PYRIMETHANIL (226)

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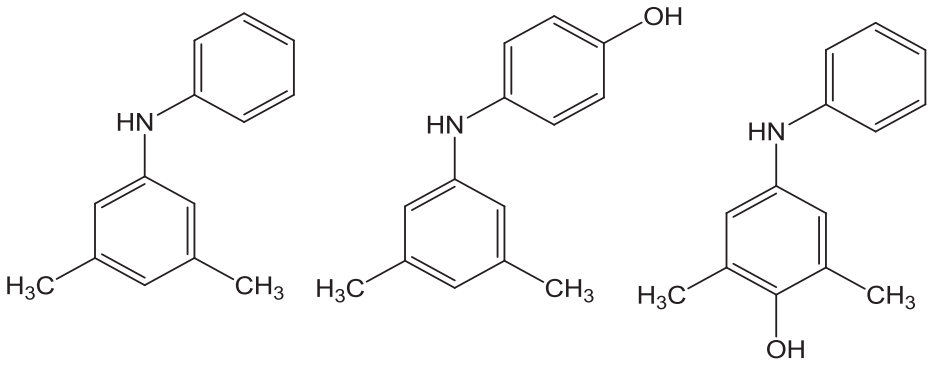
EXPLANATION

Pyrimethanil is an anilinopyrimidine fungicide that was first reviewed by the JMPR in 2007. During this review, maximum residue levels for commodities from field and post-harvest uses were recommended and subsequently adopted by the Codex Alimentarius Commission as Codex MRLs. Among these were maximum residue levels for pre-harvest uses on apricot, plums and peach and on post-harvest uses on pome fruit and cherries.

The sponsors (Janssen and IR-4) have since provided additional studies on the properties of pyrimethanil in a motion to re-evaluate the maximum residue levels of pyrimethanil on pome and stone fruits. Further, preharvest residue data on lemon and ginseng have also been submitted.

Structural Formulae



PYRIMETHANIL AEC614276 AEC614277

RESIDUE ANALYSIS

Description of analytical methods

A number of analytical methods developed to determine pyrimethanil residues in plant matrices, including those used in pre- and post-harvest trials on pome fruit and stone fruit, were submitted and reviewed by JMPR in 2007. For plant commodities, methods consisted of organic solvent extraction (acetone or methanol), clean-up, and analysis by either gas chromatography with mass spectrometric detection (GC/MS), or by high performance liquid chromatography with ultraviolet detection (HPLC/UV). The HPLC/UV method was validated for apples with an LOQ of 0.05 mg/kg. The GC/MS method was validated for apples, peaches, and plums with an LOQ of 0.05 mg/kg. Multiresidue methods (US FDA and DFG S 19) were also reported for pyrimethanil and validated with an LOQ of 0.05 mg/kg. The JMPR concluded that adequate analytical methods exist for both data collection and enforcement purposes for pyrimethanil residues in plant commodities.

The new field trial studies used analytical methods similar to those reviewed by the 2007 JMPR. Among the new field trial data submitted to the 2013 JMPR, ginseng is the only new crop for which no data were submitted to the 2007 JMPR. Ginseng samples were analysed for pyrimethanil residues via GC/MS after an acetone homogenization/extraction step, an acid/base partitioning procedure, and additional clean up by silica SPE column. The method LOQ was 0.05 mg/kg; at this spiking level, method validation recoveries were 101 ± 8% (n=6).

Method validation and procedural recoveries

A summary of the method validation and procedural recoveries for the new pome and stone fruit studies for 2013 JMPR review are provided in Table 1. Average method and concurrent recoveries were all within the acceptable range of 70–120%, with relative standard deviations (RSD) below 20%.

Table 1 Summary of Method Validation and Procedural Recoveries

Analyte	Crop	Fortification mg/kg	n	Range Recovery (%)	Mean recovery (%)	% RSD	Method	Reference
Method Validation								
Pyrimethanil	Apple	0.05-5.0	15	92-109	97	4.6	GC/MSD	06001
Pyrimethanil	Apple	0.05-5.0	18	87-131	106	12	GC/MSD	AGR 406
Pyrimethanil	Pear	0.05-5.0	18	85-113	98	8.7	GC/MSD	AGR 406
Pyrimethanil	Apple	0.2-1.2	6	90-110	101	8.6	HPLC/UV	AGR 521
Pyrimethanil	Pear	0.2-2.3	6	87-96	91	3.4	HPLC/UV	AGR 521
Pyrimethanil	Cherry	0.05-5.0	11	81-100	92	6.1	GC/MSD	PR 08701
Procedural Recoveries								
Pyrimethanil	Apple	0.05; 0.5	2	95.9, 96.3	96	-	GC/MSD	AGR 511
Pyrimethanil	Apple	2.2	3	101-107	104	2.9	LC/MS	AGR 1234
Pyrimethanil	Pear	2.2	3	105-116	112	5.4	LC/MS	AGR 1234
Pyrimethanil	Cherry	0.5; 15	5	87-93	91	2.8	GC/MSD	PR 08701

Storage Stability Studies

The 2007 JMPR received data for pyrimethanil demonstrating adequate residue stability for at least one year in the following crop matrices held in frozen storage: apple, grape, tomato, lettuce, carrot, pea, peach, and plum. Ginseng samples were stored frozen for a maximum of 259 days in the field trials. The supporting storage stability study showed recoveries of 80, 89, and 90% (86% average) after 259 days of storage at < -20 °C, for control samples spiked at 0.50 mg/kg.

