PROPARGITE (113)

First draft prepared by David Lunn, New Zealand Food Safety Authority, Wellington, New Zealand.

EXPLANATION

Propargite was first evaluated by the JMPR for residues in 1977 and toxicology in 1978, with subsequent evaluations in 1978, 1979, 1980 and 1982. A periodic review (toxicology) was conducted by JMPR in 1999 when an ADI of 0-0.01 mg/kg bw was estimated and it was concluded that an acute reference dose was not necessary. A periodic review of residues was conducted in 2002 and MRLs were recommended by JMPR for many crops and animal commodities. MRLs for beans (dry), pears, potato, pears, strawberry and walnuts were among those not proposed because of insufficient data or GAP information.

The CCPR (36th Session, 2004, paragraph 141, ALINORM 04/27/24) retained the existing Codex MRLs for beans (dry), pear, potato, strawberry and walnuts for 4 years under the periodic review procedure so that additional data could be provided to support these MRLs.

Information on registered uses and data from supervised residue trials on beans (dry), potato and walnuts, together with additional information on methods of analysis and residue stability in stored analytical samples, were provided to the Meeting by the USA manufacturer. Advice was also received from The Netherlands that propargite was not authorised for use on agricultural crops in that country.

Additional GAP information and summaries of residue trials conducted in Japan on tea, citrus, apples, grapes, peaches and cherries were provided by the Japanese manufacturer.

METHODS OF RESIDUE ANALYSIS

Animal metabolism

The meeting received analytical method descriptions and validation data for propargite in beans (dry), walnuts and potato. These methods involved minor variations on a method ME-208, capable of determining both propargite and the metabolite t-butyl phenoxy cyclohexanol (TBPC).

The reported methods involved the acetonitrile extraction of residues in homogenized plant matrices, with the filtered extract being washed with hexane before being mixed with 10% NaCl and partitioned into either petroleum ether or hexane. After concentration and clean-up using a Florisil® column, the extracts were evaporated to dryness or near dryness. In some studies (potato and dry beans), the primary metabolite (TBPC) was then derivatised by incubation with triethylamine and heptafluorobutyric anhydride. Extracts were then resuspended in either hexane or toluene and analyzed for propargite using a gas chromatograph equipped with a mass selective detector (GC-MSD) in the selected ion monitoring mode.

Table 1. Propargite analytical methods.

Beans (dry), Potato

Dzialo, 2006 [Ref: 2005-006], Korpalski, 2006 [Ref: RP-04002]

Analytes: Propargite and metabolite TBPC GC-MSD ME-208 ver 5

LOQ: 0.02 mg/kg (dry beans), 0.01 mg/kg (potato)

Description Samples were extracted with acetonitrile, filtered, washed with hexane and back-

extracted with hexane-saturated acetonitrile. After evaporation of the acetonitrile extract to near dryness and the addition of 10% NaCl solution, residues were

partitioned into hexane. Clean-up involved elution with 10% acetone in hexane through a Florasil® column. After evaporation to dryness, extracts were incubated in triethylamine and heptafluorobutyric anhydride (to derivatise the TBPC metabolite) and extracted into hexane. Analysis for propargite was by GC using a mass selective detector (ions 135 or 350, 173 or 335).

Potato

Korpalski, 2006 [Ref: RP-97013]

Analytes: Propargite and metabolite TBPC GC-MSD CAL 004-50

LOQ: 0.01 mg/kg

Description Samples were extracted with acetonitrile, filtered and washed with hexane. After

evaporation of the acetonitrile extract to about 50ml, residues were partitioned into petroleum ether/10% NaCl solution. Clean-up was by elution with 15% acetone/petroleum ether through a Florasil column. After evaporation and

resuspension in toluene residues of propargite were analysed by GC using a mass

selective detector (ions 135 or 350, 173 or 335).

Walnut (nutmeat)

Russell & Dzialo, 2006 [Ref: 2005-008]

Analytes: Propargite GC-MSD GRL-12307

LOQ: 0.02 mg/kg

Description Samples were extracted with acetonitrile, filtered, washed with hexane and back-

extracted with hexane-saturated acetonitrile. After evaporation of the acetonitrile extract to near dryness and the addition of 10% NaCl solution, residues were partitioned into hexane. Clean-up involved elution with 10% acetone in hexane through a Florasil® column. After evaporation to dryness, extracts were resuspended in hexane. Analysis for propargite was by GC using a mass selective detector (ions

350, 335).

Method validation studies were provided for all the reported analytical methods, with samples of beans (dry), walnut (nutmeat) and potato being fortified with propargite at levels ranging from 0.01 mg/kg to 10 mg/kg. Average recovery rates ranged from 89% to 112% in the various substates. Data from these validation studies are summarised in Table 2.

Table 2. Analytical recoveries for spiked propargite in various substrates.

