (n = 8).

For maximum residue level estimation, the combined kresoxim-methyl data set for apples and pears, matching the critical GAP for pome fruit in the USA is: < 0.05 (14), 0.05 (2), 0.06 (4), 0.07, 0.08 (3) and 0.09 mg/kg (n = 25).

For dietary risk assessment, total residues (parent, 490M1 and 490M9, expressed as kresoxim-methyl) in apples from trials matching the GAP in the USA were: < 0.1 (7), 0.1 (2), 0.11 (2), 0.12 (2), and 0.13 (4) mg/kg and in pears were: < 0.1 (2), 0.11 (2), 0.13, 0.14, 0.19 and 0.2 mg/kg.

The combined data set for total residues in apples and pears, matching the GAP in the USA is: < 0.1 (9), 0.1 (2), 0.11 (4), 0.12 (2), 0.13 (5), 0.14, 0.19 and 0.2 mg/kg (n = 25).

The Meeting estimated a maximum residue level of 0.15 mg/kg for kresoxim-methyl and an STMR of 0.11 mg/kg for total residues in pome fruit except persimmon, Japanese to replace the previous recommendation for pome fruit.

Fate of residues during processing

The 2018 JMPR reviewed information on the fate of kresoxim-methyl and metabolites 490M1 and 490M9 residues during processing of apples.

Table 1 Processing factors for total residues in apple commodities estimated by the 2018 JMPR for dietary exposure estimation

Raw commodity [STMR]	Processed commodity	Individual processing factors	Mean or best estimate processing factor	$STMR-P = \\ STMR_{RAC} \times PF \\ (mg/kg)$	Median residue = STMR _{RAC} × PF (mg/kg)
Apple [0.11 mg/kg]	Apple sauce	0.23, 0.26, 0.27, 0.29, 0.31, 0.50, 0.63	0.29	0.032	
	Wet pomace	0.31, 0.47, 1.4, 2.1, 2.2, 2.6, 2.7, 4.0	2.2		0.24
	Apple juice	0.10, 0.10, 0.12, 0.13, 0.26, 0.30, 0.31, 0.63	0.2	0.022	
	Dried apples	0.23, 0.30, 0.42, 0.61	0.39	0.043	
	Dried pomace	4.5, 8.7, 9.1, 16	8.9		0.98

Residues in animal commodities

Farm animal dietary burden

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the JMPR in 2018 and by the current Meeting.

The additional residue burdens arising from the consumption of wet apple pomace do not change the conclusions of the 2018 JMPR. For <u>beef and dairy cattle</u>, the maximum and mean dietary burdens remain at 3.2 ppm and 1.5 ppm, respectively.

Wet apple pomace is not a component of the poultry diets, and maximum and mean dietary burdens for poultry estimated by the 2018 JMPR remain unchanged.

Animal commodity maximum residue levels

The Meeting agreed that since the kresoxim-methyl maximum and mean livestock dietary burdens have not changed, the 2018 JMPR recommendations for animal commodities need not be revised.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed below in Table 2 are suitable for establishing maximum residue limits and for IEDI assessments.

Definition of the residue for compliance with the MRL for plant commodities: Kresoximmethyl

Definition of the residue for dietary risk assessment for plant commodities: Sum of kresoximmethyl and metabolites (2E)-(methoxyimino){2-[(2-methylphenoxy)methyl]phenyl}acetic acid (490M1), and (2E)-{2-[(4-hydroxy-2-methylphenoxy)methyl]phenyl}(methoxyimino)acetic acid (490M9) including their conjugates, expressed as kresoxim-methyl

Definition of the residue for compliance with the MRL and dietary risk assessment for animal commodities: Sum of metabolites (2E)-(methoxyimino){2-[(2-methylphenoxy)methyl]phenyl}acetic acid (490M1), and (2E)-{2-[(4-hydroxy-2-methylphenoxy)methyl]phenyl}(methoxyimino)acetic acid (490M9), expressed as kresoxim-methyl

The residue is not fat-soluble.

Table 2 Residue levels suitable for establishing maximum residue levels and for dietary exposure

CCN	Commodity	Recomm	nended	STMR or		
			m residue level	STMR-P		
		(mg/kg)		mg/kg		
		New	Previous			
FP 0009	Pome fruit	W	0.2			
FP 0009	Pome fruit (except Persimmon, Japanese)	0.15		0.11		
	Apple sauce			0.032		
JF 0226	Apple juice			0.022		
DF 0226	Apples, dried			0.043		

Table 3 Additional values used in estimating livestock dietary burdens

CCN	Commodity	Median residue (-P) (mg/kg)	(mg/kg)
	Apple pomace (wet)	0.24	

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for kresoxim-methyl (and applying to metabolites 490M1 and 490M9) is 0–0.3 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for kresoxim-methyl were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2019 JMPR Report.

The IEDIs ranged from 0–0.4% of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of kresoxim-methyl from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The 2018 JMPR decided that an ARfD for kresoxim-methyl is unnecessary. The Meeting therefore concluded that the acute dietary exposure to residues of kresoxim-methyl from the uses considered is unlikely to present a public health concern.

Threshold of toxicological concern (TTC) consideration for metabolites

Metabolite 490M2

The 2018 JMPR applied the TTC approach to assess the metabolite 490M2 and concluded that the maximum long-term dietary exposure (0.30 $\mu g/kg$ bw per day) was below the 1.5 $\mu g/kg$ bw per day threshold for a Cramer Class III compound.

The current Meeting noted that with the additional residue contribution from the pome fruit commodities considered by the Meeting, the maximum long-term dietary exposure for metabolite 490M2 increased to 0.34 $\mu g/kg$ bw per day. The Meeting concluded that dietary exposure to residues of 490M2 in food commodities considered by the current and previous Meetings is unlikely to present a public health concern.

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