USE PATTERN

Pyrimethanil may be applied both pre-harvest and post-harvest for disease control in a range of crops. The various national GAPs relevant to the pre-harvest treatment and post-harvest treatment studies reported herein are summarized in Table 2 and in Table 3, respectively. For pome fruit, a combination of pre-harvest and post-harvest applications can be followed by a thermofog treatment except in the situation where a dip/drench treatment has already been made. For stone fruit, combinations of pre-harvest and post-harvest treatments are permitted, but no thermofog treatments have been registered.

Table 2 Summary of Pre-harvest GAP Uses of Pyrimethanil in/on Pome and Stone Fruit, Ginseng and Lemon [a]

Crop	Country	Formulation	Application				PHI (Days)
			Method	kg ai/ha	kg ai/hL	No. or max (kg ai/ha/ season)	
Pome Fruit	Belgium	400 g/L SC	Foliar	0.45	0.22	5	28
	France	400 g/L SC	Foliar		0.02	4	28
	Germany	400 g/L SC	Foliar		0.03	5	--
	Greece	400 g/L SC	Foliar		0.08	2	28
	Italy	400 g/L SC	Foliar		0.03-0.04	5	14
	Netherlands	400 g/L SC	Foliar		0.03	5	28
	UK	400 g/L SC	Foliar		0.04	5	--
	USA	600 g/L SC	Foliar		--	1.8	72
Stone Fruit (except cherry)	USA	600 g/L SC	Foliar	0.8	--	2.4	2
Ginseng	USA	600 g/L SC	Foliar	0.78	--	2.35	30
Lemon	USA	600 g/L SC	Foliar	0.78	--	0.78	7

[a] All submitted to 2007 JMPR except ginseng and lemon.

Table 3 Summary of Post-harvest GAP Uses of Pyrimethanil in/on Pome Fruit and Stone Fruit [a]

Crop	Country	Formulation (Pyrimethanil content)	Application			
			Method	Time (minutes)	Rate, kg ai/hL	No. (max)
Dip, drench, aqueous line spray, wax line spray						
Apple, Pear	Chile	400 g/L SC	Dipping	1	0.05–0.1	1
			Drench	1	0.05–0.1	1
			Aqueous line spray	1	0.1	1
			Wax line spray	1	0.2	1
Apple, pear	Uruguay	200 g/L SC	Dipping		0.05	2
			Drench		0.05	2
Cherry	Chile	400 g/L SC	Dipping	0.5-1	0.04	1
			Wax line spray	0.5-1	0.04	1
Peach, Plum, Nectarines	Chile	400 g/L SC	Aqueous line spray	1	0.1	1
			Wax line spray	1	0.2–0.3	1
Pear	Belgium	200 g/L SC	Dip		0.03	1
			Drench		0.03	1
Pear	Italy	200 g/L SC	Dipping	0.3-0.5	0.03	1
			Drench	0.3-0.5	0.03	1
Pear	Netherlands	200 g/L SC	Dipping		0.03	1
			Aqueous line spray		0.03	1
Pear	South Africa	200 g/L SC	Dipping	1	0.03	1
Pear	Spain	200 g/L SC	Drench		0.04	1
Pome fruit	Argentina	400 g/L SC	Dipping	1	0.05-0.1	1
			Drench	1	0.05-0.1	1
			Aqueous line spray	1	0.1	1
			Wax line spray	1	0.2	1
Pome fruit	USA	400 g/L SC	Dipping	1	0.05–0.1	Up to maximum combination of 2 methods: (1) drench + dip; (2) drench + wax; (3) drench + aq. Spray; (4) dip + wax; (5) dip + aq. Spray; (6) aq. Spray + wax
			Drench	1	0.05–0.1	
			Aqueous line spray	1	0.1	
			Wax line spray	1	0.2	
Dip, drench, aqueous line spray, wax line spray						
Stone fruit	USA	400 g/L SC	Dip tanks	0.5	0.05	1
			high volume line application	0.5	0.05	1
			low volume line application (except cherry)	0.5	0.2	1
Thermofogging						
Apple	Belgium	160 g/L NH	Thermofogging		5.6-8 g ai/ 1000 kg fruit	1
Apple, pear	Italy	160 g/L NH	Thermofogging		8 g ai/1000 kg fruit	1
Apple, pear	Chile	160 g/kg NH	Thermofogging		6.4-9.6 g ai/ 1000 kg of fruit	1
Pome fruit	South Africa	160 g/L NH	Thermofogging		9.6 g ai/1000 kg fruit	1
Pome fruit	USA	160 g/L NH	Thermofogging		9.6 g ai/1000 kg of fruit	1 Do not apply to fruit already treated via drench or dip/wash applications

[a] Submitted to 2007 JMPR, but additional trials and complete GAPs submitted for 2013 JMPR consideration [In 2007, the only thermofog GAP was from Chile as a proposed use on pome fruit].

