PROPAMOCARB (148)

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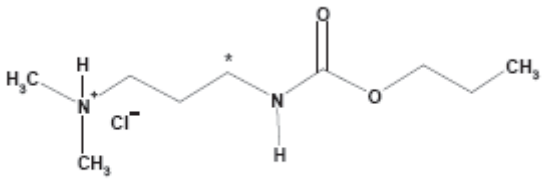
Propamocarb hydrochloride is a systemic carbamate fungicide with specific activity against Oomycete species that cause seed, seedling, root, foot and stem rots and foliar diseases in a number of edible crops. The compound was firstly evaluated by the JMPR in 1984, and was then reviewed by JMPR in 1986, 1987 and 2005, an ADI of 0–0.4 mg/kg bw and an ARfD of 2 mg/kg bw were established in 2005. Propamocarb was evaluated by the 2006 JMPR for residue and analytical aspect within the periodic review programme. The residue definition in plant for both enforcement and dietary intake purpose is propamocarb (free base), and the residue definition in animal products for both enforcement and dietary intake purpose is propamocarb, and propamocarb is not fat soluble.

The residue data in/on onion, broccoli, cauliflower, Brussels sprouts, head cabbage, kale, leek and lima bean was submitted to JMPR, and were evaluated by current Meeting. In addition, new analytical methods as well as new studies on animal metabolism and feeding, rotational crops and processed commodities are received and evaluated.

ANIMAL METABOLISM

Laying hen

The metabolism and distribution of propamocarb in laying hens were studied using [^{14}C]-propamocarb hydrochloride by Beedle and Miller (2010, MEPRX029, M-366633-01-1). The structural formula and the position of the ^{14}C label are shown below.



Propamocarb
* = [^{14}C] radiolabel

Twelve laying hens were dosed orally, via capsule, with [^{14}C] propamocarb hydrochloride at a rate of 1.02 mg/kg body weight (approximately 19 ppm in the feed) once daily for fourteen consecutive days. Eggs were collected once daily during the treatment period. Approximately 6 to 8 hours after the last dose, the hens were sacrificed, and edible tissues (liver, leg muscle, breast muscle, omental fat, subcutaneous fat, and renal fat) were collected. Tissue and egg samples were frozen immediately after collection and all of the samples were analysed within 6 months.

The total radioactive residue (TRR) in the egg and tissues was determined by oxidative combustion followed by liquid scintillation counter (LSC) or by direct LSC. Identification and quantitation of the residues in the egg and tissue extracts were accomplished by using reverse phase high performance liquid chromatography (HPLC) and liquid chromatography-mass spectrometry/ mass spectrometry (LC-MS/MS).

Eggs, liver and muscle samples were extracted with acetonitrile/water (4:1) containing 1% acetic acid, blended, centrifuged and decanted from the solids. The extraction and centrifugation were repeated five times. The combined acetonitrile/water/acetic acid extract was radioassayed. The acetonitrile/water extracted solids were refluxed overnight in acetonitrile/water (4:1) containing 1% acetic acid. After cooling, centrifugation and decantation, the acetonitrile/water/acetic acid reflux extract was radioassayed. If un-extracted radioactivity remained in the solids (eggs), the solids were refluxed with extraction solvent followed by a dilute base (2 N KOH). Un-extracted residues in solids of the liver were enzymatically released by agitation with protease at 37 °C and pH 7.4 overnight. All

the extracts were combined and concentrated via rotary evaporator. The sample was radioassayed, and an aliquot was analysed by HPLC.

Fat samples were extracted with hexane, blended, centrifuged and decanted from the solids. The extraction and centrifugation were repeated once. The hexane extracts were combined and radioassayed. The combined hexane extract was partitioned three times with acetonitrile. The combined acetonitrile layers were radioassayed. After that, water was added to the hexane extract two times for a partition. The combined water layers and the hexane extract were radioassayed. The hexane-extracted solids were homogenized with acetonitrile/water (4:1) containing 1% acetic acid, blended, centrifuged and decanted from the solids. The extraction and centrifugation were repeated three times. The acetonitrile/water extracts were combined, radioassayed, and concentrated to an aliquot which was analysed by HPLC. The acetonitrile/water extracted solids were air-dried overnight at room temperature and aliquots were radioassayed. The hexane extract was concentrated to an oily residue via rotary evaporator. An aliquot of 2N potassium hydroxide (KOH) in ethanol was added to the concentrated sample. The sample was refluxed, cooled to room temperature and water was added to the sample which was partitioned two times with hexane. The combined hexane layers were back-extracted with water. The hexane fraction and the water fraction were radioassayed.

The TRR in eggs increased from day-1 through day-7 and reached a plateau at day-8. The TRR (expressed in Propamocarb hydrochloride equivalents) in the egg samples ranged from 0.015 mg/kg in the day-1 eggs to 0.254 mg/kg in the day-11 eggs, at maximum.

The TRR in the tissue samples from the hens dosed with Propamocarb hydrochloride for fourteen consecutive days was 0.492 mg/kg in liver, 0.135 mg/kg in leg muscle, 0.117 mg/kg in breast muscle, 0.042 mg/kg in omental fat, 0.042 mg/kg in subcutaneous fat and 0.065 mg/kg in renal fat.

The majority of the residues (92% to 99% of the TRR) in the egg and tissues were extractable and only 1% to 8% of the TRR (0.001 to 0.038 mg/kg) of the residues in egg and tissues were un-extractable. The major residues in the egg and tissues were parent propamocarb (2% to 12% of the TRR; < 0.001 to 0.046 mg/kg) and desmethyl propamocarb (6% to 45% of the TRR; 0.003 to 0.113 mg/kg). The minor residues found in the egg and tissues were bis-desmethyl-propamocarb (< 1% to 7% of the TRR; < 0.001 to 0.029 mg/kg) and propamocarb-N-oxide (< 1% of the TRR; 0.003 mg/kg). The results of these analyses are presented in Table 1.

Table 1 Summary of characterization and identification of radioactive residues in hen matrices following the oral administration of [^{14}C] Propamocarb at a rate of 1.02 mg ai/kg body weight/day for fourteen consecutive days

Compound	Day-9 Egg TRR = 0.252 mg/kg		Liver TRR = 0.492 mg/kg		Muscle TRR = 0.126 mg/kg		Fat TRR = 0.043mg/kg	
	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg
E1, F1	4	0.010	ND	ND a)	ND	ND	8	0.004
M1-a	ND	ND			16	0.020	ND	ND
M1-b, L1-a	ND	ND	1	0.007	8	0.010	ND	ND
L1-b	ND	ND	5	0.025	ND	ND	ND	ND
L1-c	ND	ND	9	0.045	ND	ND	ND	ND
L1-d	ND	ND	3	0.013	ND	ND	ND	ND
L2-a	ND	ND	<1	0.004	ND	ND	ND	ND
L2-b	ND	ND	<1	0.001	ND	ND	ND	ND
L2-c	ND	ND	<1	0.003	ND	ND	ND	ND
M2, F2	ND	ND	ND	ND	6	0.007	2	0.001
Propmaocarb-N-oxyde (L2-d)	ND	ND	<1	0.003	ND	ND	ND	ND
Bis-desmethyl Propamocarb (E2, L3, F3, M3)	4	0.010	6	0.029	7	0.008	< 1	<0.001
Desmethyl-Propamocarb (E3, L3, F4, M4)	45	0.113	22	0.107	29	0.037	6	0.003
Propamocarb (E4, L5, F5, M5)	12	0.031	9	0.046	5	0.006	2	<0.001

Compound	Day-9 Egg TRR = 0.252 mg/kg		Liver TRR = 0.492 mg/kg		Muscle TRR = 0.126 mg/kg		Fat TRR = 0.043mg/kg	
	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg
F6	ND	ND	ND	ND	ND	ND	3	0.001
E5, F7, M6	2	0.005	ND	ND	6	0.008	<1	<0.001
L6, F8	ND	ND	3	0.015	ND (a	ND (a	1	<0.001
L7, F9, M7	ND	ND	8	0.038	5	0.006	2	<0.001
E6	4	0.009	ND	ND	ND	ND	ND	ND
Total Identified	61	0.154	37	0.185	41	0.051	9	0.004
Total Characterized	38	0.096	55	0.269	51	0.066	89	0.038
Total extractable	99	0.250	92	0.454	92	0.117	98	0.042
Unextracted	1	0.003	8	0.038	8	0.010	2	0.001
Accountability	103		105		112		112	

ND = Not Detected

Metabolic Pathway in hen

Metabolic degradation of propamocarb is rapid and extensive, with between 2% and 12% of the TRR being observed in the egg and tissues as unmetabolized parent propamocarb. Demethylation products including desmethyl-propamocarb and bis-desmethyl-propamocarb were identified as major metabolites in egg and tissue samples, indicating that demethylation is the main route of metabolism for the parent compound. A minor route of metabolism involves oxidation of the tertiary nitrogen to form propamocarb-N-oxide. The proposed metabolic pathway for the metabolism of propamocarb in hens is shown in Figure 1 below

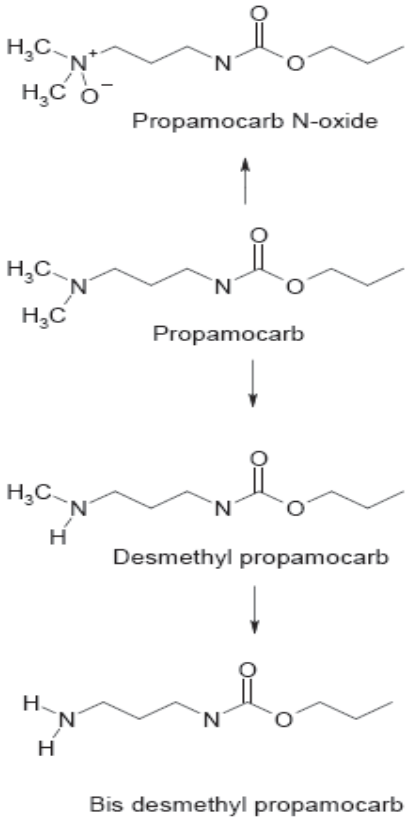


Figure 1 Proposed metabolic pathway of Propamocarb in Hens

Field crop rotational studies

Studies were conducted in Germany and France (Klein, 2004, M-226597-01-1) during 2002 and 2003, with four trials to investigate the residue level of propamocarb hydrochloride in secondary crops (Lamb's lettuce with a PBI of 52–59 days and wheat with a PBI of 81–102 days) after application to cabbages as the primary crop. No residues of propamocarb were found in any sample taken from the rotational crops, i.e., lettuce, wheat grain, wheat (green material) and wheat forage.

Cabbage plants were treated twice by drench applications to seedbeds. The first application was carried out at an application rate of 72.2 kg/ha of propamocarb hydrochloride at BBCH 00–11, directly after sowing and the second drench application 14 days after the first at an application rate of 36.1 kg/ha of propamocarb hydrochloride at BBCH 10–13. After transplanting of the young cabbage plants into the field, two additional foliar treatments were carried out at BBCH 15–45. Both spray treatments were applied at 3.61 kg/ha of propamocarb hydrochloride, the first immediately after transplanting and the second 39 to 66 days later at BBCH 41–45 (20 to 50% of the expected head size reached). Samples of cabbage were taken at day 0, 7, 14, 21 and 27–29 after the last application. After the harvest of the primary crop, the following (rotational) crops wheat and lamb's lettuce were sown in the plots.

Samples of lamb's lettuce were taken at day 111–267 (BBCH 46) and day 217–273 (BBCH 49) after the last treatment. In trial 02R460-4 in France, lamb's lettuce was abandoned due to poor germination and poor plant growth. Samples of wheat (green material) were taken at day 308–348 (BBCH 71) after the last application, wheat grain and wheat straw at day 362–369 (BBCH 89). Samples of soil were taken directly after the last application, at the time of lettuce sowing (day 52–59), at the time of wheat sowing (day 81–102), at the time of lamb's lettuce harvest (day 217–273) and at the time of wheat harvest (day 362–369).

Samples of cabbage, lamb's lettuce, wheat grain, wheat (green material) and wheat straw were analysed for residues of Propamocarb (free base) according to method 00880 by LC-MS/MS (Mende P., 2001; M-200511-02-1 or C015449) and soil samples were analysed for residues of Propamocarb (free base) according to method 20001397/01-RVS by LC-MS/MS (Mende P., 2002; M-215230-01-1 or C023560). The limit of quantification (LOQ) for Propamocarb hydrochloride was established and validated at 0.01 mg/kg in/on cabbage (head), lamb's lettuce (whole plant with root) and wheat grain, at 0.02 mg/kg for soil and 0.05 mg/kg for wheat green material and wheat straw.

Table 2 Residues in rotational crops after applications of propamocarb in the primary crop cabbage

Crop (Variety)	Country Site	Application				Residues			
		No	kg/ha (ai)	kg/hL (ai)	GS	Portion analysed	DAT [a] (days)	PCH [b] (mg/kg)	PMB [c] (mg/kg)
Cabbage, white (Perfekta)	Germany Gersthofen	4	3.61-72.2	0.181-0.60	42	cabbage, head	0	0.07	0.06
							7	0.07	0.06
							14	0.06	0.05
L Lettuce (Vita)							21	0.03	0.03
							28	0.03	0.03
Wheat (Magnus)									
						lettuce [d]	241	<0.01	<0.01
						wheat [e]	264	<0.01	<0.01
						wheat grain	348	<0.05	<0.05
						wheat straw	369	<0.01	<0.01
							369	<0.05	<0.05
						soil			
							0	0.21	0.18
							59	<0.02	<0.02
							102	<0.02	<0.02
							264	<0.02	<0.02
							369	<0.02	<0.02

Crop (Variety)	Country Site	Application No	kg/ha (ai)	kg/hL (ai)	GS	Residues Portion analysed	DAT [a] (days)	PCH [b] (mg/kg)	PMB [c] (mg/kg)
Cabbage, white (Agressor) L Lettuce (Vit) Wheat (Drifter)	Germany Bornheim	4	3.61-72.2	0.181-0.72	41	cabbage, head	0	2.1	1.8
							7	0.09	0.08
							14	0.05	0.04
							21	0.03	0.03
							29	0.02	0.02
						lettuce [d]	111	<0.01	<0.01
							217	<0.01	<0.01
						wheat [e]	317	<0.05	<0.05
						wheat grain	362	<0.01	<0.01
						wheat straw	362	<0.05	<0.05
						soil	0	0.76	0.64
							54	<0.02	<0.02
							82	<0.02	<0.02
							217	<0.02	<0.02
							362	<0.02	<0.02
Cabbage, white (Kilor) L Lettuce (Dunkel-grüner vollherzi-ger) Wheat (Charger)	Germany Vechta-Langfoerden	4	3.61-72.2	0.181-0.60	43	cabbage, head	0	5.0	4.2
							7	0.16	0.13
							14	0.12	0.10
							21	0.06	0.05
							27	0.06	0.05
						lettuce [d]	267	<0.01	<0.01
							273	<0.01	<0.01
						wheat [e],	326	<0.05	<0.05
						wheat grain	367	<0.01	<0.01
						wheat straw	367	<0.05	<0.05
						soil	0	1.2	1.0
							52	<0.02	<0.02
							81	<0.02	<0.02
							273	<0.02	<0.02
							367	<0.02	<0.02
Cabbage, white (Destiny) L Lettuce (Dunkel-grüner vollherzi-ger) Wheat (recital)	France Soucelles	4	3.61-72.2	0.181-0.72	45	cabbage, head	0	2.6	2.2
							7	0.38	0.32
							14	0.24	0.20
							21	0.24	0.20
							28	0.07	0.06
						wheat [e],	308	<0.05	<0.05
						wheat grain	362	<0.01	<0.01
						wheat straw	362	<0.05	<0.05
						soil	0	0.30	0.25
							57	0.04	0.03
							98	<0.02	<0.02
							362	<0.02	<0.02