Commodity	Analyte	Spike conc,	n	R	ecovery%	Method	Reference
		mg/kg		mean	range		
Beans (dry)	propargite	0.02	6	91	81-97	ME-208 ver 5	GRL-12308
Beans (dry)	propargite	0.05	4	94	81-110	ME-208 ver 5	GRL-12308
Beans (dry)	propargite	0.2	2	89	78-107	ME-208 ver 5	GRL-12308
		Overall	12	91	RSD 14%		
Potato	propargite	0.01	8	89	86-96	CAL 0400-50	RP-97019
Potato	propargite	0.5	4	101	92-113	CAL 0400-50	RP-97019
Potato	propargite	10	4	98	95-101	CAL 0400-50	RP-97019
Potato	propargite	Overall	16	94	RSD 7.3%		
Potato	propargite	0.1	8	106	96-120	ME-208 ver 5	RP-04029
Potato	propargite	1.0	3	102	95-111	ME-208 ver 5	RP-04029
Potato	propargite	10	3	96	93-98	ME-208 ver 5	RP-04029
		Overall	14	103	RSD 7.4%		
Walnut (nutmeat)	propargite	0.02	6	102	86-120	GRL-12307	GRL-12307
Walnut (nutmeat)	propargite	0.05	3	90	78-109	GRL-12307	GRL-12307

Commodity	Analyte	Spike conc, n		R	ecovery%	Method	Reference
		mg/kg		mean	range		
Walnut (nutmeat)	propargite	0.1	3	112	102-121	GRL-12307	GRL-12307
		Overall	12	102	RSD 14.5%		

Stability of residues in stored analytical samples

The Meeting received information on the stability of residues of propargite in various alfalfa, almond, barley, carrot and lettuce substrates stored frozen and analysed at various intervals. In these studies, samples were extracted with hexane/2-propanol and analysed for propargite by GC-FPD (sulphur mode) after Florasil® column and gel permeation chromatography clean-up. The results of these studies are summarised in Table 3. Values were uncorrected for analytical method recovery.

Table 3. Frozen storage stability of propargite residues.

Matrix	Temp	Storage	Fortification	Method	% Residue:	s remaining	Reference
	(°C)	period ¹	level (mg/kg)	recovery%		Mean	
Barley (grain)	-20	0	0.1	74	71, 83	77	RP-89064
		1m		69	54, 57	55	
		2m		90	56, 68	62	
		7m		71	51, 63	52	
		9m		89	78, 81	80	
		12m		72	49, 57	53	
Barley (straw)	-20	0d	0.1	84	83, 79	81	RP-89064
		1m		75	78. 74	76	
		2m		106	92, 91	91	
		7m		113	100, 103	102	
		9m		114	99, 87	93	
		12m		83	48, 54	51	
Carrot (root)	-20	0d	0.1	121	106, 104	105	RP-89064
•		1m		112	87, 85	86	
		2m		123	81, 76	78	
		7m		113	88, 87	87	
		9m		107	72, 83	78	
		12m		120	76, 76	76	
Carrot (top)	-20	0	0.1	113	97, 94	95	RP-89064
		1m		94	85, 76	80	
		2m		113	84, 96	90	
		7m		103	91, 95	93	
		9m		80	85, 70	77	
		13m		70	44, 42	43	
Lettuce	-20	0d	0.1	111	101, 112	107	RP-89064
		1m		114	87, 109	98	
		2m		97	93, 104	99	
		7m		103	106, 104	105	
		9m		109	102, 103	103	
		12m		112	93, 95	94	
Almond hulls	-20	0d	1.0	108 ¹	104, 104	104	RP-91057.
		1m		84 ¹	85, 78	82	
		3m		101 ¹	87, 85	86	
		6m		89 ¹	63, 70	67	
		8m		87 ¹	83, 82	83	
		12m		98 ¹	93, 90	92	
Almond kernels	-20	0d	1.0	105 ¹	104, 104	104	RP-91057
		1m		97 ¹	88, 95	92	
		3m		94 ¹	88, 88	88	
		6m		85 ¹	87, 67	77	
		8m		99¹	88, 93	91	
		12m		99 ¹	82, 87	85	

Matrix	Temp	Storage	Fortification	Method	% Residues	s remaining	Reference
	(°C)	period ¹	level (mg/kg)	recovery%		Mean	
Alfalfa regrowth	-20	0d	1.0	95 ¹	100, 100	100	RP-91062
hay (dry)		1m		99 ¹	90, 104	97	
		3m		80^{1}	93, 90	92	
		6m		87 ¹	88, 77	83	
		8m		93¹	90, 78	84	
		12m		98 ¹	92, 82	87	
Alfalfa regrowth	-20	0d	1.0	102 ¹	112, 104	108	RP-91062
hay (fresh)		1m		1131	117, 104	111	
		3m		90 ¹	92, 92	92	
		6m		901	88, 88	88	
		8m		1021	100, 100	100	
		12m,		97 ¹	97, 85	91	
Alfalfa seed	-20	0d	1.0	106 ¹	112, 108	110^{3}	RP-91062
screenings		1m		1011	108, 104	106	
		3m		110^{1}	72, 112	92	
		6m		90 ¹	88, 92	90	
		8m		1081	112, 112	112	
		12m		101 ¹	100, 90	95	
Alfalfa seed	-20	0d	1.0	108 ^{1,2}	121, 104	113^{2}	RP-91062
		1m		1081	100, 98	99	
		3m		89 ¹	88, 92	90	
		6m		1121	92, 97	95	
		8m		1081	98, 83	91	
		12m		104 ¹	88, 85	87	

¹) Average of two replicates

USE PATTERN

Propargite is registered in a number of countries for control of mites on a wide range of fruit trees, nuts, vines, vegetables, ornamentals and field crops such as cotton, maize and peanuts. The manufacturer provided USA labels for two emulsifiable concentrate formulations and updated information on GAP. Uses relevant to this evaluation are summarised in Table 4 below.