RESIDUES FROM SUPERVISED TRIALS ON CROPS

Pre-harvest Lemon Trials

The 2013 Meeting received data reflecting residues of pyrimethanil on lemons following foliar spray according to the USA GAP (600 g/L SC, single foliar application at 0.78 kg ai/ha).

Table 4 Pyrimethanil Residues in Lemon following Pre-Harvest Treatment (Reference PR 09085)

Lemon Year Variety	Application Rate (kg ai/ ha)	Number of Applications	DAT	Pyrimethanil Residue (mg/kg) Whole Fruit [Average]
GAP, USA	0.78	1	7	--
2004 04-CA73: Porterville, CA (Pryor)	0.69	1	7	0.26 0.27 [0.265]
2004 04-CA77: Ivanhoe, CA (Lisbon)	0.817	1	7	0.22 0.19 [0.205]
2004 04-CA74: Orange Cove, CA (Lisbon)	0.711	1	7	0.068 0.095 [0.815]
2004 04-CA76 : Orange Cove, CA (Lisbon)	0.707	1	7	0.12 0.24 [0.180]
2005 04-CA75: Riverside, CA (Lisbon)	0.703	1	7	0.22 0.31 [0.265]

Pome fruits

A number of pre- and post-harvest supervised trials on pome fruit were submitted and reviewed by the JMPR in 2007. Those data are included in the table below.

Table 5 Summary of pyrimethanil/pome fruit residue data reviewed by 2007 JMPR

Application	Crop	GAP	Residues (mg/kg)
Pre-harvest	Apple	USA	<0.05 (7), 0.06, 0.10, 0.12, 0.15, 0.16
	Apple	Italy	0.56
	Pear	USA	<0.05 (6)
Post harvest- aq. spray, wax spray	Apple	Spain	1.2, 1.3, 2.0, 2.1
		Belgium	0.57, 1.7
		USA	0.27, 0.28, 0.33, 0.39, 0.64, 0.70, 1.1, 1.1, 1.2, 1.5
	Pear	Belgium	0.32, 0.55
		Spain	0.57, 0.66
		USA	0.13, 0.18, 0.32, 0.45, 0.56, 0.86, 1,1, 1.1
Post-harvest, dip, drench	Apple	Belgium	0.53, 0.81, 0.89, 0.89, 0.92, 1.0, 1.3, 1.5, 1.9, 1.9, 2.0, 2.1, 2.3, 3.1, 3.3
	Pear	Belgium	0.61, 0.96, 2.1, 1.5, 1.0, 1.1, 1.1, 1.2, 2.8, 3.6
Post-harvest, dip + spray	Apples	USA	0.44, 0.51, 0.55, 0.67, 0.76, 0.79, 0.86, 1.0, 1.1, 1.2, 1.2, 1.4, 1.5, 1.5
	Pear	USA	0.36, 0.43, 0.56, 0.84, 0.86, 0.91, 1.5, 1.8, 1.9, 2.0, 2.5
Post-harvest, thermofogging	Apple	USA	0.43
		Belgium	1.1, 1.4, 1.4, 1.5, 1.6, 4.9, 6.4, 7.1
	Pear	Belgium/Italy	1.0, 1.6, 1.8, 3.5

New Post-Harvest Trials on Pome Fruits

The 2013 Meeting received new and updated labels for post-harvest uses of pyrimethanil. In addition, 15 post-harvest dipping/drenching trials on apples and 10 on pears conducted from 2001-2005 in Australia, Italy, France, Spain and Belgium, as well as 7 thermofogging trials from the USA (2007)

and Belgium (2001) were submitted. All dip/drench trials followed the GAP in Belgium (200 g ai/L SC, dip/drench at the rate of 0.03 kg ai/hL). Note: Netherlands and Italy have similar GAPs. Table 6 summarizes the post-harvest trials on pome fruit, with residues according to GAP underlined.

Table 6 Pyrimethanil residues in pome fruit resulting from post-harvest treatments