[a] DALT: Days after last treatment
[b] PCH = Propamocarb hydrochloride
[c] PMB = Propamocarb
[d] lettuce, whole plant with root
[e] wheat green material

Table 3 Recovery of Propamocarb in lamb's lettuce (whole plant with root), white cabbage (head), wheat (green material, grain and straw) and in soil*

StudyTrial No., Trial SubID, GLP, Year	Crop / plant origin	Portion analysed	Active substance	Fortification level (mg/kg)	Recovery (%) Single values	n	Mean	RSD
02R460 02R460-1 02R460-2 02R460-3 02R460-4 GLP yes 2002	Lamb's lettuce	Whole plant with root	Propamocarb	0.010	91 95 98 94 88	5	93	4.1
				0.100	103 97 84 91 88	5	93	8.1
		Overall Recovery				10	93	6.1
	White cabbage	Head	Propamocarb	0.010	78 79	2	79	-
				0.100	80 80	2	80	-
				6.0	103	1	103	-
		Overall Recovery				5	84	13
	Wheat	Green material	Propamocarb	0.050	85 91 100 101 102 99 100 105 94 98	5 5	96 99	7.8 4.0
		Overall Recovery				10	98	6.1
		Grain	Propamocarb	0.010	84 89	2	85	-
				0.100	94 94	2	94	-
		Overall Recovery				4	90	5.3
		Straw	Propamocarb	0.050	67 81 89 83 93	5	83	12
				0.500	89 92 89 95 90	5	91	2.8
		Overall Recovery				10	87	9.4
	Soil	-	Propamocarb	0.020	88 84	2	86	-
				0.200	97 92	2	95	-
				10	100 98	2	99	-
		Overall Recovery				6	93	6.7

* Recovery samples for Propamocarb determination were prepared by fortification of untreated samples with Propamocarb free base reference substance and calculated as Propamocarb hydrochloride.

Four rotational crop studies in The Netherlands, France, Spain and Italy (Melrose and Portet, 2010, M-349882-02-1, M-349137-02-1, M-361470-01-1, and M-349147-02-1) were conducted in/on lettuce as primary crop, followed by lettuce, carrots and winter wheat or winter barley as following rotational crops, with an intended plant black interval (PBI) of 30 days during the years 2008 to 2010.

Propamocarb was applied on lettuce as the primary crop with three spray applications at 2.5 L/ha corresponding to 1.325 kg propamocarb/ha per application. The applications were carried out with 7–13 days interval. The first treatment on lettuce (primary crop) was conducted at BBCH 14–42, whilst the last application was carried out at BBCH 19–48, 5–7 days before the anticipated commercial harvest. Lettuce (primary crop) was harvested at normal harvest stage, 32–69 days after planting. No lettuce samples were taken for analysis. Harvested primary crop lettuce was destructed and the remaining plant parts were incorporated by a mulling machine or a little rotary machine. At the 27–38 day plant back interval for carrots, 26–46 day plant back interval for lettuce and 30–38 day plant back interval for cereals the plots were prepared for crop planting/sowing (rotational crops) following normal agronomic practices for each crop type in the regions. The carrots were harvested at BBCH 46–49, the lettuce was harvested at BBCH 45–49, and the cereals were harvested at BBCH 29–89.

Lettuce, carrot and cereal samples were analysed for residues of propamocarb according to method 00880/M002 by LC-MS/MS with a LOQ of 0.01 mg/kg for carrot (root and leaf), lettuce

(head), winter wheat and winter barley (grain) and with a LOQ of 0.05 mg/kg for winter wheat and winter barley (green material and straw). Residues were determined and expressed as propamocarb.

Table 4 Recovery of Propamocarb in lettuce, carrots and cereals (secondary crops)

Crop	Portion analysed	Fortification level (mg/kg)	Recovery (%)		
			Single values	n	Mean
Carrot	leaf	0.01	87, 84, 79, 90, 84, 80, 80	7	83
		0.10	89, 90, 94, 91, 74, 77, 86, 86	8	86
	Overall Recovery			15	85
	root	0.01	84, 82, 80, 73, 84, 78, 69	7	79
		0.10	97, 98, 93, 92, 99, 87, 89, 90	8	93
	Overall Recovery			15	86
Lettuce	head	0.01	89, 86, 93, 92, 98, 83	6	90
		0.10	100, 101, 95, 97, 98, 78, 82	7	93
	Overall Recovery			13	92
Winter wheat	grain	0.01	70, 63, 82, 87, 69, 70	6	74
		0.1	83, 76, 67, 77, 76	5	76
	Overall Recovery			11	75
	green material	0.05	84, 60, 69, 92, 97, 90, 91	7	83
		0.5	73, 71, 69, 91, 92	5	79
	Overall Recovery			12	81
	straw	0.05	86, 77, 77, 93, 94, 86, 70	7	83
		0.5	76, 73, 77, 81, 80	5	77
	Overall Recovery			12	80
Winter barleyt	grain	0.01	92, 95, 98, 70	4	89
		0.1	89, 89, 91	3	90
	Overall Recovery			7	89
	green material	0.05	84, 83, 78, 83	4	82
		0.5	87, 88, 89	3	88
	Overall Recovery			7	84
	straw	0.05	75, 72, 76	3	74
		0.5	60, 74, 64	3	66
	Overall Recovery			6	70

No residues of Propamocarb could be detected (below LOQ: 0.01 mg/kg for carrots, lettuce and cereals grain, 0.05 mg/kg for cereals straw) in rotational crops at a mean plant black interval (PBI) of 31 days (from 27 to 38 days) in carrots (root and leaf), at a mean PBI of 33 days (from 26 to 46 days) in lettuce (head and leaf) and at a mean PBI of 33 days (from 30 to 38 days) in cereals (grain and straw).

RESIDUE ANALYTICAL METHODS

Analytical methods for the determination of residues of propamocarb in plant and animal matrices have been evaluated by the 2006 JMPR. The QuEChERS Method (BCS method ID 01205) for the determination of residues of Propamocarb in meat (cattle), liver (cattle), kidney (cattle), fat (cattle), milk (cattle) and egg (chicken) was developed and validated (Konrad and Neuland, 2010, M-398135-01-1 and M-387185-01-1).

The Multi Method L 00.00-115 “QuEChERS” of the Official Collection of Test Methods was performed according to § 64 LFGB with:

- extraction with water/acetonitrile (5 g homogenised specimens and 5 mL of water (7 mL for fat samples) and 10 mL of acetonitrile);
- addition of magnesium sulphate, sodium chloride and sodium citrate, liquid/liquid partition and subsequent centrifugation;
- clean up by Primary Secondary Amine (PSA) and/or by freezing-out;
- detection with liquid chromatography tandem mass spectrometry LC-MS/MS using two mass transitions.

The quantification was done by an external calibration using matrix matched standards prepared in solvents. The respective followed mass transitions are presented in Table 3 below.

Table 5 Quantification and confirmatory mass transitions

	Mass transition used for quantification (1^{st} MRM)	Mass transition used for confirmation (2^{nd} MRM)
Propamocarb	189 ->102 m/z	189 ->74 m/z

For validation of the method, recovery experiments were performed by fortifying control specimens of the matrices meat, liver, kidney, fat, milk and egg at levels of 0.01 mg/kg (LOQ) up to 0.10 mg/kg.

Matrix effects for propamocarb in meat, liver, kidney, fat, milk and egg were investigated in a preliminary test. For this purpose a calibration solution of 50 ng/mL propamocarb hydrochloride was diluted with acetonitrile / 0.05% acetic acid (1/4, v/v). The same dilution was prepared using control extracts of all matrices. The final concentrations obtained were 5 ng/mL in control matrices or in acetonitrile / 0.05% acetic acid (1/4, v/v). The results are summarized in Table 6 below.

Table 6 Results of the matrix effects assessment

Matrix	Signal of the matrix matched standard relative to the solvent standard in [%]	
	189 ->102 m/z	189 ->74 m/z
Liver	96	93
Meat	78	75
Kidney	95	100
Egg	97	98
Fat	94	90
Milk	99	98

The tests for meat showed a signal depression of up to 25%. Only slight effects were observed for liver, kidney, egg, fat and milk.

The limit of quantification (LOQ) was set at 0.01 mg/kg for propamocarb (expressed as propamocarb) in all the sample materials (meat, liver, kidney, fat, milk and egg).

The limit of determination (LOD) was 0.003 mg/kg (30% of LOQ) for propamocarb (expressed as propamocarb) in all the sample materials (meat, liver, kidney, fat, milk and egg). The chromatographic peaks of propamocarb were greater than the signal equivalent to three times the background noise.

The linearity was demonstrated by injecting standards of propamocarb hydrochloride at concentrations between 0.100 and 20.0 ng/mL. Linearity test was performed by injecting eight standard solutions. Regression coefficients R were higher than 0.999.

The mean recoveries for each fortification level should be in the range of 70–110%. Although single recoveries below 60% (e.g. for egg and fat) were noted, mean values were between 70–110% with a relative standard deviation ≤ 20%. The overall relative standard deviation and the standard deviation for each fortification level were ≤ 20%.

Table 7 Recovery results from method validation of Propamocarb in animal tissues with the quantification MRM (189 ->102 m/z)

Animal	Portion analysed	Fortification level (mg/kg)		Recovery (%) Single values				n	Mean	RSD [a]	Study No. Year
Cattle	Liver	Propamocarb	0.01	87	89	88	81	5	85	4.9	BAY-1032V 2010
					80						
			0.10	78	79	81	78	5	78	3.3	
					74						
	Overall Recovery							10	82	6.0	
Cattle	Meat	Propamocarb	0.01	84	82	85	83	5	83	1.9	
					81						
			0.10	78	78	75	78	5	77	1.8	
					76						
	Overall Recovery							10	80	4.3	
Cattle	Kidney	Propamocarb	0.01	83	83	83	84	5	82	2.9	
					78						
			0.10	68	73	73	72	5	72	3.0	
					73						
	Overall Recovery							10	77	7.6	
Cattle	Milk	Propamocarb	0.01	76	81	78	70	5	77	5.5	
					79						
			0.10	77	76	74	81	5	76	3.8	
					74						
	Overall Recovery							10	77	4.4	
Chicken	Egg	Propamocarb	0.01	74	77	77	73	5	75	2.5	
					74						
			0.10	53*	70	82	68	5	70	16	
					78						
	Overall Recovery							10	73	11	
Cattle	Fat	Propamocarb	0.01	78	81	80	63	5	78	12	
					88						
			0.10	78	78	82	77	5	78	3.7	
					74						
	Overall Recovery							10	78	8.2	

[a] RSD: Relative Standard Deviation RSD = SD / Mean recovery × 100 %

*Mean value between 70 and 110% with RSD < 20%.

Table 8 Recovery results from method validation of Propamocarb in animal tissues with the confirmatory MRM (189 ->74 m/z)

Animal origin	Portion analysed	Active substance Fortification level (mg/kg)		Recovery (%) Single values				n	Mean	RSD [(a)]	Study Trial No. Year
Cattle	Liver	Propa-mocarb	0.01	86	73	76		5	79	7.1	BAY-103 2V 2010
				83	75						
			0.10	76	78	78		5	77	2.3	
				74	78						
	Overall Recovery							10	78	5.2	
Cattle	Meat	Propa-mocarb	0.01	78	83	77		5	81	3.8	
				84	81						
			0.10	78	79	78		5	78	0.6	
				78	78						
	Overall Recovery							10	79	3.0	
Cattle	Kidney	Propa-mocarb	0.01	89	80	85		5	85	3.9	
				86	84						
			0.10	73	79	71		5	74	4.3	
				73	72						
	Overall Recovery							10	79	8.4	
Cattle	Milk	Propa-mocarb	0.01	74	89	83		5	79	9.4	
				70	80						
			0.10	76	79	71		5	75	4.0	
				77	74						

Animal origin	Portion analysed	Active substance	Fortification level (mg/kg)	Recovery (%) Single values	n	Mean	RSD [(a)]	Study Trial No. Year
	Overall Recovery				10	77	7.4	
Chicken	Egg	Propa-mocarb	0.01	76 78 83 72 71	5	76	6.4	
			0.10	51* 69 86 67 78	5	70	19	
	Overall Recovery				10	73	13	
Cattle	Fat	Propa-mocarb	0.01	80 82 81 59 84	5	77	13	
			0.10	79 79 83 80 78	5	80	2.4	
	Overall Recovery				10	79	9.1	

An independent lab validation (ILV) was reported by Weber, 2010 (reference M-387185-1). For this ILV of the analytical method of propamocarb in muscle (cattle), liver (cattle), kidney (cattle), fat (cattle), milk (cattle) and whole egg (chicken), recovery experiments were performed at fortification levels of 0.01 mg/kg (LOQ) and 0.10 mg/kg in all matrices.

The mean recovery at each fortification level should be in the range of 70–110%. Although single recoveries above 110% (e.g. for kidney) were noted, mean values were between 70–110% with a relative standard deviation ≤ 20%. The overall relative standard deviation for each fortification level was ≤ 20%. The method was therefore considered to be valid for the determination of propamocarb residues in muscle, kidney and liver.

With slightly changed conditions in the sample preparation procedure compared to original BCS method 01205 (extraction by shaking vigorously for five minutes instead of one, no freeze out) the mean recoveries were between 70–110 % for whole milk, fat and whole egg for both levels (LOQ and ten times LOQ), and the overall relative standard deviation for each fortification level was ≤ 20%.

The data presented demonstrate that the QuEChERS method (BCS method 01205) is suitable and validated for the determination of residues of propamocarb in animal tissues (meat, liver, kidney, fat, milk and egg) with a LOQ of 0.01 mg/kg. Satisfactory specificity, linearity, accuracy, precision, repeatability and reproducibility have been obtained and therefore have proven its applicability as enforcement method.