Table 4. Propargite: Registered uses of relevance to this evaluation.

Crop	Country	Form	Applicati	on			PHI	Comments	
		(EC - g/litre) (WP - g/kg)	Method	kg ai/ha (kg ai/hL)	Water, L/ha	No	(days)		
Beans (dry)	USA	EC 785	foliar	1.8 – 2.8	190 min (ground) 47 min (air)	21	14	West of the Rocky Mountains only. Do not use vines or trash for feed or forage	
Potato	USA	EC 785	foliar	1.4 – 2.3	190 - 470 (ground) 94 min (air)	21	14	Pacific Northwest only. NOT through irrigation	
Potato	USA	EC 719	foliar	1.7 – 2.5	190 - 470 (ground) 94 min (air)	21	14	Pacific Northwest only. May be applied through sprinkler irrigation	
Walnuts	USA	EC 719	foliar	1.7 - 5.0	935 min	2^{1}	21	ground application	
Walnuts	USA	EC 719	foliar	2.5 – 3.4	190 min	2 ¹		aerial application	
Tea	Japan	EC 569	foliar	0.43 - 1.5	1500 - 4000	2	14	No label sighted ³	
Citrus	Japan	WP 300	foliar	0.8 – 2.8 (0.04)	2000 - 7000	2	14	No label sighted ³	
Apple	Japan	WP 300	foliar	0.8 – 2.8 (0.04)	2000 - 7000	2	14	No label sighted ³	
Grapes	Japan	WP 300	foliar	0.6 – 2.1 (0.03)	2000 - 7000	2	14-21 ²	No label sighted ³	
Peach	Japan	WP 300	foliar	0.8 – 2.8 (0.04)	2000 - 7000	2	21	No label sighted ³	

Crop	Country		Applicati		PHI	Comments		
		(EC - g/litre) (WP - g/kg)		kg ai/ha (kg ai/hL)	Water, L/ha	No	(days)	
Cherries	Japan	WP 300	foliar	0.8 – 2.8 (0.04)	2000 - 7000		after harvest	No label sighted ³

- 1) Minimum spray interval of 21 days
- ²) PHI of 14 days for large berries; 21 days for small berries
- ³) GAP information provided by the manufacturer

RESIDUES RESULTING FROM SUPERVISED TRIALS

The Meeting received information on supervised field trials involving foliar applications of propargite on the following crops:

Citrus	Japan	Table 5
Apples	Japan	Table 6
Peaches	Japan	Table 7
Cherries	Japan	Table 8
Grapes	Japan	Table 9
Beans (dry)	USA	Table10
Potato	USA	Table 11
Walnut	USA	Table 12
Tea	Japan	Table 13

Trials from the USA were well documented with laboratory and field reports. Laboratory reports included method validation including procedural recoveries with spiking at residue levels similar to those occurring in samples from the supervised trials. Dates of analyses or duration of residue sample storage were also provided. Although trials included control plots, no residues in control samples exceeded the LOQ. Control data have therefore not been included in the following tables. Residue data are recorded unadjusted for recovery.

The summaries of the Japanese trials included application details and the propargite residues found, but no information on the analytical methods or whether the reported results had been corrected for recovery.

When residues were not detected they are shown as below the LOQ (e.g. < 0.01 mg/kg). Residues, application rates and spray concentrations have generally been rounded to two significant figures or, for residues near the LOQ, to one significant figure. Residue values from the trials conducted according to maximum GAP have been used for the estimation of maximum residue levels. These results are double underlined.

Citrus

Table 5. Residue data summary of supervised trials on citrus in Japan, involving foliar applications of propargite.