POME	Postharvest Application					Residues	Reference
country, year (variety)	Form. (pyrimethanil content)	Treatment Method	Rate (kg ai/hL)	No.	Sampling (day)	mg/kg (mean)	
APPLES							
GAP, Belgium	200 g/L EC	Dip/drench	0.03	1			
Belgium, 2001 Apple/ Golden Delicious	LAg 2001 334 100 g/L EC	Dipping for 30 seconds	0.01	1	0	0.35, 0.39 (0.37)	AGR 406
					7 months	0.27, 0.33 (0.30)	
			0.02	1	0	0.49, 0.54 (0.52)	
					7 months	0.44, 0.52 (0.48)	
			0.03	1	0	0.54, 0.52 (0.53)	
					7 months	0.50, 0.49 (0.50)	
Belgium, 2001 Apple/ Golden Delicious	LAg 2001 206 150 g/L EC	Dipping for 30 seconds	0.03	1	0	0.91, 0.81 (0.86)	AGR 406
					7 months	0.89	
			0.04	1	0	1.2, 1.5 (1.4)	
					7 months	1.2	
			0.06	1	0	1.3, 1.9 (1.6)	
					7 months	1.7	
Belgium, 2001 Apple/ Jonagold	LAg 2001 206 150 g/L EC	Dipping for 30 seconds	0.03	1	0	1.4, 1.3 (1.4)	AGR 406
					7 months	1.9	
			0.04	1	0	1.7, 1.8 (1.8)	
					7 months	2.0	
			0.06	1	0	2.3, 2.9 (2.6)	
					7 months	2.2	
Trial 2132 AN1 France, 2002 Apple/ Golden	LAg 2002 258 200 g/L SC	Pre-harvest only	-	-		0.15	AGR 511
		Pre + post-harvest dip for 30 sec	0.03	1	0	0.76	
		Dip for 30 sec	0.03	1	0	1.0	
Trial 2132 AN2 France, 2002 Apple/ Golden	LAg 2002 258 200 g/L SC	Pre-harvest only	-	-		0.21	AGR 511
		Pre + post-harvest dip for 30 sec	0.03	1	0	0.63	
		Dip for 30 sec	0.03	1	0	0.92	
AGR 521 Italy, 2002 Apple/ Golden	LAg 2002 228 150 g/L EC	Drenching for 1 min	0.03	1	1 14 36 59 72	1.8 1.5 1.9 2.3 2.3	AGR 521
AGR 521 Italy, 2002 Apple/ Stark	LAg 2002 228 150 g/L EC	Drenching for 1 min	0.03	1	1 14 36 59 72	1.6 1.6 1.6 2.0 1.8	AGR 521

POME	Postharvest Application					Residues	Reference
country, year (variety)	Form. (pyrimethanil content)	Treatment Method	Rate (kg ai/hL)	No.	Sampling (day)	mg/kg (mean)	
AGR 521 Italy, 2002 Apple/ Pink Lady	LAg 2002 228 150 g/L EC	Drenching for 1 min	0.03	1	1 14 36 59 72	1.9 1.2 1.2 1.8 1.9	AGR 521
AGR 521 Italy, 2002 Apple/ Fuji	LAg 2002 228 150 g/L EC	Drenching for 1 min	0.03	1	1 14 36 59 72	1.9 1.7 1.8 2.1 1.8	AGR 521
AGR 521 Italy, 2002 Apple/ Golden	LAg 2002 258 200 g/L SC	Drenching for 1 min	0.03	1	1 14 36 59 72	0.69 1.3 1.2 1.1 0.98	AGR 521
AGR 521 Italy, 2002 Apple/ Stark	LAg 2002 258 200 g/L SC	Drenching for 1 min	0.03	1	1 14 36 59 72	0.58 0.78 0.75 0.82 0.89	AGR 521
AGR 521 Italy, 2002 Apple/ Pink Lady	LAg 2002 258 200 g/L SC	Drenching for 1 min	0.03	1	1 14 36 59 72	0.65 0.56 0.70 0.71 0.81	AGR 521
AGR 521 Italy, 2002 Apple/ Fuji	LAg 2002 258 200 g/L SC	Drenching for 1 min	0.03	1	1 14 36 59 72	0.80 1.1 1.1 1.1 1.5	AGR 521
AGR 1234 Australia, 2005 Apple/ Fuji	LAg 2002 258 200 g/L SC	Dipping for 30 seconds	0.03	1	0 day: Whole fruit Peel Pulp	 3.1 17 0.7	AGR 1234
AGR 1234 Australia, 2005 Apple/ Fuji	LAg 2002 258 200 g/L SC	Dipping for 30 seconds	0.03	1	0 day: Whole fruit Peel Pulp	 3.3 12 0.7	AGR 1234
PEAR							
AGR 521 Italy, 2002 Pear/ Decana	LAg 2002 228 150 g/L EC	Drenching for 1 min	0.03	1	1 14 36 59 72	0.73 0.80 0.93 0.94 0.96	AGR 521
AGR 521 Italy, 2002 Pear/Kaiser	LAg 2002 228 150 g/L EC	Drenching for 1 min	0.03	1	1 14 36 59 72	1.7 1.9 2.1 1.8 1.8	AGR 521
AGR 521 Italy, 2002 Pear/Abate	LAg 2002 228 150 g/L EC	Drenching for 1 min	0.03	1	1 14 36 59 72	1.2 1.4 1.5 1.4 1.4	AGR 521
AGR 521 Italy, 2002 Pear/ Conference	LAg 2002 228 150 g/L EC	Drenching for 1 min	0.03	1	1 14 36 59 72	1.0 1.0 0.95 0.98 0.91	AGR 521