Stability of residues in stored analytical samples

JMPR in 2006 has reviewed the storage stability of propamocarb (free base) and propamocarb hydrochloride in plant materials and animal tissues and products. The conclusion of the review shows that the compounds are stable in frozen storage in the tested plant commodities for 14 to 26 months and in animal commodities for at least 6 months. No evidence of residue degradation was seen in any of the studies.

A study of storage stability in commodities with high water content has been performed in cabbages (Everitt and Charter, 2000, M-198306-01-1), and was submitted to the Meeting. Cabbage samples (10 g) were fortified with Propamocarb hydrochloride at a concentration equivalent to 0.5 mg/kg propamocarb (free base) and stored in a deep-freezer at about -18 °C. Samples were removed at intervals of up to 39 months (day 0 and after 3, 7, 18, 25 and 39 months) with three replicates per interval for immediate residue analysis. A range of 80 to 116% of the added residues remained after the storage period. This indicates that residues of propamocarb hydrochloride in cabbage leaves are stable for a period of at least 39 months when stored deep frozen (-18 °C).

Table 9 Storage stability of Propamocarb hydrochloride in cabbage

Storage interval [months]	Fortification level [mg/kg] [a]	Recovered residues in stored samples							Reference
		%Residues remaining				Procedural recovery			
		Single recoveries uncorrected [%]			Mean recovery uncorrected [%]	Single recoveries [%]		Mean recovery [%]	
0	0.50	114	116	104	111	78	105	92	M-198306-01-1
3	0.50	92	96	94	94	87	85	86	
7	0.50	84	84	86	85	69	73	71	
18	0.50	84	96	80	87	66	88	77	
25	0.50	84	92	76	84	77	79	78	
39	0.50	90	82	96	89	84	92	88	

Fortified with Propamocarb hydrochloride, but fortification level equivalent Propamocarb (free base)

USE PATTERN

Formulations containing propamocarb hydrochloride, alone or co-formulated with other active ingredients, are registered for use on a wide variety of crops in many countries. Registrations cover foliar treatment of vegetable crops and potatoes, soil drench, application via drip irrigation to vegetables and ornamentals and as seed treatments. Registered uses of propamocarb and propamocarb hydrochloride in crops and countries which were relevant to this evaluation are shown in Tables 10 to 17. Representative labels covering the critical GAP were provided to the Meeting.

Table 10 Registered uses of Propamocarb in onion

Crop	Country	Application				PHI days
		Method	Rate kg ai/ha	Water L/ha	Max. No.	
Onion	Albania		0.875-1.0	400-1000	3	7
Onion	Chile		0.75-0.937	400	3	7
Onion	Colombia		0.562-0.75	500	1	7
Onion	Colombia		0.937-1.25	500	3	7
Onion	Cuba		0.75-0.937	300-600	3	7
Onion	Cuba		0.937	200-600	3	14
Onion	Cuba		0.795	200-600	3	7
Onion	Czech Republic		1.0	200-600	3	
Onion	Dominican Republic		0.75-0.937	300	3	7
Onion	Dominican Republic		0.937	200-600	3	14
Onion	Dominican Republic		0.79-1.32	200-600	3	7
Onion	El Salvador		0.75-0.937	200-600	3	7
Onion	El Salvador		0.937	200-600	3	14
Onion	El Salvador		0.79-1.32	200-600	3	7
Onion	Estonia		1.0	300-500	3	7
Onion	France		1.0	400-1000	2	7
Onion	Guatemala		0.75-0.937	300-600	3	7
Onion	Guatemala		0.937	200-600	3	14
Onion	Guatemala		0.79-1.32	200-6003	3	7
Onion	Guatemala		0.795	200-600	3	7
Onion	Guyana		0.937	200-600	3	14
Onion	Honduras		0.75-0.937	300-600	3	7
Onion	Honduras		0.937	200-600	3	14
Onion	Honduras		0.795	200-600	3	7
Onion	Israel		0.75	100-300	1	3
Onion	Italy		1.0	1000	3	7
Onion	Jamaica		0.75-0.937	300-600	3	7
Onion	Korea, Republic of		0.866	1200	3	30
Onion	Latvia		1.0	300-600	3	7
Onion	Lithuania		1.0	300-600	3	7
Onion	Nicaragua		0.937	200-600	3	14
Onion	Nicaragua		0.79-1.32	200-600	3	7
Onion	Panama		0.75-0.937	300-600	3	7

Crop	Country	Application				PHI days
		Method	Rate kg ai/ha	Water L/ha	Max. No.	
Onion	Panama		0.79-1.32	200-600	3	7
Onion	Peru		0.75	400	2	14
Onion	Poland		1.0	700	3	7
Onion	Romania		0.875	600-1000	2	7
Onion	Saudi Arabia		1.083	600-1000	4	14
Onion	Switzerland		0.75	300-500	3	14
Onion	Trinidad and Tobago		0.937	200-600	3	14
Onion	Uruguay		0.124-0.156	800-1000	3	21

F: Foliar Spraying

Table 11 Registered uses of Propamocarb in Broccoli

Crop	Country	Application				PHI days
		Method	Rate kg ai/ha	Water L/ha	Max. No.	
Broccoli	Belgium	F	1.0	400-600	3	14
Broccoli	Chile	F	0.9375	400	3	17
Broccoli	Chile	F	1.325	400-600	3	14
Broccoli	Cuba	F	0.795	200-600	3	7
Broccoli	Cyprus	F	1.0	1000	3	14
Broccoli	Dominican Republic	F	1.444	200-400	1	7
Broccoli	Dominican Republic	F	1.325	200-600	3	7
Broccoli	El Salvador	F	1.325	200-600	3	7
Broccoli	Estonia	F	1.0	300-600	3	14
Broccoli	France	F	1.0	400-1000	1	14
Broccoli	Greece	F	1.0	1000	3	14
Broccoli	Guatemala	F	1.444	200-400	1	7
Broccoli	Guatemala	F	1.325	200-600	3	7
Broccoli	Guatemala	F	0.795	200-600	3	7
Broccoli	Latvia	F	1.0	300-600	3	14
Broccoli	Lithuania	F	1.0	300-600	3	14
Broccoli	Luxembourg	F	1.0	300-1000	3	14
Broccoli	Nicaragua	F	1.083	300-600	1	7
Broccoli	Nicaragua	F	1.325	200-600	3	7
Broccoli	Panama	F	1.083	300-600	1	7
Broccoli	Panama	F	1.325	200-600	3	7
Broccoli	Spain	F	1.0	500-1000	3	14
Broccoli	Switzerland	F	0.75	300-500	3	14

F: Foliar Spraying

Table 12 Registered uses of Propamocarb in Cauliflower

Crop	Country	Application				PHI days
		Method	Rate	Water	Max.	
Cauliflower	Belgium	F	1.0	400-600	3	14
Cauliflower	Chile	F	0.75-0.937	400	3	18
Cauliflower	Chile	F	1.06-1.325	400-600	3	14
Cauliflower	Cuba	F	0.795	200-600	3	7
Cauliflower	Cyprus	F	1.0	1000	3	14
Cauliflower	Dominican Republic	F	0.795-1.325	200-600	3	7
Cauliflower	El Salvador	F	0.795-1.325	200-600	3	7
Cauliflower	Estonia	F	1.0	200-400	3	14
Cauliflower	France	F	1.0	400-1000	1	14
Cauliflower	Germany	F	1.155	400-600	2	21
Cauliflower	Greece	F	1.0	1000	3	14
Cauliflower	Guatemala	F	0.795-1.325	200-600	3	7
Cauliflower	Guatemala	F	0.795	200-600	3	7

Crop	Country	Application				PHI days
		Method	Rate	Water	Max.	
Cauliflower	Honduras	F	0.795	200-600	3	7
Cauliflower	Hungary	F	0.75-1.0	400-600	3	14
Cauliflower	Latvia	F	1.0	300-600	3	14
Cauliflower	Lithuania	F	1.0	300-600	3	14
Cauliflower	Lithuania	F	1.325	1250	2	3
Cauliflower	Luxembourg	F	1.0	300-1000	3	14
Cauliflower	Nicaragua	F	0.795-1.325	200-600	3	7
Cauliflower	Panama	F	0.795-1.325	200-600	3	7
Cauliflower	Switzerland	F	0.75	300-500	3	14

F: Foliar Spraying

Table 13 Registered uses of Propamocarb in Brussels sprouts

Crop	Country	Application				PHI days
		Method	Rate kg ai/ha	Water L/ha	Max. No.	
Brussels sprouts	Belgium	F	1.0	400-600	3	14
Brussels sprouts	Chile	F	0.75-0.937	400	3	17
Brussels sprouts	Chile	F	1.06-1.325	400-600	3	14
Brussels sprouts	Estonia	F	1.0	200-400	3	14
Brussels sprouts	France	F	1.0	400-1000	1	14
Brussels sprouts	Hungary	F	0.75-1.0	500	3	14
Brussels sprouts	Latvia	F	1.0	300-600	3	14
Brussels sprouts	Lithuania	F	1.0	300-600	3	14
Brussels sprouts	Luxembourg	F	1.0	300-500	3	14

F: Foliar Spraying

Table 14 Registered uses of Propamocarb in Head cabbage

Crop	Country	Application				PHI days
		Method	Rate kg ai/ha	Water L/ha	Max. No.	
Cabbage, red	Belgium	F	1.0	400-600	3	14
Cabbage, white	Chile	F	0.75-0.937	400	3	17
Cabbage, white	Chile	F	1.06-1.325	400-600	3	14
Cabbage, white	Cuba	F	0.75-0.937	300-600	3	7
Cabbage, red	Cyprus	F	1.0	1000	3	14
Cabbage, white	Dominican Republic	F	0.75-0.937	300-600	3	7
Cabbage, white	Estonia	F	1.0	200-400	3	14
Cabbage, white	France	F	1.0	400-1000	1	14
Cabbage, red	Germany	F	1.083	400-600	2	21
Cabbage, red	Greece	F	1.0	1000	3	14
Cabbage, white	Guatemala	F	0.75-0.937	300-600	3	7
Cabbage, white	Honduras	F	0.75-0.937	300-600	3	7
Cabbage, white	Hungary	F	0.75-1.0	400-600	3	14
Cabbage, white	Jamaica	F	0.75-0.937	300-600	3	7
Cabbage, red	Lithuania	F	1.0	300-600	3	14
Cabbage, white	Lithuania	F	1.325	1250	2	3
Cabbage, white	Panama	F	0.75-0.937	300-600	3	7
Cabbage, white	Spain	F	1.0	500-1000	3	14
Cabbage, white	Switzerland	F	0.75	300-500	3	14
Cabbage, field	Trinidad and Tobago	F	0.937	200-600	3	14

F: Foliar Spraying

Table 15 Registered uses of Propamocarb in Kale

Crop	Country	Application				PHI days
		Method	Rate kg ai/ha	Rate water	Max. No.	
Kale, curly	Belgium	F	1.0	400-600	3	14
Kale, curly	Germany	Drench	15.9	2-3L/m²	2	n.a.
Kale, curly	Slovakia	Drench	15.9	2-3L/m²	2	n.a.
Kale, curly	Ireland	Drench	15.9	2-4 L/m²	2	n.a.
Kale, curly	UK	Drench	15.9	2-4 L/m²	2	n.a.
Kale, curly	Thailand	Drench plus Foliar spray	15.9 1.083	2-3L/m² 1000	1 1	n.a. 14

*PCH = Propamocarb hydrochloride (salt); PMB = Propamocarb (free base); n.a. = not applicable

Table 16 Registered uses of Propamocarb in Leek

Crop	Country	Application				PHI days
		Method	Rate kg ai/ha	Water L/ha	Max. No.	
Leek, common	Albania	Foliar Spray	0.875-1.0	400-1000	4	14
Leek, common	Estonia	Foliar Spray	1.0	500	2	14
Leek, common	Latvia	Foliar Spray	1.0	300-600	2	14
Leek, common	Lithuania	Foliar Spray	1.0	300-600	2	14
Leek, common	Syrian Arab. Rep.	Foliar Spray	0.75-1.0	300-600	1-2	14

Table 17 Registered uses of Propamocarb in lima bean

Crop	Country	Application				PHI in days
		Method	Total Rate kg ai/ha	Water L/ha	Max. No.	
Lima bean	US	Foliar broadcast	1.68		4	0

RESIDUE FROM SUPERVISED TRIALS ON CROPS

New residue trials in broccoli, cauliflower, Brussels sprouts, head cabbage, kale, onions, leeks and Lima bean were submitted to the meeting to support establishment of new MRLs. The formulation used in trials was suspension concentrate (SC).

Onion

A total of twenty one residue trials were performed in/on onion with the propamocarb hydrochloride under field conditions in Europe in 2006 and 2007. The results are shown in Table 18.

Table 18 Residues of propamocarb following foliar application to onion (SC formulations)

Country Location Year, Variety	Application				Sample analysed	DAT (days)	Residues as Propamocarb mg/kg	Report
	kg ai/ha	Water L/ha	kg ai/hL	No.				
France, Bouafle 2006 Jaunes des Cevennes	1.0	500	0.20000	3	bulb	0 3 7	0.48 0.25 <u>0.05</u>	RA-2306/06
Germany, Burscheid 2006 Stuttgarter Riesen	1.0	300	0.33313	3	bulb	0 3 7	0.57 0.13 <u>0.05</u>	RA-2306/06
Belgium, Wangenies 2006 Summit	1.0	450	0.22250	3	bulb	0 3 7	0.19 0.01 <u>0.02</u>	RA-2306/06
Germany, Kohlhof 2006 Takstar	1.0	500	0.20000	3	bulb	0 3 7	0.29 0.12 <u>0.05</u>	RA-2306/06

Country Location Year, Variety	Application				Sample analysed	DAT (days)	Residues as Propamocarb mg/kg	Report
	kg ai/ha	Water L/ha	kg ai/hL	No.				
Germany, Schiffer-stadt 2006 Hyskin	1.05-1.08	420-430	0.250	3	bulb	0 7 10 14	2.5 0.41 0.24 0.09	MR-07/212
Germany, Schiffer-stadt 2006 Savel	0.86-1.08	344-648	0.167-0.250	3	bulb	0 7 10 14	4.2 1.3 0.46 0.44	MR-07/212
France, Champien 2007 Boston	1.0	300	0.333	3	bulb	0 3 7	0.07 0.02 0.01	RA-2634/07
Germany, Burscheid 2007 Stuttgarter Riesen	1.0	300	0.333	3	bulb	0 3 7	0.15 0.02 0.02	RA-2634/07
United Kingdom, West Row/BSE 2007, Sherpa	1.0	300	0.333	3	bulb	0 3 7	0.38 0.32 0.21	RA-2634/07
The Netherlands, Wieringer-werf 2007, Hybell	1.0	800	0.125	3	bulb	0 3 7	0.12 <0.01 <0.01	RA-2634/07
Germany, Rotters-dorf 2007 Dacapo	1.0	400	0.250	3	bulb	0 7 10 14	3.2 1.4 1.1 1.2	MR-08/050
Germany, Aholming 2007, Dacapo	1.0	400	0.250	3	bulb	7 14	0.86 0.52	MR-08/050
Germany, Schiffer-stadt 2007, Kaigaro	1-1.06	400-424	0.250-0.251	3	bulb	7 14	0.52 0.21	MR-08/050
France, St Jory (Midi-Pyrenees) 2006, Elodie	1.0	600	0.16688	3	bulb	0 3 7	0.38 0.15 0.07	RA-2307/06
Spain, Malgrat de Mar (Barce-lona) 2006, Orion	1.0	500-600	0.16688-0.20000	3	bulb	0 3 7	0.53 0.09 0.05	RA-2307/06
Italy, Bologna (Emilia - Romagna) 2006, Density 5	1.0	500	0.20000	3	bulb	0 3 7	0.13 0.05 0.02	RA-2307/06
Portugal, Alcochete (Ribatejo e Oeste) 2006, Cebola-de Alcochete	1-1.0813	500-540	0.20000	3	bulb	0 4 7	0.34 0.05 0.03	RA-2307/06
France, Sathonay Village (Rhone-Alpes) 2007, Proteus	1.0	600	0.1667	3	bulb	0 3 7	<0.01 0.02 <0.01	RA-2635/07
Spain, Gava - Barcelona (Cataluña) 2007, Figueras	0.9188-1.0	736-800	0.125	3	bulb	0 3 7	0.17 0.09 0.05	RA-2635/07
Italy, Poggio Renatico (FE), 2007, Rossa di Toscana	1.0	600	0.1667	3	bulb	0 4 7	0.14 0.08 0.02	RA-2635/07
Portugal, Francisco Alcochete (Ribatejo e Oeste) 2007, Spring Star	1.0	500	0.2000	3	bulb	0 3 7	0.30 0.04 0.04	RA-2635/07

Broccoli

Ten field residue trials were conducted with the propamocarb hydrochloride on Broccoli in Europe from 2005 to 2007. The results are shown in Table 19.