CITRUS	Applicati	ion			PHI,	Residue	s (mg/kg)	Reference &
Country, year (variety)	Form	kg ai/ha	kg ai/hL	no.	(days)	Pulp	Whole fruit	Comments
Mandarins								
Japan, Osaka, 1979 (Unshu)	WP 300	1.6	0.04	2	14	< 0.04		NN-0510 (S55-3-5-NNC.1)
Japan, Kagawa, 1979 (Unshu)	WP 300	2.0	0.04	2	14	< 0.04		NN-0510 (S55-3-5-NNC.2)
Japan, Osaka, 1979 (Unshu)	WP 300	1.6	0.04	2	14	0.02		NN-0510 (S55-3-5-IET.3)
Japan, Kagawa, 1979 (Unshu)	WP 300	2.0	0.04	2	14	0.01		NN-0510 (S55-3-5-IET.4)
Japan, Saga, 1973 (Unshu)	WP 300	1.32	0.04	2	14	< 0.04		NN-0510 (S55-3-5-IET.5)
Japan, Wakayama, 1973 (Unshu)	WP 300	2.4	0.04	2	14	0.02		NN-0510 (S55-3-5-IET.6)
Japan, Saga, 1973 (Unshu)	WP 300	1.32	0.04	2	14	0.08		NN-0510 (S55-3-5-NNC.7)
Japan, Wakayama, 1973 (Unshu)	WP 300	2.4	0.04	2	14	< 0.08		NN-0510 (S55-3-5-NNC.8)
Natsudaidai								
Japan, Yamaguchi, 1994 (Shin-Amanatsu)	WP 300	2.0	0.04	2	14		1.4	NN-0510 (H7.5.25-IET.1)
Japan, Tokushima, 1994 (Amanatsu)	WP 300	1.6	0.04	2	14		2.4	NN-0510 (H7.5.25-IET.2)
Japan, Yamaguchi, 1995 (Common-Natsu)	WP 300	2.0	0.04	2	14		1.9	NN-0510 (H8.7.1-IET.3)
Japan, Ohita, 1995 (Amanatsu)	WP 300	1.6	0.04	2	14		0.94	NN-0510 (H8.7.1-IET.4)
Japan, Yamaguchi, 1995 (Common-Natsu)	WP 300	2.0	0.04	2	14		2.1	NN-0510 (H8.5.10-JEO.5)
Japan, Ohita, 1995 (Amanatsu)	WP 300	1.6	0.04	2	14		1.1	NN-0510 (H8.5.10-JEO.6)
Japan, Aichi, 1997 (Kawano-Natsudaidai)	WP 300	1.6	0.04	2	14		0.7	NN-0510 (H10.3.10-JEO.7)
Japan, Mie, 1997 (Shin-Amanatsu)	WP 300	2.0	0.04	2	14		0.61	NN-0510 (H10.3.10-JEO.8)
Japan, Wakayama, 1997 (Kawano-Natsudaidai)	WP 300	1.6	0.04	2	14		1.6	NN-0510 (H10.3.10-JEO.9)
Japan, Ehime, 1997 (Kawano-Natsudaidai)	WP 300	1.6	0.04	2	14		1.2	NN-0510 (H10.3.10-JEO.10)
Japan, Fukuoka, 1997 (Kawano-Natsudaidai)	WP 300	1.6	0.04	2	14		1.8	NN-0510 (H10.3.10-JEO.11)

Apple

Table 6. Residue data summary of supervised trials on apples in Japan, involving foliar applications of propargite.

APPLE	Applicat	ion			PHI,	Residues	Reference &
Country, year (variety)	Form	kg ai/ha	kg ai/hL	no.	(days)	(mg/kg)	Comments
Japan, Aomori, 1997 (Fuji)	WP 300	2.0	0.04	1	14	1.24	NN-0510 (H9.12.18-IET.1)
Japan, Nagano, 1997 (Fuji)	WP 300	2.0	0.04	1	14	0.74	NN-0510 (H9.12.18-IET.2)
Japan, Aomori, 1997 (Fuji)	WP 300	2.0	0.04	1	14	1.13	NN-0510 (H10.2.23-JEO.3)
Japan, Nagano, 1997 (Fuji)	WP 300	2.0	0.04	1	14	0.7	NN-0510 (H10.2.23-JEO.4)

Grape

Table 7. Residue data summary of supervised trials on grapes in Japan, involving foliar applications of propargite.

GRAPE	Applicat	ion			PHI,	Residues	Reference &
Country, year (variety)	Form	kg ai/ha	kg ai/hL	no.	(days)	(mg/kg)	Comments
Japan, Osaka, 1996 (Delaware)	WP 300	0.6	0.03	1	28	1.12	NN-0510 (H9.1.27-IFES.1)
Japan, Okayama, 1996 (Muscat of Alexandria)	WP 300	0.6	0.03	1	28	0.46	NN-0510 (H9.1.27-IFES.2)
Japan, Osaka, 1996 (Delaware)	WP 300	0.6	0.03	1	28	1.22	NN-0510 (H8.12.18-ARSO.3)
Japan, Okayama, 1996 (Muscat of Alexandria)	WP 300	0.6	0.03	1	14	0.7	NN-0510 (H8.12.18-ARSO.4)
Japan, Yamanashi, 1971 (Neo-Muscat)	WP 300	0.6	0.03	4	19	1.94	NN-0510 (S46-NNC.5)
Japan, Yamanashi, 1971 (Neo-Muscat)	WP 300	0.6	0.03	7	19	2.83	NN-0510 (S46-NNC.5)

Peach

Table 8. Residue data summary of supervised trials on peaches in Japan, involving foliar applications of propargite.

PEACH	Applicat	ion			PHI,	Residues	Reference &
Country, year (variety)	Form	kg ai/ha	kg ai/hL	no.	(days)	(mg/kg)	Comments
Japan, Fukushima, 1981 (Hakuhou)	WP 300	1.6	0.03	2	21	0.02	NN-0510 (S56.10.27-JFRL.1)
Japan, Nagano, 1981 (Ohkubo)	WP 300	2.0	0.03	2	21	< 0.02	NN-0510 (S56.10.27-JFRL.2)
Japan, Fukushima, 1981 (Hakuhou)	WP 300	1.6	0.03	2	21	0.02	NN-0510 (S56.10.15-SAL.3)
Japan, Nagano, 1981 (Ohkubo)	WP 300	2.0	0.03	2	21	< 0.02	NN-0510 (S56.10.15-SAL.4)

PEACH	Application					Residues	Reference &
Country, year (variety)	Form	kg ai/ha	kg ai/hL	no.	(days)	(mg/kg)	Comments
Japan, Kagawa, 1973 (Sunago-wase)	WP 300	0.8	0.03	2	20	< 0.02	NN-0510 (S48.1.7-JFRL.5)

Residues reported in fruit without skin

Cherry

Table 9. Residue data summary of supervised trials on cherries in Japan, involving foliar applications of propargite after harvesting.