POME	Postharvest Application					Residues	Reference
country, year (variety)	Form. (pyrimethanil content)	Treatment Method	Rate (kg ai/hL)	No.	Sampling (day)	mg/kg (mean)	
AGR 521 Italy, 2002 Pear/ Decana	LAg 2002 258 200 g/L SC	Drenching for 1 min	0.03	1	1 14 36 59 72	0.38 0.34 0.61 0.33 0.50	AGR 521
AGR 521 Italy, 2002 Pear/Kaiser	LAg 2002 258 200 g/L SC	Drenching for 1 min	0.03	1	1 14 36 59 72	1.2 0.91 0.96 1.0 0.94	AGR 521
AGR 521 Italy, 2002 Pear/Abate	LAg 2002 258 200 g/L SC	Drenching for 1 min	0.03	1	1 14 36 59 72	0.83 0.83 1.1 0.90 0.91	AGR 521
AGR 521 Italy, 2002 Pear/ Conference	LAg 2002 258 200 g/L SC	Drenching for 1 min	0.03	1	1 14 36 59 72	0.91 0.76 1.1 0.81 1.0	AGR 521
AGR 1234 Australia, 2005 Pear/ De Malines	LAg 2002 258 200 g/L SC	Dipping for 30 seconds	0.03	1	0 day: Whole fruit Peel Pulp	 2.8 11 0.2	AGR 1234
AGR 1234 Australia, 2005 Pear/ De Malines	LAg 2002 258 200 g/L SC	Dipping for 30 seconds	0.03	1	0 day: Whole fruit Peel Pulp	 3.6 18 0.3	AGR 1234

One thermofogging trial was conducted in the US in 2007, following the GAP there (160 g/ai/L HN, one application at 9.6 kg ai/1000 kg fruits) (Report 06001). Three of the five thermofogging trials were carried out in Belgium in 2001 following the GAP (± 25%) in the country (160 g ai/L HN, one application at the rate of 5.6 to 8 kg ai/1000 kg fruits). The trials are summarized in Table 7, with residues according to GAP underlined.

Table 7 Pyrimethanil residues in pome fruit resulting from thermofogging

POME	Postharvest Application					Residues	Reference
country, year (variety)	Form.	Treatment Method	Rate (g ai/1000 kg fruit)	No.	Sampling (day)	mg/kg	
APPLES							
GAP, USA	160 g/kg HN	thermofogging	9.6	1	1		
Trial 06001 USA, 2007 Apple/ Red Delicious	160 g/kg HN	Thermofogging	9.6	1	1	0.26, 0.88, 0.25, 0.34 (0.43)	06001
GAP, Belgium	160 g/kg HN	thermofogging	5.6-8	1			
Belgium, 2001 Apple/ Golden; Jonagold	160 g/kg HN	Thermofogging	4.7	1	0	4.8, 3.3, 6.2, 1.7 (4.0)	AGR 406
					7 months	4.8, 4.2, 6.8. 1.7 (4.4)	
Belgium, 2001 Apple/ Golden; Jonagold	160 g/kg HN	Thermofogging	8	1	0	5.7, 4.3, 8.6, 4.7 (5.8)	AGR 406
					7 months	5.5, 5.7, 8.7 5.5 (<u>6.4</u>)	
Belgium, 2001 Apple/ Golden;	160 g/kg HN	Thermofogging	10	1	0	5.0, 4.9, 5.4, 7.9 (5.9)	AGR 406

POME	Postharvest Application					Residues	Reference
country, year (variety)	Form.	Treatment Method	Rate (g ai/1000 kg fruit)	No.	Sampling (day)	mg/kg	
Jonagold					7 months	5.4, 6.8, 6.5, 9.5 (7.1)	
Belgium, 2001 Apple/ Golden ; Jonagold	150 g/L HN	Aerobrume (= thermofog)	2.3	1	0	1.2, 2.8, 3.1, 2.9 (2.5)	AGR 406
					7 months	1.3, 3.4, 4.0, 2.7 (2.9)	
Belgium, 2001 Apple/ Golden; Jonagold	150 g/L HN	Aerobrume (= thermofog)	4.0	1	1	7.4, 3.0, 2.8, 4.2 (4.4)	AGR 406
					7 months	7.1, 3.5, 3.3, 6.8 (4.4)	
Belgium, 2001 Apple/ Golden; Jonagold	LAg 2001 206 (150 g/L HN)	Aerobrume (= thermofog)	6.4	1	1	6.6, 2.8, 3.3, 3.9 (4.2)	AGR 406
					7 months	6.5, 3.9, 3.6, 5.7 (4.9)	

Stone fruits

A number of pre- and post-harvest supervised trials on stone fruit were submitted and reviewed by the JMPR in 2007. Those data are included in the table below.

Table 8 Summary of pyrimethanil/stone fruit residue data reviewed by 2007 JMPR

Application	Crop	GAP	Residues (mg/kg)
Pre-harvest	Apricot	USA	0.6, 0.64, 0.94, 1.3, 1.7
	Peach	USA	1.5, 0.38, 0.54, 0.94, 0.99, 1.1, 1.2, 1.3, 1.3, 1.5, 1.6, 2.6
	Plum	USA	1.2, 0.05, 0.44, 0.58, 0.59, 0.59, 0.61, 0.62
Post-harvest, dip	Cherry	Chile	0.82, 1.0, 1.1, 1.2, 1.4, 1.4, 1.4, 1.5

New post-harvest trials on cherry

Five post-harvest trials on sweet cherry were conducted in the USA during 2006, in support of the GAP in the US (400 g ai/L SC, 0.05 kg ai/hL for dip and high volume line application and 0.2 kg ai/hL for low volume line application (Report PR 080701). At each trial, fruit samples were dipped for approximately 30 seconds in a pyrimethanil solution containing 400 g ai/378 litres (0.11 kg ai/hL). Two other treatments were examined at a high-volume application of 1000 kg fruits, applied at a spray concentration of 0.1 kg ai/hL. Fruit wax was added to the mixtures in all treatments. The trials are summarized below.