Table 19 Residues of propamocarb following foliar application to Broccoli (SC formulations)

Country Location Year, Variety	Application				Sample analysed	PHI (days)	Residues as Propamocarb mg/kg	Report
	kg ai/ha	Water L/ha	kg ai/hL	No.				
France, Fondettes 2005 Monaco	1.0	300	0.33313	3	curd whole plant without roots	14 21 0 3 8	0.16 0.03 22 9.0 3.4	RA-2156/05
Netherlands, Zwaagdijk-Oost 2005, Montop	1.0	600	0.16688	3	curd	0 15 21	5.5 0.17 0.07	RA-2156/05
Belgium, Bornival 2005 Monopoly	1.0	450	0.22250	3	curd	0 3 7 14 21	2.8 2.5 0.97 0.29 0.07	RA-2156/05
Germany, Leichlingen 2005, Volta F1	1.0	500	0.20000	3	curd	0 14 21	7.4 0.29 0.07	RA-2156/05
Germany, Brühl- Schwardorf 2007, Patinon	1.0	600	0.16667	3	curd	0 14 22	2.5 0.01 <0.01	RA-2628/07
Greece, Marathonas 2005 Marathon	1.0	500	0.20000	3	curd	0 3 7 14 21	2.8 1.3 1.1 0.20 0.21	RA-2157/05
France, Fenouillet 2005 Empereur	1.0	600	0.16688	3	curd	0 14 21	3.6 1.7 1.2	RA-2157/05
Spain, Lebrija Sevilla 2006 Marathon	1.0	500	0.20000	3	curd	0 3 7 14 21	3.6 2.5 1.4 0.97 0.66	RA-2157/05
Italy, Catania 2005 Catanese	1.0	500-600	0.16688- 0.20000	3	curd	0 14 21	5.0 0.32 0.19	RA-2157/05
France, Castesarrasin 2007, Chevalier	1.0	600	0.16667	3	curd	0 14 21	3.9 0.52 0.63	RA-2628/07

Cauliflower

Ten field residue trials were conducted with the propamocarb hydrochloride on cauliflower in Europe from 2005 to 2007. The results are shown in Table 20.

Table 20 Residues of propamocarb following foliar application to cauliflower (SC formulations)

Country Location Year, Variety	Application				Sample analysed	PHI (days)	Residues as Propa-mocarb (mg/kg)	Report
	kg ai/ha	Water L/ha	kg ai/hL	No.				
France, Fondettes 2005 FARGO	1.0	600	0.16688	3	curd	0 4 7 14 21	0.24 0.09 0.05 0.03 0.02	RA-2154/05
Netherlands, Zwaagdijk-Oost 2005, Freemont	1.0	600	0.16688	3	curd	14 21	<0.01 <0.01	RA-2154/05

Country Location Year, Variety	Application				Sample analysed	PHI (days)	Residues as Propamocarb (mg/kg)	Report
	kg ai/ha	Water L/ha	kg ai/hL	No.				
Belgium, Bornival 2006 Thalassa	1.0	450	0.22250	3	curd	0 3 7 14 21	0.29 0.24 0.17 <u>0.04</u> 0.02	RA-2154/05
Germany, Leichlingen 2005, Veronie F1	1.0	500	0.20000	3	curd	14 21	<u>0.08</u> 0.02	RA-2154/05
Germany, Langenfeld-Reusrath 2007, Freedom	1.0	600	0.16667	3	curd	14 21	<u>0.02</u> <0.01	RA-2628/07
France, Fenouillet 2005 Aviron	1.0	600	0.16688	3	curd	0 3 7 14 21	0.15 0.12 0.11 0.05 <u>0.06</u>	RA-2155/05
Greece, Kato Souli 2005 White Magic	1.0	500	0.20000	3	curd	0 14 21	2.1 <u>0.82</u> 0.55	RA-2155/05
Spain, Gava 2006 Flora Blanca	1.0	600	0.16688	3	curd	7 14 20	0.62 <u>0.02</u> <0.01	RA-2155/05
Italy, Catania 2005 Violetto	1.0	600	0.16688	3	curd	0 14 21	3.1 <u>0.20</u> 0.06	RA-21 55/05
Spain, Alginet 2007, Movidick	1.0	500-800	0.125-0.200	3	curd	14 21	<u>0.01</u> <0.01	RA-2628/07

Brussels sprouts

Eight field residue trials were conducted with the Propamocarb hydrochloride on Brussels sprouts in Europe from 2005 to 2006. The results are shown in Table 21.

Table 21 Residues of propamocarb following foliar application to Brussels sprouts (SC formulations)

Country Location Year, Variety	Application					PHI	Residues as Propamocarb mg/kg	Report
	kg ai/ha	Water L/ha	kg ai/hL	No.				
France, Fontaine L'Etalon 2005 Maximus	1.0	300	0.33313	3	sprout	0 4 7 14 21	1.1 0.48 0.35 0.21 <u>0.25</u>	RA-2152/05
Netherlands, Zwaagdijk-Oost 2005, Genius	1.0	600	0.16688	3	sprout	0 14 21	0.97 0.44 <u>0.49</u>	RA-2152/05
Germany, Werl-Westönnen 2005 Cyrus	1.0-1.06	300-318	0.33313	3	sprout	0 3 7 15 21	2.7 1.9 1.5 <u>0.99</u> <u>1.3</u>	RA-2152/05
Germany, Langenfeld-Reusrath 2005, Genius	1.0	300	0.33313	3	sprout	0 14 21	1.4 <u>0.64</u> 0.64	RA-2152/05
Germany, Vechta - Langförden 2006, Camus	1.0	300	0.33313	3	sprout	0 14	0.67 <u>0.48</u>	RA-2303/06
Belgium, Geer	0.94-	423-450	0.22250	3	sprout	0	0.38	RA-

Country Location Year, Variety	Application					PHI	Residues as Propamocarb mg/kg	Report
	kg ai/ha	Water L/ha	kg ai/hL	No.				
2006, Maximus	1.0					14	0.20	2303/06
France, Fontaine l'Etalon 2006 Louis	1.0	300	0.33313	3	sprout	0 3 7 14 21	0.64 0.83 0.51 0.41 0.46	RA-2303/06
Germany, Langenfeld-Reusrath 2006 Genius	1.0	300	0.33313	3	sprout	0 3 7 14 21	0.47 0.36 0.45 0.24 0.23	RA-2303/06

Head cabbage

Twelve field trials were conducted with the propamocarb hydrochloride on head cabbage in Europe from 2005 to 2006. The results are shown in Table 22.

Table 22 Residues of propamocarb following foliar application to head cabbage (SC formulations)

Country Location Year, Variety	Application				Sample analysed	PHI (days)	Residues as propamocarb mg/kg	Report
	kg ai/ha	Water L/ha	kg ai/hL	No.				
Germany, Bornheim 2005 Savoy: Alaska	1	400	0.25	3	head	0 3 7 14 21	3.7 1.3 0.52 0.18 0.13	RA-2152/05
Belgium, Gembloux 2005, red: Regilus	1	450	0.2225	3	head	0 14 21	0.04 0.03 0.02	RA-2150/05
France. Ennemain 2005, Savoy Ice Prince	1	300	0.33313	3	head	0 3 7 14 21	0.52 0.5 0.55 0.24 0.19	RA-2150/05
Netherlands, Zwaagdijk-Oost 2005, Red Integra	1	600	0.16688	3	head	0 14 21	0.37 0.16 0.21	RA-2150/05
Netherlands, Zwaagdijk-Oost 2006,Savoy: Produsa	1	600	0.16688	3	head	0 14	0.6 0.08	RA-2308/06
Germany, Bornheim 2006, Savoy: Visa	1	300	0.33313	3	head	0 13	4.4 0.36	RA-2308/06
France, Bouafle 2006 white: Première	1	300	0.16688	3	head	0 3 7 14 21	12 4 0.39 0.13 0.07	RA-2308/06
Germany,	1	600	0.33313	3	head	0	0.92	RA-2308/06

Country Location Year, Variety	Application kg ai/ha	Water L/ha	kg ai/hL	No.	Sample analysed	PHI (days)	Residues as propamocarb mg/kg	Report
Leichlingen 2006 red: Rodima								
						3	0.76	
						7	0.64	
						14	0.32	
						21	0.11	
France, St Alban 2005 white: DELUS B285	1	600	0.16688	3	head	0	0.47	RA-2151/05
						3	0.19	
						7	0.21	
						14	0.23	
						21	0.08	
Greece, Kato Agios Ioannis 2005, white: Baner	1	300	0.33313	3	head	0	0.73	RA-2151/50
						14	0.02	
						21	0.1	
Spain, Gavà 2006	1	500-600	0.16688-0.2	3	head	0	0.41	RA-2309/06
						14	0.06	
white: Megaton								
Italy, Andria 2006 white: Sapalla	1	500	0.2	3	head	0	0.77	RA-2309/06
						14	0.28	

Kale

Nine field trials were conducted with the propamocarb hydrochloride on kale in Europe from 2006 to 2007. The results are shown in Table 23.

Table 23 Residues of propamocarb following foliar application on kale (SC formulations)

Country Location Year Variety	Application kg ai/ha	Water L/ha	kg ai/hL	No.	Sample analysed	DAT (days)	Residues as Propamocarb mg/kg	Report
Germany, Oberbes-singen 2006 curly:Winnetou	0.961-1.025	600-900	0.112-0.171	3	leaf	0 7 10 14	6.8 1.5 1.1 0.46	MR-07/212
Germany, Köln 2006 curly: Winterbor	1.0	600	0.17	3	leaf	0 7 10 14	13 9.7 6.0 4.0 [a]	MR-07/212
Germany, Köln 2006 curly:Winterbor	1.0	600	0.17	3	leaf	0 7 10 14	14 6.5 6.0 3.9	MR-07/212
Germany, Schifferstadt 2006 curly: Winterbor	0.960-1.040	388-624	0.167-0.250	3	leaf	0 7 10 14	24 [b] 10 7.0 5.2	MR-07/212
Germany, Butzbach, 2007, curly: Winnetou	1.0	600	0.17	3	leaf	14	4.0	MR-08/050
Germany, Reken – Hülsen, 2007, curly: Verdura	1.0	600	0.17	3	leaf	14	0.33	MR-08/050
Germany, Reken – Hülsen, 2007 curly: Verdura	1.0	600	0.17	3	leaf	14	0.39	MR-08/050
Germany, Bonn, 2007 curly: Westländer	1.0	600	0.17	3	leaf	14	11.8	MR-08/050

Country Location Year Variety	Application				Sample analysed	DAT (days)	Residues as Propamocarb mg/kg	Report
	kg ai/ha	Water L/ha	kg ai/hL	No.				
Germany, Bonn 2007, curly: Winnetou	1.0	600	0.17	3	leaf	14	10.7	MR-08/050

[a] In the corresponding control sample (day 14) residues of 0.01 mg/kg were found
[b] In the corresponding control sample (day 0) residues of 0.04 mg/kg were found

Leek

Twelve field residue trials were conducted with the Propamocarb hydrochloride on Leek in Europe from 2005 to 2006. The results are shown in Table 24.

Table 24 Residues of propamocarb following foliar application to Leek (SC formulations)

Country Location Year, Variety	Application				Sample analysed	PHI (days)	Residues as Propamocarb mg/kg	Report
	kg ai/ha	Water L/ha	kg ai/hL	No.				
Belgium, Wayaux 2005 Shelton	1	450	0.22250	3	whole plant without roots	0 3 7 14 21	2.3 2.6 1.9 0.9 0.83	RA-2111/05
Netherlands, Zwaagdijk-Oost 2005 Shelton	1	600	0.16688	3	whole plant without roots	0 3 7 14 21	6.2 7.5 4.1 4.0 2.4	RA-2111/05
Germany, Langenfeld-Reusrath 2005, Pandora	1	300	0.33313	3	whole plant without roots	0 14 21	2.0 0.24 0.15	RA-2111/05
France, Faverolles 2005 Hiverna	1	300	0.33313	3	whole plant without roots	0 13 22	15 5.5 0.12	RA-2111/05
France, Faverolles 2006 Diana	1	300	0.33313	3	whole plant without roots	0 14	23 15	RA-2302/06
Germany, Langenfeld-Reusrath 2006, Pandora	1	300	0.33313	3	whole plant without roots	0 14	5.0 0.74	RA-2302/06
Netherlands, Zwaagdijk-Oost 2006 Roxton	1	600	0.33313	3	whole plant without roots	0 14	9.9 2.6	RA-2302/06
Germany, Bornheim - Sechtem 2006, Amundo	1	300	0.33313	3	whole plant without roots	0 15	6.9 2.4	RA-2302/06
Italy, Lusia 2005 Sabina	1	600	0.16688	3	whole plant without roots	0 3 7 14 21	10 4.6 4.9 1.1 0.60	RA-2112/05
Spain, Brenes Sevilla 2005 Heracles	1	400	0.25000	3	whole plant without roots	0 3 7 14 21	15 15 15 11 4.7	RA-2112/05

Country Location Year, Variety	Application				Sample analysed	PHI (days)	Residues as Propamocarb mg/kg	Report
	kg ai/ha	Water L/ha	kg ai/hL	No.				
France, St Alban 2005 Davensy	1	600	0.16688	3	whole plant without roots	0 14 21	14 4.4 2.6	RA-2112/05
Portugal, Torres Novas 2005, Lancelot	1	400	0.25000	3	whole plant without roots	0 14 21	6.4 1.1 0.52	RA-2112/05

Lima Beans

Five field trials were conducted with the Propamocarb hydrochloride on Lima Beans (seed and forage) in United States from 2005 to 2006. The results are shown in Table 25.