CHERRY Country, year (variety)	Applicat	ion		PHI,	Residues	Reference &	
	Form	kg ai/ha	kg ai/hL	no.	(days)	(mg/kg)	Comments
Japan, Yamagata, 1995 (Satonishiki)	WP 300	1.6	0.04	2	311	< 0.01	NN-0510 (H8.9.1-IET.1)
Japan, Fukushima, 1995 (Satonishiki)	WP 300	2.0	0.04	2	297	< 0.01	NN-0510 (H8.9.1-IET.2)
Japan, Yamagata, 1995 (Satonishiki)	WP 300	1.6	0.04	2	311	< 0.01	NN-0510 (H8.7.29-JEO.3)
Japan, Fukushima, 1995 (Satonishiki)	WP 300	2.0	0.04	2	297	< 0.01	NN-0510 (H8.7.29-JEO.4)

Beans (dry)

In six trials in the USA, involving a range of dry bean varieties, propargite was applied by either tractor mounted or backpack boom sprayers to single replicate plots of 81 to 110 square metres. Two treatments were made to maturing crops, 21 days apart, with the second treatment being about 14 days before commercial harvest. Application rates were all within 5% of the target rates. Three duplicate samples (min 1 kg) of mature dry beans were taken from each treatment plot (with one sample from the control plots) and these were frozen within 2.5 hours of sampling. After frozen storage for 73-137 days, the samples were analysed for propargite using method ME-208 ver 5. Recovery rates in these trials ranged from 73 - 115% (fortification at 0.023 and 0.23 mg/kg, n=4) and the reported LOQ was 0.02 mg/kg.

Table 10. Residue data summary of supervised trials on beans (dry) in the USA, involving foliar treatments with propargite.

BEANS (DRY)	Applicat	ion			PHI, Res	Residues ¹	Reference & Comments
Country, year (variety)	Form	kg ai/ha	kg ai/hL	no.	(days)	(mg/kg)	
USA, South Dakota, 2005 (Navy bean - Norstar)	EC 785	2.8	1.5	2	15	0.08	CC 2005-006 (DGD-05-001)
USA, Washington, 2005 (Pinto bean - Othello)	EC 785	2.8+ 2.7	1.5+ 1.5	1+ 1	7+7 ²	0.02	CC 2005-006 (DGD-05-002)
USA, California, 2005 (Garbanzo bean – Sierra)	EC 785	2.8+ 2.7	1.5+ 1.5	1+ 1	14	0.21	CC 2005-006 (DGD-05-003)
USA, Michigan, 2005 (Navy bean - Vista)	EC 785	2.8	1.5	2	13	0.16	CC 2005-006 (DGD-05-004)
USA, Michigan, 2005 (Red kidney bean – CA Early Light)	EC 785	2.8	1.5	2	14	0.07	CC 2005-006 (DGD-05-005)

BEANS (DRY)	` '					Residues ¹	Reference &
Country, year (variety)	Form	kg ai/ha	kg ai/hL	no.	(days)	(mg/kg)	Comments
USA, Pennsylvania, 2005 (??? – Great Northern)	EC 785	2.8	1.5	2	9+5 ³	<u>0.1</u>	CC 2005-006 (DGD-05-006)

- 1) Results are the mean values from analysis of three duplicate samples
- 2) Bean plants harvested 7 days after treatment and allowed to dry for 7 days before manual threshing
- 3) Bean plants harvested 9 days after treatment and allowed to dry for 5 days before manual threshing

Potato

In eight trials conducted in the USA in 1997 and 1998, propargite was applied by either tractor mounted or backpack boom sprayers to single replicate plots of 72 to 140 square metres. Two treatments were made to maturing crops, 21 days apart, with the second treatment being about 14 days before commercial harvest. Application rates were all within 5% of the target rates. Three duplicate samples (min 24 tubers or 4 kg) were taken from each treatment plot (with one sample from the control plots). In one trial, three additional samples were taken at 7 day intervals after treatment. Samples were frozen within 1.5 hours of sampling and after frozen storage for 28-160 days, were analysed for propargite using method CAL 004-50. Recovery rates in these trials ranged from 94 – 100% (fortification at 0.01 and 1.0 mg/kg) and the reported LOQ was 0.01 mg/kg.

In four additional trials conducted in the USA in 2004, propargite was applied by either tractor mounted or backpack boom sprayers to single replicate plots of 72 to 110 square metres. Two treatments were made to maturing crops, 14 days apart, with the second treatment being about 14 days before commercial harvest. Application rates were all within 5% of the target rates. Three duplicate samples (min 3 kg) were taken from each treatment plot (with one sample from the control plots) and these were frozen within 3 hours of sampling. After frozen storage for 137-154 days, the samples were analysed for propargite using method ME-208 version 5. The mean recovery rate in these trials was 91% (RSD 13%, n=16) following fortification at 0.01 mg/kg and 10 mg/kg. The reported LOQ was 0.01 mg/kg.

Table 11. Residue data summary of supervised trials on potato in the USA, involving foliar applications of propargite.