Table 9 Pyrimethanil residues in cherries resulting from post-harvest treatments

CHERRY	Postharvest Application					Residues	Reference
country, year (variety)	Form. (pyrimethanil content)	Treatment Method	**Rate** (kg ai/hL)	No.	Sampling (day)	mg/kg (mean)	
GAP, USA	400 g/L SC	Dip, 30 sec	0.05	1			
		High volume applic, 30 sec	0.05	1			
Trial 06-CA 100 USA, 2006 Cherry/Bing	Penbotec 400 SC (400 g/L SC)	Dipping with wax for 30 seconds	0.11	1	0	2.2, 2.1 (2.2)	PR 08701
Trial 06-WA10 USA, 2006 Cherry/Bing	Penbotec 400 SC (400 g/L SC)	Dipping with wax for 30 seconds	0.11	1	0	12, 13 (13)	PR 08701

CHERRY	Postharvest Application					Residues	Reference
country, year (variety)	Form. (pyrimethanil content)	Treatment Method	**Rate** (kg ai/hL)	No.	Sampling (day)	mg/kg (mean)	
Trial 06-MI40 USA, 2006 Cherry/Bing	Penbotec 400 SC (400 g/L SC)	Dipping with wax for 30 seconds	0.11	1	0	5.4, 5.9 (5.7)	PR 08701
Trial 06-CA 100 USA, 2006 Cherry/Bing	Penbotec 400 SC (400 g/L SC)	High volume spray with wax	0.11	1	0	1.2, 1.2 (1.2)	PR 08701
Trial 06-WA10 USA, 2006 Cherry/Bing	Penbotec 400 SC (400 g/L SC)	High volume spray with wax	0.11	1	0	12, 12 (12)	PR 08701

Pre-harvest Ginseng trials

The 2013 Meeting received data reflecting residues of pyrimethanil on ginseng following foliar spray according to the USA GAP (600 g/L SC, foliar application at 0.78 kg ai/ha on a 7 to 14-day interval, seasonal maximum of 2.35 kg ai/ha). Three-year old ginseng plants were treated and the roots were harvested 29 days after the last application. The roots were dried in a commercial drying facility. Untreated and treated roots were placed on separate racks at opposite ends of a grower's commercial drying room. The roots were dried at approx. 18–27 °C from 10/3 to 10/06 and at approx. 90–115 °F from 10/6 to 10/17/2007 when they were sampled.

Table 10 Pyrimethanil Residues in Dried Ginseng following Pre-Harvest Treatment (Reference PR 09707)

Ginseng Year Variety	Application Rate (kg ai/ ha)	Number of Applications	Total Rate (kg ai/ ha)	RTI (days)	DAT	Pyrimethanil Residue (mg/kg) Whole, Dried Root [Average]
2007 MI11: Edgar, WI (American Ginseng)	0.78	3	2.372	6	29	0.35 0.47 [0.41]
2007 MI12: Nutterville, WI (American Ginseng)	0.78	3	2.391	6	29	0.11 0.088 [0.099]
2007 MI13: Mosinee, WI (American Ginseng)	0.78	3	2.377	6	29	0.48 0.69 [0.585]

APPRAISAL

Pyrimethanil was most recently evaluated for toxicology and residues by the JMPR in 2007. The Meeting derived an ADI of 0.2 mg/kg bw per day and decided that an ARfD is unnecessary.

In 2007 the Meeting agreed that the residue definition for both enforcement and dietary intake for plant commodities is parent pyrimethanil. The Meeting further concluded that the residue definition for both enforcement and dietary exposure considerations for milk is the sum of pyrimethanil and 2-anilino-4,6-dimethylpyrimidin-5-ol, expressed as pyrimethanil; and for livestock tissues (excluding poultry) is the sum of pyrimethanil and 2-(4-hydroxyanilino)-4,6-dimethylpyrimidine, expressed as pyrimethanil.

The compound was listed by the Forty-fourth Session of the CCPR for the evaluation of additional MRLs. The 2013 JMPR received residue data for pome fruit, stone fruit, lemons and ginseng.

Methods of analysis

The Meeting received information on the analytical methods used for determination of pyrimethanil residues in samples obtained from supervised trials on pome fruit, stone fruit, lemon, and ginseng. The residues were measured using GC/MS or HPLC/UV with LOQs of 0.05 mg/kg. The methods were reviewed by the JMPR in 2007, which concluded that adequate analytical methods for pyrimethanil exist for both data collection and enforcement purposes. The methods used in the trials submitted to the 2013 Meeting are essentially identical to those accepted at the 2007 Meeting.