Table 25 Residues of propamocarb following foliar application to Lima beans seeds

Country Location Year, Variety	Application				Sample analysed	PHI (days)	Residues as Propamocarb mg/kg	Report (Trial ID)
	Rate kg ai/ha	Water L/ha	Total Rate kg ai/ha	No.				
United States Salisbury, MD 2005 Burpee Improved Bush	1.44-1.47	35-36	6.54	4	Bean without Pods	0	0.25 0.26 0.255*	07263.05-MD15
United States Bridgeton, NJ 2005 Baby Lima	1.47-1.55	34-36	6.78	4	Bean without Pods	0	0.44 0.42 0.43*	07263.05-NJ 19
United States Clinton, NC Fordhook 2006	1.44-1.49	30-31	13.24	8	Bean without Pods	0	1.16 1.20 1.18*	07263.05-NC 03
United States Fremont, OH 2006 Fordhook 242	1.46-1.50	49-78	6.68	4	Bean without Pods	0	0.43 0.41 0.42*	07263.06-OH*01
United States Salisbury, MD 2006 Eastland	1.47-1.49	36	8.31	5	Bean without Pods	0	0.78 0.76 0.77*	07263.06-MD 02

*the average of two samples

Table 26 Residue field trials with Propamocarb conducted on Lima Beans forage

Country Location Year, Variety	Application				Sample analysed	PHI (days)	Residues as Propamocarb (mg/kg)	Report (Trial ID)
	Rate kg ai/ha	Water L/ha	Total Rate kg ai/ha	No.				
United States Salisbury, MD 2005 Burpee Improved Bush	1.44-1.47	35-36	6.54	4	Foliage	0	45.6 35.6 40.6*	07263.05-MD15
United States Bridgeton, NJ 2005 Baby Lima	1.47-1.55	34-36	6.78	4	Foliage	0	73.8 93.3 83.6*	07263.05-NJ 19
United States Clinton, NC 2006, Fordhook,	1.44-1.49	30-31	13.24	8	Foliage	0	46.1 42.9 44.5*	07263.05-NC 03

Country Location Year, Variety	Application				Sample analysed	PHI (days)	Residues as Propamocarb (mg/kg)	Report (Trial ID)
	Rate kg ai/ha	Water L/ha	Total Rate kg ai/ha	No.				
United States Fremont, OH 2006, Fordhook 242	1.46-1.50	49-78	6.68	4	Foliage	0	42.1 52.7 47.4*	07263.06-OH*01
United States Salisbury, MD 2006, Eastland	1.47-1.49	36	8.31	5	Foliage	0	151.2 136.3 143.8*	07263.06-MD 02

*the average of two samples

FATE OF RESIDUES DURING PROCESSING

Processing studies in tomato, spinach and lettuce have been conducted and submitted to the Meeting. These studies are described below. An overview of the processing factors obtained for the different processed commodities and the processing by-products is given in Table 30.

Tomatoes

Seven studies on the processing of tomatoes into juice, preserve and purée were conducted to determine the transfer of propamocarb from tomato fruits into juice, preserve and puree.

Four studies (Billian, 2008, M-307290-01-1) were conducted in Italy, Spain, Greece and Portugal with 3 sprays of propamocarb (SC formulation) at rate of 4.74 kg ai/ha with interval of 7 days and 1day PHI. Samples of tomato (fruit) to be processed were sampled at 1 day after last treatment.

The processing of tomato samples into fruit, washed; washings; raw juice; juice; fruit, peeled; peel; peeling water; preserves; strain rest, wet; raw puree and puree was performed in the Food Processing Laboratory of BCS-D-ROCS in Monheim am Rhein. The washing and peeling of tomatoes was done using household practice. The preparation of juice, preserves and puree simulated the industrial practice at a laboratory scale.

The tomatoes were washed in lukewarm standing water. The washed tomatoes were cut with a knife into small pieces and were heated after addition of water to 80–100 °C for 40 min in order to prevent enzymatic reactions. After this blanching process, the tomato pulp was passed through a strainer to separate raw juice and strain rest. Sodium chloride (0.5–0.7% (w/w)) was added to the raw juice. An aliquot of the laboratory sample of raw juice was taken. One part of the remaining raw juice was used for the processing into preserves (see below). Another portion of the remaining raw juice was filled into preserving cans and pasteurised. After pasteurisation an aliquot of the laboratory sample juice was taken.

For the processing of tomato into preserves, another portion of the deep-frozen tomatoes were washed in warm standing water. After a few minutes the peel could be taken off with a kitchen knife, but in contrast to other processing procedures the peeling was very difficult and a lot of pulp remained with the peel. The peeling water containing small pots of peel was sieved. Aliquots of the laboratory samples peel, peeling water and fruit, peeled were taken. After addition of raw juice a part of the remaining peeled tomatoes (ratio fruit/juice = 1/0.86) was filled into preserving cans and pasteurised. After pasteurisation, the tomato preserves were minced with a hand mixer. An aliquot of the obtained laboratory sample of tomato preserve was taken.

For the processing of tomato fruits into puree, tomatoes samples were washed in lukewarm standing water. The washed tomatoes were cut with a knife into small pieces and were heated after addition of water to 98–100 °C for 40 min in order to prevent enzymatic reactions. After this blanching process, the tomato pulp was passed through a strainer to separate raw juice and strain rest. The obtained tomato raw juice was mixed up with sodium chloride. An aliquot of the raw juice was concentrated (100–200 mbar, 75 °C) while stirring to obtain tomato raw puree (dry weight: 16%).

After taking an aliquot of the sample raw puree, the remaining raw puree was filled into preserving cans and pasteurised. After pasteurisation, the tomato puree was sampled.

Tomato samples and processed fractions were analysed for residues of propamocarb hydrochloride according to methods 00880/M001 (study RA-3639/07) and 00880/M002 (study 09-3235) by LC-MS/MS with an LOQ of 0.01 mg/kg. The molecular weights of propamocarb hydrochloride and Propamocarb were taken into consideration to determine and express the results as Propamocarb.

Table 27 Recovery data for propamocarb in tomato fruits and processed commodities

Portion analysed	Active substance	Fortification level (mg/kg)	Recovery (%) Single values	n	Mean	RSD
Fruit [a]	Propamocarb	0.01	104, 96, 96, 99, 104, 113	6	102	6.4
		0.1	101, 101, 102, 115	4	105	6.5
		50	90	1	-	-
Overall Recovery				11	102	7.1
Juice [b]	Propamocarb	0.01	94 95 99 117	4	101	10.6
		0.1	90 92 97 115	4	99	11.6
		5.0	94	1	-	-
Overall Recovery				9	99	9.9
Puree [c]	Propamocarb	0.01	89 91 93	3	91	2.2
		0.1	97 95	2	96	-
		10	86	1	-	-
Overall Recovery				6	92	4.4
Fruit [d]	Propamocarb	0.01	79 82 83 85	4	82	3.0
		0.1	70 71 72 73 79	5	73	4.8
Overall Recovery				9	77	7.4
Raw juice	Propamocarb	0.01	83	1	-	-
		0.1	69	1	-	-
Overall Recovery				2	76	-
Juice [e]	Propamocarb	5	96	1	-	-
Overall Recovery				1	-	-
Fruit, peeled [f]	Propamocarb	5	93	1	-	-
Overall Recovery				1	-	-
Whole fruit, washed	Propamocarb	0.01	75	1	-	-
		0.1	73	1	-	-
		0.5	94	1	-	-
Overall Recovery				3	81	14.4
Raw puree	Propamocarb	0.01	70	1	-	-
		0.1	68	1	-	-
Overall Recovery				2	69	-
Puree [g]	Propamocarb	5	101	1	-	-
Overall Recovery				1	-	-

FL = Fortification Level,
Fortified with Propamocarb-hydrochloride, determined as Propamocarb and calculated as Propamocarb
[a] Tomato fruit, washed; tomato peel; preserve and tomato fruit, peeled are covered by tomato fruit.
[b] Tomato washings; tomato raw juice and tomato peeling water are covered by tomato juice.
[c] Tomato raw puree and tomato strain rest are covered by tomato puree.
[d] The recoveries of the RAC tomato (fruit) were performed during the conduct of study 09-2235
[e] Tomato, washings and tomato, peeling water are covered by tomato juice.
[f] Tomato, peel and tomato, preserve are covered by tomato fruit, peeled.
[g] Tomato, strain rest is covered by tomato, puree

Residues of propamocarb in tomato fruits ranged from 2.8 to 5.9 mg/kg. Residues processed fractions were between 1.2 and 3.1 mg/kg in juice, between 0.88 and 2.0 mg/kg in preserve and between 1.8 and 4.9 mg/kg in puree.

Table 28 Residues of Propamocarb in tomato fruits (RAC) and processed tomato commodities in Italy, Spain, Greece and Portugal

Sample material	Residues of Propamocarb (mg/kg)			
	Italy	Spain	Greece	Portugal
Fruit (RAC)	2.8	5.9	3.4	5.2
Fruit, washed	1.4	2.9	1.9	3.6
Washings	0.88	1.1	0.48	1.3
Raw juice	1.0	2.9	2.0	2.3
Juice	1.2	3.1	2.0	2.3
Fruit, peeled	0.86	2.5	1.2	0.73
Peel	2.8	18	8.0	5.6
Peeling water	0.98	1.5	0.77	0.94
Preserve	0.88	2.0	1.7	1.4
Strain rest, wet	1.5	2.6	2.3	2.0
Raw puree	1.8	4.4	2.5	3.9
Puree	1.8	4.9	2.2	3.7

Three studies on tomato (Schulte and Bauer, 2011, M-406443-02-1) were conducted in Northern and Southern Europe (The Netherlands, Italy, and Germany). Propamocarb (SC formulation) was sprayed three times on tomato plants with a nominal product rate of 0.62kg ai/ha and a water rate of 1000 L/ha per application. The applications were carried out with interval of 7 days and 3 days PHI. Samples of tomato (fruit) to be processed were taken at 3 days after last treatment. Residues of propamocarb in tomato fruits ranged from 0.22 to 0.59 mg/kg. Residues in processed fractions were between 0.16 and 0.40 mg/kg in juice, between 0.13 and 0.24 mg/kg in preserve and between 0.10 and 0.19 mg/kg in puree.

Table 29: Residues of Propamocarb in tomato fruits (RAC) and processed tomato commodities in Netherland, Italy, Germany

Sample material	Residues of Propamocarb (mg/kg)		
	The Netherlands	Italy	Germany
Fruit (RAC)	0.22 [*,a]	0.59	0.35
Raw juice	0.21 [*,b]	0.39	0.17
Juice	0.19 [*,c]	0.40	0.16
Fruit, peeled	0.07	0.13	0.05
Peel	0.64	1.8	0.96
Peeling water	0.17 [*,d]	0.12	0.09
Preserve	0.13	0.24	0.14
Fruit, washed	0.09	0.22	0.20
Washings	0.17	0.09	0.11
Strain rest, wet	0.10 [*, e]	0.21	0.12
Raw puree	0.10 [*,f]	0.22	0.14
Puree	0.10 [*, g]	0.19	0.14

*These are the calculated mean values; corresponding samples were analysed twice.
Single values:
[a] 0.218 mg/kg and 0.217 mg/kg
[b] 0.229 mg/kg and 0.188 mg/kg
[c] 0.200 mg/kg and 0.181 mg/kg
[d] 0.174 mg/kg and 0.170 mg/kg
[e] 0.099 mg/kg and 0.093 mg/kg
[f] 0.121 mg/kg and 0.087 mg/kg
[g] 0.111 mg/kg and 0.097 mg/kg

Average processing factors (PF) of 0.57, 0.40 and 0.88 were calculated for tomato juice, preserve and puree respectively.

Table 30 Processing factors for the residue of Propamocarb in processed tomato commodities

Sample material	Processing factors for residues of Propamocarb							
	Italy	Spain	Greece	Portugal	Netherlands	Italy	Germany	Mean
Fruit, washed	0.50	0.49	0.56	0.69	0.41	0.37	0.57	0.51
Raw juice	0.36	0.49	0.59	0.44	0.95	0.66	0.49	0.57
Juice	0.43	0.53	0.59	0.44	0.86	0.68	0.46	0.57
Fruit, peeled	0.31	0.42	0.35	0.14	0.32	0.22	0.14	0.27
Peel	1.0	3.1	2.4	1.1	2.9	3.1	2.7	2.3
Preserve	0.31	0.34	0.50	0.27	0.59	0.41	0.40	0.40
Strain rest, wet	0.54	0.44	0.68	0.38	0.45	0.36	0.34	0.46
Raw puree	0.64	0.75	0.74	0.75	0.45	0.37	0.40	0.59
Puree	0.64	0.83	0.65	0.71	2.6	0.32	0.40	0.88

Spinach

Four field trials (Billian and Krussel, 2010, M-397716-01-1) were performed with spinach in Belgium, France, Germany and the Netherlands during 2009. Propamocarb was sprayed four times at rate of 3.7-3.98 kg as/ha per application and with interval of 9–11 days.

Spinach samples (leaves) to be processed were harvested at 14–15 days after the last application. The processing of the spinach leaves samples into washed leaf, washings, cooking water and cooked leaf according to household practice. The spinach leaves were washed in lukewarm standing water for about 2–5 min while moving the leaves around slowly. After washing, the leaves were centrifuged in a lettuce drainer. The collected water in the drainer was added to the rest of the washing water. Samples of washed leaves and washings were taken. The remaining washed leaves were cooked in a sieve in water steam (2 kg water/kg leaves) for about 8–10 min. After cooking, samples of cooked leaves and cooking water were taken.

Spinach samples (leaves) and processed fractions were analysed for residues of Propamocarb according to method 00880/M002 by LC-MS/MS with a LOQ of 0.01 mg/kg or 0.01 mg/L. Residues were determined and expressed as Propamocarb.

Table 31 Recovery data for Propamocarb in spinach leaves (RAC) and processed spinach commodities

Portion analysed	Active substance	Fortification level (mg/kg)	Recovery (%) Single values	n	Mean	RSD
Leaf and washed leaf [c]	Propamocarb	0.01 [a]	115	1	115	-
		0.10 [a]	117 97	2	107	-
		0.50 [a]	98	1	98	-
		1.0 [a]	108	1	108	-
		200 [a]	97	1	97	-
		350 [b]	87	1	87	-
Overall Recovery				7	103	11

FL = Fortification Level,
[a] Recoveries were determined for washed leaf.
[b] Recoveries were determined for leaf.
[c] These recoveries cover also washings, cooked leaf and cooking water.