POTATO	Applicat	ion		PHI,	Residues ¹	Reference &	
Country, year (variety)	Form	kg ai/ha	kg ai/hL	no.	(days)	(mg/kg)	Comments
USA, Idaho, 2004 (Russet Burbank)	EC 785	2.3	1.2	2	15	<u>< 0.01</u>	RP-04002 (DNJ-04103)
USA, Idaho, 2004 (Russet Burbank)	EC 785	2.3	1.2	2	14	<u>< 0.01</u>	RP-04002 (DNJ-04102)
USA, Oregon, 2004 (Russet Burbank)	EC 785	2.3	1.2	2	14	< 0.01	RP-04002 (DNJ-04101)
USA, Washington, 2004 (Ranger Russet)	EC 785	2.3	1.2	2	14	< 0.01	RP-04002 (DNJ-04100)
USA, Colorado, 1997 (Norkota)	EC 785	2.3	1.2	2	14	<u>< 0.01</u>	RP-97013 (SWF-97-500)
USA, Washington, 1997 (Norkota)	EC 785	2.3	1.2	2	14	<u>< 0.01</u>	RP-97013 (DNJ-97-104)
USA, Washington, 1997 Russet Burbank	EC 785	2.3	1.2	2	14	<u>< 0.01</u>	RP-97013 (DNJ-97-105)

Propargite Propargite

POTATO	Applicati	ion			PHI,	Residues ¹	Reference &
Country, year (variety)	Form	kg ai/ha	kg ai/hL	no.	(days)	(mg/kg)	Comments
USA, Idaho, 1997 (Russet Burbank)	EC 785	2.3+ 2.3	1.3+ 1.2	1+	7 14 21 28	<0.01 <0.01 <0.01 <0.01	RP-97013 (DNJ-97-106)
USA, California, 1998 (White Rose)	EC 785	2.3+ 2.3	1.3+ 1.2	1+ 1	14	<u>0.015</u>	RP-97013 (CEJ-98-107)
USA, Washington, 1998 (Russet Burbank)	EC 785	2.3	1.2	2	14	<u>0.01</u>	RP-97013 (DNJ-98-115)
USA, Idaho, 1998 (Russet Burbank)	EC 785	2.3	1.2	2	14	<u>< 0.01</u>	RP-97013 (DNJ-98-116)
USA, Idaho, 1998 (Russet Burbank)	EC 785	2.3	1.2	2	14	<u>< 0.01</u>	RP-97013 (DNJ-98-117)

¹⁾ Results are the mean values from analysis of three duplicate samples

Walnuts

In six trials in the USA, propargite was applied by airblast sprayers to single replicate plots of 16–18 trees, ranging in height from 4–9 metres. Two treatments were applied, 20-21 days apart, with the second treatment being about 21 days before commercial harvest. Application rates were all within 5% of the target rates. Three duplicate samples of nuts were hand harvested from each treatment plot (with one sample from the control plots) and the kernels removed by hand, to give at least 1kg kernels per sample. These samples were frozen within 5 hours of sampling and stored frozen for 75–104 days before analysis using method GRL-12307. Recovery rates in these trials ranged from 90–120% (fortification at 0.023 and 0.12 mg/kg, n=4) and the reported LOQ was 0.02 mg/kg.

Table 12. Residue data summary of supervised trials on walnuts in the USA, involving foliar applications of propargite.

WALNUTS	Applicat	ion			PHI,	Residues	Reference &
Country, year (variety)	Form	kg ai/ha	kg ai/hL	no.	(days)	(mg/kg)	Comments
USA, California, 2005 (Howard)	EC 719	5.1+ 4.9	0.54+ 0.52	1+ 1	20	<u>< 0.02</u>	CC-2005-008 (DGD-05-008)
USA, California, 2005 (Hartley)	EC 719	5+ 5.1	0.63+ 0.66	1+	21	≤ 0.02	CC-2005-008 (DGD-05-009)
USA, California, 2005 (Chandlers)	EC 719	5.1+ 5	0.54+ 0.54	2	20	0.14	CC-2005-008 (DGD-05-010)
USA, California, 2005 (Chandlers)	EC 719	5.1+ 4.8	0.54+ 0.54	1+ 1	20	0.13	CC-2005-008 (DGD-05-011)
USA, California, 2005 (Chandlers)	EC 719	5	0.54	2	21	0.02	CC-2005-008 (DGD-05-012)
USA, California, 2005 (Hartley)	EC 719	5.1	0.54	2	21	0.08	CC-2005-008 (DGD-05-013)

Tea

Table 13. Residue data summary of supervised trials on tea in Japan, involving foliar applications of propargite.

TEA	Application					Residues	Reference &
Country, year (variety)	Form	kg ai/ha	kg ai/hL	no.	(days)	(mg/kg)	Comments
Japan, Miyazaki, 1974 (Yabukita)	EC 596	1.52	0.038	2	14	0.24	NN-0510 (S50-7-3-JFRL.1)
Japan, Shizuoka, 1974 (Yabukita)	EC 596	1.52	0.038	2	14	1.0	NN-0510 (S50-7-3-JFRL.2)
Japan, Miyazaki, 1974 (Yabukita)	EC 596	1.52	0.038	2	14	0.3	NN-0510 (S50-7-3-SAL.3)
Japan, Shizuoka, 1974 (Yabukita)	EC 596	1.52	0.038	2	14	0.72	NN-0510 (S50-7-3-SAL.4)

APPRAISAL

Propargite [2-(4-*tert*-butylphenoxy)cyclohexyl prop-2-ynyl sulfite] was first evaluated by the JMPR for residues in 1977 and toxicology in 1978, with subsequent evaluations in 1978, 1979, 1980 and 1982. A periodic review (toxicology) was conducted by JMPR in 1999 when an ADI of 0-0.01 mg/kg bw was estimated and it was concluded that an acute reference dose was not necessary. A periodic review of residues was conducted in 2002 and MRLs were recommended for many crops and animal commodities. MRLs for beans (dry), pears, potato, pears, strawberry and walnuts were among those not proposed because of insufficient data or GAP information.