Stability of residues in stored analytical samples

Detailed information from the 2007 JMPR showed that pyrimethanil residues are stable (> 70% remaining) in frozen storage for at least 12 months in the tested commodities, i.e., apple, grape, tomato, lettuce, carrot, pea, peach, and plum. Concurrent storage stability studies were submitted with the ginseng trials and demonstrated residue stability for at least 259 days.

The periods of demonstrated stability cover the frozen storage intervals in the residue studies.

Results of supervised residue trials on crops

The 2007 JMPR received supervised trials for many crops, including pre- and post-harvest uses of pome and stone fruit. However, due to incomplete GAP information, pome fruit thermofog data were not included in the pome fruit MRL recommendation. The 2013 JMPR received complete GAP information for pome and stone fruits, as well as expanded post-harvest residue data. For completeness, all relevant pome and stone fruit supervised trial data for pyrimethanil are considered in the following sections. The USA GAP allows for pre- and post-harvest applications of pyrimethanil to pome and stone fruit; however, few trials reflect residues from the combined pre- and post-harvest applications.

Lemon

In the USA, pyrimethanil is registered for use on lemons for up to 4 treatments at a rate of 1.7 kg ai/ha, with a PHI and a retreatment interval of 7 days. Five supervised field trials are available at this GAP from the USA.

Rank-order pyrimethanil residues in lemon were (n=5): 0.18, 0.21, 0.27 (2), and 0.82 mg/kg.

The Meeting noted that there is a current MRL for citrus fruit at 7 mg/kg based on post-harvest uses and concluded that the current MRL for citrus is adequate to cover the submitted pre-harvest-use lemon data. Therefore, the Meeting confirms its previous recommendation.

Pome fruits

In 2007, the Meeting reviewed residue values on pome fruits from pre-harvest and post-harvest trials according to Belgium, France, Germany, Greece, Italy, Netherlands, United Kingdom, and USA GAPs. Residues from post-harvest GAPs were higher and served as the basis for the previous recommendations for maximum residue level, STMR, and HR estimates of 7(Po), 0.7, and 3.8 mg/kg, respectively.

The 2013 Meeting has evaluated data from the USA and Europe matching a new GAP for uses of pyrimethanil as a post-harvest thermofog treatment. Although the GAP for thermofog uses in the US has a higher application rate than the GAPs in European countries (one application at 9.6 kg ai/1000 kg fruits vs. one application at the rate of 5.6 to 8 kg ai/1000 kg fruits), the residues resulting from the trials conducted according to the GAP in Europe were approximately 10-fold higher than the trial conducted according to the US GAP; therefore, the meeting selected data according to GAP in Europe.

Residues from post-harvest trials in apples (n=8, new data in bold) were: 1.1, 1.4 (2), 1.5, 1.6, 4.9, 6.4, and 7.1 mg/kg.

Residues from post-harvest trials in pears (n=4) were: 1.0, 1.6, 1.8, and 3.5 mg/kg.

As the residue data from apples and pears are from the same population, they were combined to give the following residues (n=12, median underlined): 1.0, 1.1, 1.4 (2), 1.5, 1.6 (2), 1.8, 3.5, 4.9, 6.4, and 7.1 mg/kg. The Meeting agreed to replace its previous maximum residue level recommendation of 7 mg/kg with a new estimated STMR of 1.6 mg/kg and a maximum residue level of 15 (Po) mg/kg for pome fruit.

Stone fruits

In 2007, the Meeting recommended an STMR of 1.3 mg/kg and a maximum residue level of 4 (Po) for cherries based on the post-harvest GAP for Chile. The 2013 Meeting received new information on the post-harvest GAP in the USA. Post-harvest trials were conducted at 2× the USA GAP. Since post-harvest data may not be adjusted via proportionality, there are no new data for the Meeting to use for a recommendation. Therefore, the Meeting confirmed its prior recommendations.

Berries and other small fruits

From the 2007 JMPR:

"Eight trial were conducted on the foliar application of pyrimethanil to strawberries in theUSA, where the GAP is 600 g/L SC, 0.8 kg ai/ha, 2.4 kg ai/ha/season, 1 day PHI. All trials were at maximum GAP, and the residues in ranked order (median underlined) were: 0.79, 0.93, 0.99, 1.1, 1.2, 1.3(2), and 2.3 mg/kg. The Meeting estimated an STMR of 1.2 mg/kg and a maximum residue level of 3 mg/kg for strawberries."

The current Meeting was asked to extrapolate the strawberry field trial data to Berries and Other Small Fruits [Subgroup 004E, Low Growing Berries (including Bakeapple; Cranberry (FB 0265); Cloudberry (FB 0277); Muntries (FB 0283); Partridge berry; Squaw vine; Strawberry (FB 0275); Strawberries, wild (FB 0276); Strawberry, Musky)], reflecting the USA label allowing use on the Low Growing Berry Crop Subgroup 13-07G.