Residues of propamocarb in raw leaves were between 15 and 76 mg/kg at the recommended PHI of 14-15 days. After washing, residues of propamocarb between 21 - 70 mg/kg were found in the washed leaves. The residues of propamocarb found in the washings were between 0.19 and 0.89 mg/L. The residues of propamocarb in cooked leaves were found to decrease slightly to values between 14 and 67 mg/kg. The residues of propamocarb in cooking water were found to be between 5.3 and 26 mg/L.

Table 32 Residues of propamocarb in spinach leaves (RAC) and processed spinach commodities

Country Study No. Trial No.	Crop Portion analysed	DALT (days)	Residues (mg/kg or mg/L) Propamocarb
Germany 09-3401 09-3401-01	Spinach leaf (RAC)	15	15
	Leaf, washed	15	21
	Washings	15	0.19
	Leaf, cooked	15	14
	Cooking water	15	5.3
France 09-3401 09-3401-02	Spinach leaf (RAC)	15	56
	Leaf, washed	15	43
	Washings	15	0.56
	Leaf, cooked	15	48
	Cooking water	15	15
Belgium 09-3401 09-3401-03	Spinach leaf (RAC)	14	76
	Leaf, washed	14	70
	Washings	14	0.68
	Leaf, cooked	14	67
	Cooking water	14	6.0
The Netherlands 09-3401 09-3401-04	Spinach leaf (RAC)	14	53
	Leaf, washed	14	42
	Washings	14	0.89
	Leaf, cooked	14	46
	Cooking water	14	26

Average processing factors (PF) of 0.97 and 0.88 were calculated for washed spinach leaves and cooked leaves respectively.

Table 33 Processing factors for the residue of Propamocarb in processed spinach commodities

Sample material	Processing factors for residues of Propamocarb				
	Germany	France	Belgium	Netherlands	Mean
Leaf, washed	1.4	0.77	0.92	0.79	0.97
Leaf, cooked	0.933	0.857	0.882	0.868	0.885

Lettuce

Two studies (Billian and Reineke, 2009, M-348419-01-1) were performed in the Netherlands and Germany on lettuce under greenhouse conditions in 2008. Propamocarb(SC formulation) was sprayed four times on lettuce plants at rate of 1.325 kg as/ha, with interval of 10 days.

Four studies (Billian and Reineke, 2010, M-397890-01-1) were performed on lettuce in the greenhouse in Belgium, France, Germany and Netherland in 2009. Propamocarb (SC formulation) was sprayed four times on lettuce at rate of 3.98 kg as/ha, with interval of 9–11 days.

Lettuce samples (head) to be processed were harvested at 13 and at 14–15 days after the last application in the 2008 and the 2009 trials, respectively. The processing of the lettuce samples (head) into the processed fractions: outer leaf, head without outer leaves, leaves without stalk, and washed inner leaves simulated household practice.

Outer leaves were removed (leaf, outer), and the remaining heads separated into leaves and stalk. The separated leaves were washed in warm water and drained. Theses fractions were analysed using the method 00880/M002 by LC-MS/MS with a LOQ of 0.01 mg/kg or 0.01 mg/L.

Table 34 Recovery data for propamocarb in lettuce head (RAC) and processed lettuce commodities

Portion analysed	Active substance	Fortification level (mg/kg)	Recovery (%) Single values			n	Mean	RSD (a)
Leaf, outer	Propamocarb	0.01	93	82	94	3	90	7.4
		0.10	81	76	94	3	84	11
		50	64			1	64	-
Overall Recovery						7	83	14
Leaf, inner	Propamocarb	0.01	97	96	93	3	95	2.2
		0.10	93	93	81	3	89	7.8
		1.0	93			1	93	-
		50	82			1	82	-
Overall Recovery						8	91	6.7
Head, inner parts	Propamocarb	0.01	91	102	86	3	93	8.8
		0.10	85	69	88	3	81	13
		50	86			1	86	-
Overall Recovery						7	87	11
Leaf, inner washed	Propamocarb	0.01	94	85	93	3	91	5.4
		0.10	93	95	91	3	93	2.2
		1.0	93			1	93	-
		50	67			1	67	-
Overall Recovery						8	89	11
Washings	Propamocarb	0.01	63	68	68	3	66	4.4
		0.10	73	73	69	3	72	3.2
		50	91			1	91	-
Overall Recovery						7	72	13
Head (RAC)	Propamocarb	0.01	112			1	112	-
		0.02	96			1	96	-
		0.10	109			1	109	-
Overall Recovery						3	106	8.0
Head, inner parts [a]	Propamocarb	0.01	106			1	106	-
		0.10	102			1	102	-
		0.50	101			1	101	-
		300	97			1	97	-
Overall Recovery						4	102	3.6

[a] These recoveries cover also leaf, outer; leaf, inner; washings; leaf, inner, washed

Table 35 Residues of Propamocarb in lettuce heads (RAC) and processed lettuce commodities

Country Study No. Trial No.	Crop Portion analysed	DALT (days)	Residues (mg/kg or mg/L) Propamocarb
Netherlands 08-3137 08-3137-01	Lettuce head (RAC) Leaf, outer Head, inner parts Leaf, inner Leaf, inner, washed Washing	13	7.7 5.0 0.27 0.19 [a] 1.1 [b] 0.05
Germany 08-3137 08-3137-02	Lettuce head (RAC) Leaf, outer Head, inner parts Leaf, inner Leaf, inner, washed Washing	13	1.6 4.7 0.03 [c] 0.10 [d] 0.09 [e] < 0.01
Germany 09-3400 09-3400-01	Lettuce head (RAC) Leaf, outer Head, inner parts Leaf, inner Leaf, inner, washed Washings	14	26 57 1.4 2.7 1.1 < 0.01

Country Study No. Trial No.	Crop Portion analysed	DALT (days)	Residues (mg/kg or mg/L) Propamocarb
France 09-3400 09-3400-02	Lettuce head (RAC) Leaf, outer Head, inner parts Leaf, inner Leaf, inner, washed Washings	14	47 110 7.8 10 7.7 0.15
The Netherlands 09-3400 09-3400-03	Lettuce head (RAC) Leaf, outer Head, inner parts Leaf, inner Leaf, inner, washed Washings	14	12 41 1.2 1.5 0.83 < 0.01
Belgium 09-3400 09-3400-04	Lettuce head (RAC) Leaf, outer Head, inner parts Leaf, inner Leaf, inner, washed Washings	15	51 120 8.4 9.8 4.1 0.01

[a] this result corresponds to the mean of 3 single values (0.203 mg/kg, 0.187 mg/kg and 0.17 mg/kg)
[b] this result corresponds to the mean of 3 single values (1.19 mg/kg, 0.984 mg/kg and 0.993 mg/kg)
[c] this result corresponds to the mean of 3 single values (0.0219 mg/kg, 0.0286 mg/kg and 0.0293 mg/kg)
[d] this result corresponds to the mean of 3 single values (0.109 mg/kg, 0.101 mg/kg and 0.104 mg/kg)
[e] this result corresponds to the mean of 3 single values (0.815 mg/kg, 0.097 mg/kg and 0.0813 mg/kg)

Average processing factors of 2.3, 0.09, 0.12 and 0.09 were calculated for the transfer of Propamocarb from lettuce heads into outer leaves, head inner parts, inner leaves and inner leaves washed respectively.

Table 36: Processing factors for the residue of Propamocarb in processed lettuce commodities

Sample material	Processing factors for residues of Propamocarb						
	Nether-lands	Germany	Germany	France	Nether-lands	Belgium	Mean
Leaf, outer	0.7	3.0	2.2	2.3	3.4	2.4	2.3
Head, inner parts	0.04	0.02	0.05	0.17	0.10	0.16	0.09
Leaf, inner	0.02	0.06	0.10	0.21	0.13	0.19	0.12
Leaf, inner, washed	0.10	0.06	0.04	0.16	0.07	0.08	0.09
Washings	0.01	0.01	0.01	0.01	0.01	0.01	0.01

Table 37: Summary of the processing studies in tomato, spinach and lettuce

Commodity	Processed commodity	Processing factors Residue: PCB	Processing factor(PF) (best estimate)	Study Document
Tomato (0.515mg/kg, 2006 JMPR)	Fruit, washed	0.50, 0.49, 0.56, 0.69, 0.41, 0.37, 0.57	0.51	RA-3639/07 M-307290-01-1 09-3235 M-406443-02-1
	Raw juice	0.36, 0.49, 0.59, 0.44, 0.95, 0.66, 0.49	0.57	
	Juice	0.43, 0.53, 0.59, 0.44, 0.86, 0.68, 0.46	0.57	
	Fruit, peeled	0.31, 0.42, 0.35, 0.14, 0.32, 0.22, 0.14	0.27	
	Peel	1.0, 3.1, 2.4, 1.1, 2.9, 3.1, 2.7	2.3	
	Preserve	0.31, 0.34, 0.50, 0.27, 0.59, 0.41, 0.40	0.40	
	Strain rest, wet	0.54, 0.44, 0.68, 0.38, 0.45, 0.36, 0.34	0.46	
	Raw puree	0.64, 0.75, 0.74, 0.75, 0.45, 0.37, 0.40	0.59	
	Puree	0.64, 0.83, 0.65, 0.71, 2.6, 0.32, 0.40	0.88	
	Puree	1.1, 1.4, 1.4	1.3	2006 JMPR evaluation
	Paste	3.0, 3.2, 3.0	3.1	
Spinach	Leaf, washed	1.4, 0.77, 0.92,0.79	0.97	09-3401

Commodity	Processed commodity	Processing factors Residue: PCB	Processing factor(PF) (best estimate)	Study Document
11.2mg/kg (2006)	Leaf, cooked	0.93, 0.86, 0.88, 0.87	0.89	M-397716-01-1
Lettuce 9.9mg/kg(2006)	Leaf, outer	0.7, 3.0, 2.2, 2.3, 3.4, 2.4	2.3	08-3137 M-348419-01-1 09-3400 M-397890-01-1
	Head, inner parts	0.04, 0.02, 0.05, 0.17, 0.10, 0.16	0.09	
	Leaf, inner	0.02, 0.06, 0.10, 0.21, 0.13, 0.19	0.12	
	Leaf, inner, washed	0.10, 0.06, 0.04, 0.16, 0.07,0.08	0.09	

Livestock feeding studies

Dairy cow feeding study

A study on the transfer of propamocarb residues from feed to tissues and milk of dairy cows was provided to the meeting (Tew, 2003, M-240879-02-1; Tauber, 2004, M-243564-01-1).

In 3 dose groups of 3 cows, animals were dosed orally with propamocarb at nominal dose rates corresponding to 0.8ppm (1×), 2.4ppm (3×) or 8.0ppm (10×) in feed.

Animals were dosed each morning after milking and test animals were milked each morning and evening. Samples from each animal's evening and morning milk from study Days 0 (the day before the start of dosing), 1, 4, 8, 11, 15, 18, 22, 25, and 27 were pooled. The two aliquots of milk (evening and morning) were combined in volumes proportional to the total evening and morning volumes collected. Milk from one 10× cow and the control cow collected on study Day 27 was separated into milk fat and skim milk and analysed.

All test animals were sacrificed at the end of the 28-day dose period. Muscle, liver, kidney, and fat tissue samples were analysed for propamocarb (AE B039744) and its metabolites propamocarb-N-oxide (AE F155306), oxazolidine-2-one propamocarb (AE F132679), 2-hydroxy-propamocarb (AE F132675) and propamocarb glucuronide. Samples were initially analysed for all analytes except for propamocarb glucuronide. Samples were analysed for propamocarb glucuronide at a later date based on results from the method radio-validation study (conducted after the feeding study). The method used incorporates extraction with acetonitrile (propamocarb, propamocarb-N-oxide, oxazolidine-2-one-propamocarb and 2 hydroxy-propamocarb) or acidic methanol (propamocarb glucuronide) and detection and quantification by LC/MS/MS (Netzband D.J.; 2003; Document No.: M-240905-01-1). The LOQ and LOD in milk, milk fat and skim milk were 0.01 mg/kg and 0.003 mg/kg, respectively, for all matrices. The LOQ and LOD in beef tissues were 0.05 mg/kg and 0.017 mg/kg, respectively, for all matrices.

Table 38 Recoveries of Propamocarb and its metabolites in meat and milk from animals

Sample material	Analyte	Fortification level [mg/kg]	Recovered residues in stored samples					
			Single recoveries [%]			Mean recovery [%]	RSD [(a)]	n
Milk	Propamocarb	0.01	94	79	94	87	11	5
				94	74			
		0.05	90	95		92	3.8	2
	AE F132675	0.01	96	72	82	85	11	5
				81	92			
		0.05	97	81		89	13	2
	AE F155306	0.01	98	98	90	96	3.8	5
				97	99			
		0.05	94	89		92	3.9	2
	AE F132679	0.01	82	82	81	82	3.6	5
				79	87			
		0.05	81	88		84	5.9	2
	Propamocarb	0.01	129			129	-	1

Sample material	Analyte	Fortification level [mg/kg]	Recovered residues in stored samples			
			Single recoveries [%]	Mean recovery [%]	RSD [(a)]	n
	glucuronide					
Milk fat	Propamocarb	0.01	93	93	-	1
		0.05	103	103	-	1
	AE F132675	0.01	85	85	-	1
		0.05	90	90	-	1
	AE F155306	0.01	101	101	-	1
		0.05	103	103	-	1
	AE F132679	0.01	91	91	-	1
		0.05	88	88	-	1
Skim milk	Propamocarb	0.01	90	90	-	1
		0.05	88	88	-	1
	AE F132675	0.01	88	88	-	1
		0.05	82	82	-	1
	AE F155306	0.01	104	104	-	1
		0.05	106	106	-	1
	AE F132679	0.01	83	83	-	1
		0.05	87	87	-	1
Muscle	Propamocarb	0.05	83	83	-	1
		0.25	85	85	-	1
	AE F132675	0.05	86	86	-	1
		0.25	89	89	-	1
	AE F155306	0.05	86	86	-	1
		0.25	83	83	-	1
	AE F132679	0.05	73	73	-	1
		0.25	73	73	-	1
	Propamocarb glucuronide	0.05	99	99	-	1
Liver	Propamocarb	0.05	89	89	-	1
		0.25	90	90	-	1
	AE F132675	0.05	76	76		1
		0.25	84	84	-	1
	AE F155306	0.05	76	76	-	1
		0.25	81	81	-	1
	AE F132679	0.05	76	76	-	1
		0.25	69	69	-	1
	Propamocarb glucuronide	0.05	108 83 118	103	18	3
		0.50	103	103	-	1
Kidney	Propamocarb	0.05	91	91	-	1
		0.25	82	82	-	1
	AE F132675	0.05	96	96	-	1
		0.25	100	100	-	1
	AE F155306	0.05	86	86	-	1
		0.25	86	86	-	1
	AE F132679	0.05	112	112	-	1
		0.25	102	102	-	1
	Propamocarb glucuronide	0.05	97	97	-	1
		0.25	97	97	-	1
Fat	Propamocarb	0.05	76	76	-	1
		0.25	74	74	-	1
	AE F132675	0.05	78	78	-	1
		0.25	79	79	-	1
	AE F155306	0.05	82	82	-	1
		0.25	85	85	-	1
	AE F132679	0.05	77	77	-	1
		0.25	86	86	-	1

Sample material	Analyte	Fortification level [mg/kg]	Recovered residues in stored samples			
			Single recoveries [%]	Mean recovery [%]	RSD [(a)]	n
	Propamocarb glucuronide	0.05	104	104	-	1

Milk samples from study days 11 through 27 were analysed. The only measurable residues found in milk were from cows dosed at the 10× level and these residues consisted entirely of metabolite 2-hydroxy-propamocarb. The average residues of 2-hydroxy-propamocarb in whole milk from 10× cows ranged from 0.012 to 0.014 mg/kg with a maximum of 0.019 mg/kg at day 22. 2-hydroxy-propamocarb residues were detectable, but not quantifiable at the 3× dose level. Residues of propamocarb-N-oxide were detectable, but not quantifiable at the 10× dose level. Residues of propamocarb and oxazolidine-2-one propamocarb were not detectable in milk at the 10× level. No detectable residues of the parent or either metabolite were found at the 1× dose level. No detectable residues of any compound were found in any control sample.