The CCPR (36th Session, 2004, paragraph 141, ALINORM 04/27/24) retained the existing Codex MRLs for beans (dry), pear, potato, strawberry and walnuts for 4 years under the periodic review procedure so that additional data could be provided to support these MRLs.

Information on registered uses and data from supervised residue trials in USA on beans (dry), potato and walnuts, together with additional information on methods of analysis and residue stability in stored analytical samples, were provided to the Meeting by the USA manufacturer and additional information on GAP and summaries of residue trials in Japan on citrus, apples, peaches, cherries, grapes and tea were provided by the Japanese manufacturer. No information was provided for pears or strawberries.

Analytical methods

The meeting received analytical method descriptions and validation data for propargite in beans (dry), walnuts and potato. These methods involved minor variations on a method ME-208, capable of determining both propargite and the metabolite t-butyl phenoxy cyclohexanol (TBPC). These methods were previously evaluated by JMPR in 2002.

The reported methods involved the acetonitrile extraction of residues in homogenized plant matrices, with the filtered extract being washed with hexane before being mixed with 10% NaCl and partitioned into either petroleum ether or hexane. After concentration and clean-up using a Florisil® column, the extracts were evaporated to dryness or near dryness. In some studies (potato and dry beans), the primary metabolite (TBPC) was then derivatised by incubation with triethylamine and heptafluorobutyric anhydride. Extracts were then resuspended in either hexane or toluene and analyzed for propargite using a gas chromatograph equipped with a mass selective detector (GC-MSD) in the selected ion monitoring mode. Residues of the TBPC metabolite were not reported as

this is not included in the residue definition for either compliance with MRLs or for dietary intake estimation. Limits of quantification (LOQs) for these methods were 0.02 mg/kg for beans (dry) and walnuts (nutmeat) and 0.01 mg/kg for potato.

Stability of pesticide residues in stored analytical samples

The Meeting received information on the stability of propargite in various commodities under freezer storage (-16 to -20 °C). These studies were among those previously assessed by JMPR in 2002, where it was noted that with the exception of forage and fodder crops, more than 70% of propargite residues remained in frozen samples stored for about one year.

The Meeting agreed with the previous JMPR conclusion that propargite residues were stable in most frozen plant commodities for about one year, and could be applied to beans (dry), walnuts and potato, based on studies provided for alfalfa (seed, foliage and alfalfa hay), barley grain, almond kernels and on the potato study previously evaluated by the 2002 JMPR.

Results of supervised trials on crops

The Meeting received reports of supervised trials conducted in USA, where propargite was applied to a range of bean varieties grown for dry bean production, chick-peas, potato and walnuts and also received summaries of residue trials in Japan on citrus, apples, peaches, cherries, grapes and tea.

The Meeting agreed that the MRLs recommended at the 2002 Meeting for these latter commodities (citrus, apples, peaches, cherries, grapes and tea) were sufficient to accommodate residues arising from the Japanese GAPs, and that no further evaluation was required.

Beans (dry), chick-peas (dry)

Field trials conducted in USA on a range of bean varieties grown for dry bean production, and on chick-peas, involving two foliar applications of propargite were made available to the Meeting. Information on one additional trial on red kidney beans was provided to the JMPR 2002.

GAP in USA for *Lupinus*, *Phaseolus and Vicia spp* grown for dry bean production and for chick-peas, i.e., crops within the USA 'beans (dry)' group, is for up to two applications per season, with a maximum rate of 2.8 kg ai/ha, a 21 day interval between treatments with a PHI of 14 days. In six of the bean trials from USA matching the USA GAP, residues in beans (dry) were: 0.02, 0.07, 0.08, 0.1, 0.11 and 0.16 mg/kg and in one chick-pea trial, residues were 0.21 mg/kg.

The Meeting agreed that the results of the above trials could be combined and used to mutually support recommendations for beans (dry) and chick-peas, and could be extrapolated to similar commodities for which GAP existed in USA. The combined results were: 0.02, 0.07, 0.08, 0.1, 0.11, 0.16 and 0.21 mg/kg.

The Meeting estimated maximum residue levels of 0.3 mg/kg and STMRs of 0.1 mg/kg for beans (dry), lupin (dry), broad bean (dry) and chick-pea (dry).

Potato

Field trials conducted in USA involving two foliar applications of propargite on potatoes, were made available to the Meeting.

GAP in USA for potatoes is for up to two applications per season, with a maximum rate of 2.5 kg ai/ha, a 21 day interval between treatments and a PHI of 14 days. In eight USA trials matching USA GAP, reported residue levels in potato tubers were: < 0.01 (6), 0.01 and 0.02 mg/kg. In a further four trials with a shorter treatment interval of 14 days, but otherwise matching the USA

GAP, residue levels were all < 0.01 mg/kg. The Meeting agreed to combine the data from these two sets of trials, as the different spray intervals were not expected to influence the residue levels present in the tubers. The residue levels in the combined set of 12 trials were: < 0.01 (10), 0.01 and 0.02 mg/kg.