Taking into account the available historic data showing that pesticide residues in strawberry are generally comparable to or higher than residues in other low-growing berries, the Meeting agreed to extrapolate the residue estimates for strawberry to commodities comprising the low-growing berries subgroup. Therefore, for the low-growing berries subgroup (Subgroup 004E, FB 2009) the Meeting recommended a maximum residue level of 3 mg/kg and estimated an STMR of 1.2 mg/kg. The Meeting agreed to withdraw its previous recommendation of 3 mg/kg for strawberry.

Ginseng

In the USA, pyrimethanil is registered for use on ginseng for up to 3 treatments at a rate of 0.78 kg ai/ha, with a PHI of 30 days and a retreatment interval of 7 days. Three supervised field trials were available at this GAP from the USA.

Rank-order pyrimethanil residues in dried ginseng were (n=3): 0.099, 0.41, and 0.59 mg/kg.

The Meeting estimated an STMR value of 0.41 mg/kg and a maximum residue level value of 1.5 mg/kg for ginseng, dried.

Fate of residue during processing

In 2007, the Meeting estimated the following STMR-Ps for citrus juice, citrus pulp (dried) and citrus oil, respectively: 0.028 mg/kg; 1.3 mg/kg; 56 mg/kg. As these estimates adequately cover residues in lemon, the Meeting confirmed its prior recommendations for citrus.

The 2007 Meeting estimated a processing factor of 0.45 for apple juice, 0.37 for apple puree, and 4.1 for wet apple pomace. Applying these processing factors to the estimated STMR for pome fruit (1.6 mg/kg) resulted in STMR-P estimates of 0.72 mg/kg for apple juice, 0.59 mg/kg for apple puree, and 6.6 mg/kg for wet apple pomace. The Meeting agreed these values should replace the estimates made in 2007.

Residues in animal commodities

Dietary burden calculations for beef cattle and dairy cattle are provided below. The dietary burdens were estimated using the OECD diets listed in Appendix IX of the 2009 edition of the FAO Manual.

Potential cattle feed items include: apple pomace, almond hulls, carrot culls, citrus pulp, grape pomace, pea seed and pea straw. Pyrimethanil residues in all these feed items were as estimated by the 2007 JMPR except for apple pomace, which has a revised STMR-P of 6.6 mg/kg (the previous estimate was 2.9 mg/kg).

Summary of livestock dietary burdens (ppm of dry matter diet)

	US-Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	0.14	0.14	4.3	3.6	4.6[a]	3.9[c]	0.0	0.0
Dairy cattle	2.5	2.1	2.8	2.1	4.1[b]	3.4[d]	0.0	0.0

[a] Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian meat

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

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

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

Animal commodity maximum residue levels

The calculations used to estimate residues in animal commodities based on comparisons of the dietary burden to results of the bovine feeding study, for use in estimating maximum residue levels, STMR and HR values, are shown below.

Pyrimethanil feeding study	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
MRL beef or dairy cattle							
Feeding study [a]	3 10	< 0.01 0.017	3 10	< 0.05 < 0.05	< 0.05 < 0.05	0.08 0.13	< 0.05 < 0.05
Dietary burden and high residue	4.1	< 0.01	4.6	< 0.05	< 0.05	0.09	< 0.05
STMR beef or dairy cattle							
Feeding study [b]	3 10	< 0.01 0.017	3 10	< 0.05 < 0.05	< 0.05 < 0.05	0.066 0.12	< 0.05 < 0.05
Dietary burden and residue estimate	3.4	< 0.01	3.9	< 0.05	< 0.05	0.07	< 0.05

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

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

Residue estimates in animal commodities are unchanged relative to those recommended in 2007; therefore, the Meeting confirmed its prior recommendations: an STMR of 0.01 mg/kg for milk and estimated a maximum residue level of 0.01 mg/kg for milk. The Meeting estimated STMRs of 0.0 mg/kg for each of meat and fat and maximum residue levels of 0.05 (*) mg/kg for meat. The Meeting estimated an STMR of 0.07 mg/kg for edible offal based on the STMR value for beef cattle kidney.

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 assessment.

Definition of the residue (for compliance with MRL and dietary intake) for plant commodities: *pyrimethanil*.

The residue is not fat-soluble.

Commodity		MRL, mg/kg		STMR, mg/kg	HR, mg/kg
CCN	Name	New	Previous		
FP 0009	Pome fruits	15 Po	7	1.6	
FB 2009	Low Growing Berries	3		1.2	
FB 0275	Strawberry	W	3		
DV 0604	Ginseng	1.5		0.41	
JF 0226	Apple, Juice			0.72	

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of pyrimethanil were calculated for the 13 GEMS/Food cluster diets using STMRs/STMR-Ps estimated by the current Meeting. The ADI is 0–0.2 mg/kg bw and the calculated IEDIs were 0–5% of the maximum ADI (0.2 mg/kg bw). The Meeting concluded that the long-term intakes of residues of pyrimethanil, resulting from the uses considered by the current Meeting, are unlikely to present a public health concern.

Short-term intake

The 2007 JMPR decided that an ARfD was unnecessary and concluded that the short-term intake of pyrimethanil residues is unlikely to present a public health concern.

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