Milk from one of the 10× cows (cow #13) was collected on study Day 27 and separated into milk fat and skim milk. Residues in milk fat and skim milk were 0.013 mg/kg and 0.014 mg/kg, respectively. The residue of 2 hydroxy-propamocarb, found in the corresponding whole milk sample, was 0.014 mg/kg. These data indicate that 2 hydroxy-propamocarb does not concentrate in milk fat.

Beef tissue samples were analysed for propamocarb, 2-hydroxy-propamocarb, propamocarb-N-oxide, oxazolidine-2-one propamocarb and propamocarb glucuronide. No detectable residues of parent or metabolite were found in any control tissue. No detectable residues of parent or metabolite were found in any muscle sample. In liver, residues consisted entirely of the conjugated metabolite propamocarb glucuronide. The maximum propamocarb glucuronide residues in liver were 0.218 mg/kg (10×), 0.099 (3×) and <0.05 mg/kg (1×). In kidney, residues of propamocarb glucuronide were detected, but were below the LOQ in all 10× cows. The parent compound was detected in kidney from one 10× cow. A detectable, but not quantifiable, residue of oxazolidine-2-one propamocarb was also found in kidney from one 10× cow. In fat, the parent compound was found at levels <LOQ in two 10× cows.

Table 39 Residues of Propamocarb and its metabolites in whole milk

Day	Dose group	Residues (mg/kg)				
		Propamocarb	2-hydroxy-propamocarb	Propamocarb-N-oxide	Oxazolidine-2-one propamocarb	Propamocarb glucuronide
11	1×	ND	ND	ND	ND	not analysed
	3×	ND	< LOQ	ND	ND	not analysed
	10×	ND	0.012 [a]	< LOQ	ND	not analysed
15	1×	Not Analysed				
	3×	ND	< LOQ	ND	ND	not analysed
	10×	ND	0.013 [b]	< LOQ	ND	not analysed
18	1×	Not Analysed				
	3×	ND	< LOQ	ND	ND	not analysed
	10×	ND	0.013 [c]	< LOQ	ND	not analysed
22	1×	Not Analysed				
	3×	ND	< LOQ	ND	ND	not analysed
	10×	ND	0.013 [d]	< LOQ	ND	not analysed
25	1×	Not Analysed				
	3×	ND	< LOQ	ND	ND	not analysed
	10×	ND	0.013 [e]	< LOQ	ND	not analysed
27	1×	Not Analysed				
	3×	ND	< LOQ	ND	ND	not analysed
	10×	ND	0.014 [f]	< LOQ	ND	ND

ND: < LOD LOD = 0.003 mg/kg and LOQ = 0.01 mg/kg for all analytes in whole milk

[a] average of three values : < 0.01; 0.013 and 0.012 mg/kg

[b] average of three values : 0.013; 0.015 and 0.011 mg/kg

[c] average of three values : 0.010; 0.015 and 0.013 mg/kg

[d] average of three values : < 0.01; 0.019 and 0.011 mg/kg

[e] average of three values : 0.012; 0.017 and 0.010 mg/kg
[f] average of three values : 0.013; 0.016 and 0.014 mg/kg

Table 40 Residues of Propamocarb and its metabolites in skim milk

Day	Dose group	Residues (mg/kg)				
		Propamocarb	2-hydroxy-propamocarb	Propamocarb-N-oxide	Oxazolidine-2- one propamocarb	Propamocarb glucuronide
27	10×	ND	0.014	< LOQ	ND	not analysed

ND: < LOD LOD = 0.003 mg/kg and LOQ = 0.01 mg/kg for all analytes in skim milk

Table 41 Residues of Propamocarb and its metabolites in milk fat

Day	Dose group	Residues (mg/kg)				
		Propamocarb	2-hydroxy-propamocarb	Propamocarb-N-oxide	Oxazolidine-2- one propamocarb	Propamocarb glucuronide
27	10×	ND	0.013	< LOQ	ND	not analysed

ND: < LOD LOD = 0.003 mg/kg and LOQ = 0.01 mg/kg for all analytes in milk fat

Table 42 Residues of Propamocarb and its metabolites in beef muscle

Day	Dose group	Residues (mg/kg)				
		Propamocarb	2-hydroxy-propamocarb	Propamocarb-N-oxide	Oxazolidine-2- one propamocarb	Propamocarb glucuronide
28	1×	not analysed				
	3×	not analysed				
	10×	ND	ND	ND	ND	ND

ND: < LOD LOD = 0.017 mg/kg and LOQ = 0.05 mg/kg for all analytes in beef muscle

Table 43 Residues of Propamocarb and its metabolites in beef liver

Day	Dose group	Residues (mg/kg)				
		Propamocarb	2-hydroxy-propamocarb	Propamocarb-N-oxide	Oxazolidine-2-one propamocarb	Propamocarb glucuronide
28	1×	not analysed				< LOQ
	3×	not analysed				0.088 [a]
	10×	ND	ND	ND	ND	0.183 [b]

ND: < LOD LOD = 0.017 mg/kg and LOQ = 0.05 mg/kg for all analytes in beef liver
[a] average of three values : 0.077; 0.087 and 0.099 mg/kg
[b] average of three values : 0.165; 0.165 and 0.218 mg/kg

Table 44 Residues of Propamocarb and its metabolites in beef kidney

Day	Dose group	Residues (mg/kg)				
		Propamocarb	2-hydroxy-propamocarb	Propamocarb-N- oxide	Oxazolidine-2- one propamocarb	Propamocarb glucuronide
28	1×	not analysed				
	3×	not analysed				
	10×	< LOQ	ND	ND	< LOQ	< LOQ

ND: < LOD LOD = 0.017 mg/kg and LOQ = 0.05 mg/kg for all analytes in beef kidney

Table 45 Residues of Propamocarb and its metabolites in beef fat

Day	Dose group	Residues (mg/kg)				
		Propamocarb	2-hydroxy-propamocarb	Propamocarb-N-oxide	Oxazolidine-2- one propamocarb	Propamocarb glucuronide
28	1×	not analysed				
	3×	not analysed				
	10×	< LOQ	ND	ND	ND	ND

ND: < LOD LOD = 0.017 mg/kg and LOQ = 0.05 mg/kg for all analytes in beef fat.

In summary, no detectable residues of propamocarb or its metabolites 2 hydroxy-propamocarb, propamocarb-N-oxide, and oxazolidine-2-one propamocarb were present in the milk or edible tissues of cattle exposed to propamocarb at a level of 0.8 mg/kg in their diet. The data also indicate that residues of the conjugated metabolite propamocarb glucuronide may be present in liver at levels below 0.05 mg/kg.

Laying hen feed study

Feeding study with of propamocarb (Nguyen, 2011, M-409874-01-1) was conducted in laying hens. Seventy two laying hens (*Gallus Gallus domesticus*) were dosed orally, via capsule, for 36 consecutive days with Propamocarb at dose rates of 0 mg/kg feed/day (control, 12 hens, 6 subgroups), 1.2 ppm feed/day (0.3× dose group, 12 hens, 3 subgroups), 4.1 ppm feed/day (1× dose group, 12 hens, 3 subgroups), 12.3 ppm feed/day (3× dose group, 12 hens, 3 subgroups) and 41.1 ppm feed/day (10× dose group, 24 hens, 6 subgroups). Eggs were collected twice daily during the dosing period. Egg samples, from the 10× dose group, were analysed for propamocarb and N-desmethyl propamocarb (expressed as propamocarb) residue on study days 0, 2, 4, 7, 14, 21, 29, and 36. On day 36, six of the control hens, all hens of the 0.3×, 1× and 3× dose group and the hens of three of the six 10× dose group subgroups were sacrificed and liver, muscle (thigh and breast), and fat (abdominal and subcutaneous) tissues were collected and pooled by sub-group for analysis. In the following N-desmethyl propamocarb is always expressed as propamocarb.

The remaining three of the six subgroups of the 10× dose group hens entered into the depuration phase of the study, where eggs and tissues were analysed throughout a three week period following the administration of the last dose. On day 42, egg and tissue samples from six hens (two control and four 10× dose group hens) in the depuration phase were analysed. On study day 49, egg and tissue samples from another six hens (two control and four 10× dose group hens) in the depuration phase were analysed. On study day 56, egg and tissue samples from the remaining six hens (two control and four 10× dose group hens) in the depuration phase were collected and analysed.

Tissue and egg samples were analysed for total propamocarb residue (propamocarb and N-desmethyl propamocarb) by high performance liquid chromatography-electrospray ionization / tandem mass spectrometry (LC-MS/MS) using matrix matched standards. The limit of quantitation (LOQ) was 0.01 mg/kg for each analyte in eggs and poultry tissues. The LOD for Propamocarb were 0.0024 mg/kg in eggs, 0.0013 mg/kg in liver, 0.0010 mg/kg in muscle, and 0.0014 mg/kg in fat. The LOD for N-desmethyl propamocarb were 0.0033 mg/kg in eggs, 0.0011 mg/kg in liver, 0.0011 mg/kg in muscle, and 0.0028 mg/kg in fat.

Table 46 Recoveries of propamocarb and N-desmethyl propamocarb in eggs, fat, liver and muscle tissues

Sample material	Analyte	Fortification level [mg/kg]	Recovered residues in stored samples							
			Single recoveries [%]					Mean recovery [%]	RSD (a)	n
Eggs	N-desmethyl Propamocarb	0.010	98	82 81	107 91	108	99 82	93	12	8
		0.100	106	99	104	78	86 82	93	13	6
		0.250	87	88 85 91	90 86 89	76 79 83	76 77 84	84	6.4	13
		0.500	81	75 80	81 79 82	83	94 93	83	7.6	9
	Propamocarb	0.010	105	90 88	105 90	104	100 87	96	8.4	8
		0.100	85	87	85	90	92 90	88	3.3	6
		0.250	82	86 90 105	87 93 94	82 89 96	84 82 94	89	7.6	13
		0.500	93	89	94	93	101	94	4.3	9

Sample material	Analyte	Fortification level [mg/kg]	Recovered residues in stored samples							
			Single recoveries [%]						Mean recovery [%]	RSD (a)	n
			100	92 91 97							
Fat	N-desmethyl Propamocarb	0.010	96 96	82	107	91	90	106	95	9.3	7
		0.100	90	87	97	90	88		91	4.3	5
		0.250	85	103	91	74			88	14	4
	Propamocarb	0.010	103 108	97 103	109	100	100		103	4.3	7
		0.100	81	83	90	83	93		86	6.0	5
		0.250	81	100	92	92			91	8.6	4
Liver	N-desmethyl Propamocarb	0.010	93	97 94	92	89	95	99	94	3.5	7
		0.100	100	96	97	101	90		97	4.5	5
		0.250	81						81	-	1
		0.500	72	72	69				71	2.4	3
	Propamocarb	0.010	102 101	96 108	100	106	103		102	3.9	7
		0.100	88	83	83	90	98		88	7.0	5
		0.250	96						96	-	1
		0.500	80	83	78				80	3.1	3
Muscle	N-desmethyl Propamocarb	0.010	97	95 93	97	100	90	98	96	3.5	7
		0.100	86	88	86	105	79		89	11	5
		0.250	75	78	74	90			79	9.3	4
	Propamocarb	0.010	95	98 97	97	101	92	99	97	3.0	7
		0.100	84	88	85	101	86		89	7.9	5
		0.250	84	85	83	90			86	3.6	4

Propamocarb residues in the eggs were below LOD (0.0024 mg/kg) at Day 42, 49 and 56. N-desmethyl propamocarb residues in the eggs were 0.0136 at Day 42 and less than LOD (0.0033 mg/kg) at Day 49 and 56, respectively.

Propamocarb and N-desmethyl propamocarb residues in fat, liver, and muscle in the depuration phase were below the corresponding LODs.

The highest mean propamocarb residues were found in the 35 days eggs, 10× dose group. In eggs of the 35th days, the average propamocarb residue was 0.056 mg/kg in the 10× dose group, 0.016 mg/kg in the 3× dose group, 0.005 mg/kg in the 1× dose group and 0.0012 mg/kg in the 0.3× dose group. Maximum residues in anyone hen were 0.062 mg/kg in the 10× dose group, 0.016 mg/kg in the 3× dose group, 0.005 mg/kg in the 1× dose group and 0.0013 mg/kg in the 0.3× dose group. Values are presented in Table 40.

Table 47 Residues of propamocarb and its metabolite N-desmethyl propamocarb in eggs

Day	Dose group	Residues (mg/kg)						
		Propamocarb			N-desmethyl Propamocarb			Total Propamocarb
		Min	Max	Mean	Min	Max	Mean	Mean
2	10×	0.0104	0.0182	0.0140	0.0351	0.0608	0.0480	0.0620
4	10×	0.0257	0.0302	0.0283	0.1300	0.1480	0.1402	0.1685
7	10×	0.0344	0.0380	0.0363	0.2052	0.2484	0.2241	0.2604
14	10×	0.0334	0.0408	0.0355	0.2298	0.2694	0.2457	0.2811
21	10×	0.0334	0.0442	0.0388	0.2500	0.3193	0.2864	0.3252
28	10×	0.0380	0.0476	0.0428	0.2675	0.3188	0.2922	0.3350
30	10×	0.0437	0.0520	0.0491	0.2854	0.3293	0.3015	0.3506
35	0.3×	0.0010	0.0013	0.0012	0.0102	0.0132	0.0116	0.0128
	1×	0.0042	0.0050	0.0047	0.0368	0.0424	0.0389	0.0436
	3×	0.0151	0.0162	0.0157	0.0867	0.0991	0.0921	0.1078
	10×	0.0487	0.0615	0.0559	0.3201	0.4053	0.3458	0.4017

Day	Dose group	Residues (mg/kg)						
		Propamocarb			N-desmethyl Propamocarb			Total Propamocarb
42	10×	<LOD	<LOD	<LOD	0.0128	0.0142	0.0136	0.0160
49	10×	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
56	10×	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD

The LOD in eggs was 0.0024 mg/kg for propamocarb, 0.0033 mg/kg for N-desmethyl propamocarb and 0.0058 mg/kg for total propamocarb.