The Meeting estimated a maximum residue level of 0.03 mg/kg for potato and estimated an STMR of 0.01 mg/kg.

Walnuts

Field trials conducted in USA on walnuts, involving two foliar (air blast) applications of propargite were made available to the Meeting.

GAP in the USA for walnuts allows up to two applications per season, with a maximum rate of 2.5 kg ai/ha, a 21 day interval between treatments and a PHI of 21 days. In six USA trials matching USA GAP, reported residue levels in walnut kernels (nutmeat) were: < 0.02(2), 0.02, 0.08, 0.13 and 0.14 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg for walnuts and estimated an STMR of 0.05 mg/kg.

Animal commodity maximum residue levels

The Meeting noted that the GAP for dry bean varieties in USA included a condition that treated vines or trash should not be used for animal forage or fodder, and that the potential contribution to the farm animal dietary burden from residues in potato culls would be insignificant (when compared to the contribution from other fruit and vegetable by-products such as citrus pulp).

The Meeting therefore concluded that the farm animal dietary burden estimated by the JMPR in 2002 was still valid and confirmed the existing maximum residue limits and STMRs estimated for propargite in 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 levels and for IEDI assessment.

Definition of the residue (for compliance with MRLs and for estimation of dietary intake): *propargite*. This definition applies to both plant and animal commodities.

The residue is fat-soluble.

CNN	Commodity Name	MRL	(mg/kg)	STMR or STMR-
		New Previous		P
				(mg/kg)
VD0071	Beans (dry)	0.3	0.2	0.1
VD0523	Broad bean (dry)	0.3		0.1
VD0524	Chick-pea (dry)	0.3		0.1
VD0545	Lupin (dry)	0.3		0.1
VR0589	Potato	0.03	0.1*	0.01
TN0678	Walnuts	0.3	0.1*	0.05

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of propargite has resulted in recommendations for new maximum residue limits and STMR values for several new commodities. Data on consumption were available for 32 commodities from this and previous evaluations, and this data was used to calculate dietary intake. The results are shown in Annex 3 of the 2006 JMPR Report.

The IEDIs in the 13 GEMS/Food cluster diets, based on the estimated STMRs were 3–30% of the maximum ADI (0.01 mg/kg bw). The Meeting concluded that the long-term dietary intake of residues of propargite from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The 2002 JMPR concluded that it was unnecessary to establish an ARfD for propargite. The Meeting therefore concluded that the short-term dietary intake of residues of propargite from uses that have been considered by the JMPR is unlikely to present a risk to consumers.

REFERENCES

Author, Date, Title, Institute, Report Reference, Document No.

Anon. 2005. Residue Summary Data on Propargite Residues in Tea, Citrus, Apples, Grapes, Peaches and Cherries in Japan, Nihon Nohyaku Co Ltd., Unpublished NN-0510

Dzialo, D. 2006. Omite 6E® on Walnuts: Magnitude of the Residue Study. Study No. 2005-008, Chemtura Corporation, Unpublished. CC-2005-008

Black, H.M. 2006. Validation of a Working Method for the Determination of Propargite in or on Walnut Nutmeat. Study No. GRL-12307, Crompton Co./Cie, A Chemtura Company, Guelph, Canada, Unpublished. GRL-12307

Black, H.M. 2006. Validation of a Working Method for the Determination of Propargite in or on Dry Beans. Study No. GRL-12308, Crompton Co./Cie, A Chemtura Company, Guelph, Canada, Unpublished. GRL-12308

Korpalski, S. 2006. Comite® on Potatoes: Magnitude of the Residue. Study No. RP-04002, Chemtura Corporation, Unpublished. RP-04002

Korpalski, S. 2006. Comite® on Potatoes: Magnitude of the Residue. Study No. RP-97013, Chemtura Corporation, Unpublished. RP-97013

Popadic, C.M. 1993. Stability of Propargite and OMITE® Glycol Ether in Barley, Lettuce, Carrots and Soil Matrices Stored in Frozen Storage. Study No. RP-89064, Uniroyal Chemical Co., Unpublished. RP-89064

Popadic, C.M. 1993. Stability of Propargite in Almond Nuts and Hulls Stored in Frozen Storage. Study No. RP-91057, Uniroyal Chemical Co., Unpublished. RP-91057

Popadic, C.M. 1994. Stability of Propargite in Alfalfa Seed, Seed Screenings and Fresh and Dry Hay Stored in Frozen Storage. Study No. RP-91062, Univoyal Chemical Co., Unpublished. RP-91062

Russell, R. and Dzialo, D. 2006. Comite® on Dry Beans: Magnitude of the Residue Study. Study No. 2005-006, Chemtura Corporation, Unpublished. CC-2005-006

Webster, S. 1998. Residue Analytical Method Validation for Propargite and TBPC in Potatoes, Mint, and Stonefruit. Study No. RP-97019, Uniroyal Chemical Co., Unpublished RP-97019.

Wood, B.J. 2005. Residue Analytical Method Validation for Propargite in Cottonseed, Cotton Gin By-Products, and Potato Matrices by GC/MSD. Study No. RP-04029, Crompton Co./Cie, A Chemtura Company, Guelph, Canada, Unpublished. RP-04029