In the 35 day fat tissue, the highest mean propamocarb residues were 0.0097 mg/kg in the 10× dose group, 0.0021 mg/kg in the 3× dose group and below 0.0014 mg/kg (LOD) in the 1× and 0.3× dose groups. Maximum residues in anyone hen were 0.028 mg/kg in the 10× dose group, 0.0036 mg/kg in the 3× dose group, <LOD in the 1× and 0.3× dose group.

In the 35 day fat tissue, the highest mean N-desmethyl propamocarb residues were 0.0492 mg/kg in the 10× dose group, 0.0062 mg/kg in the 3× dose group, 0.0039 mg/kg in the 1× dose group and 0.0028 mg/kg in the 0.3× dose group. Values are presented in Table 41.

Table 48 Residues of propamocarb and its metabolite N-desmethyl propamocarb in fat

Day	Dose group	Residues (mg/kg)						
		Propamocarb			N-desmethyl Propamocarb			Total Propamocarb
		Min	Max	Mean	Min	Max	Mean	Mean
35	0.3×	<LOD	<LOD	<LOD	<LOD	0.0028	0.0028	0.0042
	1×	<LOD	<LOD	<LOD	0.0035	0.0046	0.0039	0.0053
	3×	<LOD	0.0036	0.0021	0.0034	0.0111	0.0062	0.0083
	10×	<LOD	0.0282	0.0097	0.0093	0.1445	0.0492	0.0589
42	10×	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
49	10×	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
56	10×	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD

The LOD in fat was 0.0014 mg/kg for Propamocarb, 0.0028 mg/kg for N-desmethyl Propamocarb and 0.0042 mg/kg for total Propamocarb.

In the 35 day liver tissue, the highest mean propamocarb residues were 0.0159 mg/kg in the 10× dose group, 0.0082 mg/kg in the 3× dose group, 0.0037 mg/kg in the 1× dose group and 0.0019 mg/kg in the 0.3× dose group. Maximum residues in anyone hen were 0.025 mg/kg in the 10× dose group, 0.015 mg/kg in the 3× dose group, 0.0055 mg/kg in the 1× dose group and 0.0021 mg/kg in the 0.3× dose group.

In the 35 day liver tissue, the highest mean N-desmethyl propamocarb residues were 0.119 mg/kg in the 10× dose group, 0.0393 mg/kg in the 3× dose group, 0.0239 mg/kg in the 1× dose group and 0.0083 mg/kg in the 0.3× dose group. Values are presented in Table 42.

Table 49 Residues of propamocarb and its metabolite N-desmethyl propamocarb in liver

Day	Dose group	Residues (mg/kg)						
		Propamocarb			N-desmethyl propamocarb (expressed as propamocarb)			Total Propamocarb
		Min	Max	Mean	Min	Max	Mean	Mean
35	0.3×	0.0015	0.0021	0.0019	0.0074	0.0101	0.0083	0.0102
	1×	0.0021	0.0055	0.0037	0.0147	0.0346	0.0239	0.0275
	3×	0.0035	0.0153	0.0082	0.0271	0.0631	0.0393	0.0476
	10×	0.0069	0.0247	0.0159	0.1051	0.1299	0.1190	0.1349
42	10×	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
49	10×	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
56	10×	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD

The LOD in liver was 0.0013 mg/kg for propamocarb, 0.0011 mg/kg for N-desmethyl Propamocarb and 0.0024 mg/kg for total Propamocarb.

In the 35 day muscle tissue, the highest mean propamocarb residues were 0.0104 mg/kg in the 10× dose group, 0.0050 mg/kg in the 3× dose group, 0.0022 mg/kg in the 1× dose group and 0.0010 mg/kg in the 0.3× dose group. Maximum residues in anyone hen were 0.013 mg/kg in the 10× dose group, 0.0086 mg/kg in the 3× dose group, 0.0028 mg/kg in the 1× dose group and 0.0010 mg/kg in the 0.3× dose group.

In the 35 day muscle tissue, the highest mean N-desmethyl propamocarb residues were 0.1017 mg/kg in the 10× dose group, 0.0250 mg/kg in the 3× dose group, 0.0149 mg/kg in the 1× dose group and 0.0053 mg/kg in the 0.3× dose group. Values are presented in Table 43.

Table 50 Residues of propamocarb and its metabolite N-desmethyl propamocarb in muscle

Day	Dose group	Residues (mg/kg)						
		Propamocarb			N-desmethyl propamocarb			Total Propamocarb
		Min	Max	Mean	Min	Max	Mean	Mean
35	0.3×	<LOD	0.0010	0.0010	0.0040	0.0065	0.0053	0.0063
	1×	0.0018	0.0028	0.0022	0.0120	0.0202	0.0149	0.0171
	3×	0.0028	0.0086	0.0050	0.0197	0.0321	0.0250	0.0300
	10×	0.0084	0.0129	0.0104	0.0940	0.1033	0.1017	0.1120
42	10×	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
49	10×	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
56	10×	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD

The LOD in muscle was 0.0010 mg/kg for propamocarb, 0.0011 mg/kg for N-desmethyl Propamocarb and 0.0021 mg/kg for total Propamocarb.

Conclusion

Feed consumption, body weights, and egg production were not adversely affected by daily oral administration of propamocarb to laying hens for 35 consecutive days at the average dose rate of 1.2 mg/kg feed (0.3×), 4.1 mg/kg feed (1×), 12.3 mg/kg feed (3×), and 41.1 mg/kg feed (10×).

The mean maximum propamocarb residues in the egg samples from the 10×, 3×, 1×, and 0.3× feeding levels were at day 35: 0.056 mg/kg, 0.016 mg/kg, 0.0047 mg/kg, and 0.0012 mg/kg respectively.

In the fat, the mean maximum propamocarb residues at day 35 was 0.0097 mg/kg in the 10× dose group, 0.0021 mg/kg in the 3× dose group, <LOD in the 1× and 0.3× dose group.

In the liver, the mean maximum propamocarb residues at day 35 was 0.016 mg/kg in the 10× dose group, 0.0082 mg/kg in the 3× dose group, 0.0037 mg/kg in the 1× dose group, and 0.0019 mg/kg in the 0.3× dose group.

In the muscle tissue, the mean maximum propamocarb residues at day 35 was 0.010 mg/kg in the 10× dose group, 0.005 mg/kg in the 3× dose group, 0.0022 mg/kg in the 1× dose group, and 0.001 mg/kg in the 0.3× dose group.

Depuration of residue (mean total Propamocarb residues) was observed from the eggs from day 35 to day 42; 0.402 mg/kg to 0.016 mg/kg respectively. No propamocarb and N-desmethyl propamocarb residue from eggs were observed at subsequent time points, <LOQ (0.01 mg/kg). In fat, liver, and muscle depuration residues were <LOQ (0.01 mg/kg) at Day 42 (and subsequent time points) indicating that propamocarb and N-desmethyl propamocarb residues were rapidly eliminated from the animals.

APPRAISAL

Propamocarb is a systemic carbamate fungicide with specific activity against Oomycete species that cause seed, seedling, root, foot and stem rots and foliar diseases in a number of edible crops. The compound was first evaluated by the JMPR in 1984, and was then reviewed by JMPR in 1986, 1987 and 2005, an ADI of 0–0.4 mg/kg bw and an ARfD of 2 mg/kg bw were established in 2005. Propamocarb was evaluated within the periodic review programme for residue and analytical aspects by JMPR in 2006.

The residue definition in plant and animal products for both enforcement and dietary intake purposes is propamocarb (free base. Propamocarb is not considered fat soluble.

The meeting received information on GAP and supervised residue trials in/on onion, leek, broccoli, cauliflower, Brussels sprouts, head cabbage, kale and lima bean. A new analytical method was provided for propamocarb in animal matrices, as well as new studies in laying hen metabolism, feeding studies on lactating cow and laying hens, rotational crops and processed commodities.

Animal metabolism

Laying hen

A metabolism study with propamocarb in laying hens was received by the Meeting. Laying hens were orally dosed via capsule with [^{14}C] propamocarb hydrochloride at a rate of approximately 19 ppm in the feed (1.0 mg/kg body weight) once daily for fourteen consecutive days. The majority of the residues (92% to 99% of the TRR) in the egg and tissues could be extracted.

The TRR in eggs increased from day-1 through too day-7 and reached a plateau, at day-8, of about 0.25 mg eq/kg. The TRR in the tissue samples were highest in liver (0.492 mg/kg) with 0.14 mg/kg in leg muscle, 0.12 mg/kg in breast muscle and 0.042 mg/kg in fat (0.065 mg/kg in renal fat).

The major residues in the eggs and tissues were parent propamocarb (2% in fat, 5% in muscle, 9% in liver and 12% in eggs) and desmethyl propamocarb (6% in fat, 22% in liver, 29% in muscle, and 45% in eggs). The minor residues found in the eggs and tissues were bis-desmethyl-propamocarb (< 1% to 7%) and propamocarb-N-oxide (< 1%).

In summary, the metabolic degradation of propamocarb is rapid and extensive in laying hens with desmethyl-propamocarb and propamocarb being the major residues in all tissues (mostly in liver, eggs and muscle). Demethylation is the main route of metabolism for the parent compound. A minor route of metabolism involves oxidation of the tertiary nitrogen to form propamocarb-N-oxide. The pathway and metabolism profile found in laying hen is consistent to that of the lactating cow metabolism study evaluated by 2006 JMPR.

Field crop rotational studies

Rotational crop studies were conducted in Germany and France during 2002/2003. Four applications of 72.2, 36.1, 3.61 and 3.61 kg ai/ha propamocarb were applied to cabbage as the primary crop, and Lamb's lettuce and wheat were grown as rotational crops with a plant-back interval (PBI) of 52–102 days. No residues of Propamocarb were found above LOQ in Lamb's lettuce, wheat grain, wheat (green material) and wheat straw.

Four rotational crop studies were conducted in the Netherlands, France, Spain and Italy from 2008 to 2010 .Three spray applications of 1.325 kg ai/ha. propamocarb with 7–13days interval were applied to lettuce as primary crop, and carrots, lettuce and wheat or barley were grown as rotational crops, with plant-back intervals (PBI) of 26–46 days. No residues of propamocarb were found above LOQ in any of these rotational crops.

In rotational field studies with wheat, sugar beet, table beet, dry bean and soya beans conducted in USA in 1997 (four applications at rates of 1.68 kg ai/ha.), which was evaluated by 2006 JMPR, there was no residues detected in wheat grain and straw, soya bean seed, beetroot and beet

tops and dry bean from a 30 day PBI, and residues were in the range of 0.229 to 0.51 mg/kg only in wheat hay and forage from a 30 day PBI.

The meeting noted that the GAP of propamocarb (3–4 applications of 1 kg ai/ha.) approximates the application rate in the new studies and was lower than in the 1997 studies. The Meeting agreed that no residue in food and feed commodities are expected from rotational crops following the registered uses.

Methods of analysis

The meeting received the information on multiresidue QuEChERS Method (BCS method ID 01205) for analysis of residues of propamocarb in meat (cattle), liver (cattle), kidney (cattle), fat (cattle), milk (cattle) and egg (chicken) (mass transitions at m/z 102 and 74). The limit of quantification (LOQ) was at 0.01 mg/kg in meat, liver, kidney, fat, milk and egg. The method was confirmed by results of an independent laboratory validation which repeated mean recovery rates of 80–88% in all matrices.

Stability of residues in stored analytical samples

The meeting received information on storage stability of propamocarb in frozen cabbage samples. Propamocarb hydrochloride was stable for a period of at least 39 months.

Results of supervised residue trials on crops

The meeting received supervised residue trial data for propamocarb in/on bulb onion, leek, broccoli, cauliflower, Brussels sprouts, head cabbage, kale and lima bean.

Bulb vegetables

Bulb onion

In 21 trials conducted in Europe according to GAP in Italy (three foliar applications of 1.0 kg ai/ha, 7days PHI), residues were < 0.01(2), 0.01, 0.02(4), 0.03, 0.04, 0.05(5), 0.07, 0.21, 0.41, 0.52, 0.86, 1.3 and 1.4 mg/kg. The Meeting estimated a maximum residue level of 2 mg/kg, a STMR of 0.05 mg/kg and a HR of 1.4 mg/kg for propamocarb in onion bulb.

Leek

In 12 trials conducted in Europe according to GAP in Albania (four foliar applications at 1.0 kg ai/ha, 14days PHI), residues were 0.24, 0.74, 0.9, 1.1(2), 2.4, 2.6, 4.0, 4.4, 5.5, 11 and 15 mg/kg. The meeting estimated a maximum residue level of 30 mg/kg, a STMR of 2.5 mg/kg and a HR of 15 mg/kg for propamocarb in leek.

Brassica vegetables

Broccoli

In ten trials conducted in Europe according to GAP in Spain (three foliar applications of 1.0 kg ai/ha, 14 days PHI), residues were 0.01, 0.16, 0.17, 0.21, 0.29(2), 0.32, 0.63, 0.97 and 1.7 mg/kg. The meeting estimated a maximum residue level of 3 mg/kg, a STMR of 0.29 mg/kg and a HR of 1.7 mg/kg for propamocarb in broccoli.

Cauliflower

In ten trials conducted in Europe according to GAP in Greece (three foliar applications of 1.0 kg ai/ha, 14 days PHI), residues were < 0.01, 0.01, 0.02(2), 0.03, 0.04, 0.06, 0.08, 0.20 and 0.82 mg/kg. The meeting estimated a maximum residue level of 2 mg/kg, a STMR of 0.035 mg/kg and a HR of 0.82 mg/kg for propamocarb in cauliflower to replace the previous recommendation of 0.2 mg/kg.

Brussels sprouts

In eight trials conducted in Europe matching the GAP of Belgium (three foliar applications of 1.0 kg ai/ha, 14 days PHI), residues were 0.20, 0.25, 0.24, 0.46, 0.48, 0.49, 0.64 and 1.3 mg/kg. The meeting estimated a maximum residue level of 2 mg/kg, a STMR of 0.47 mg/kg and a HR of 1.3 mg/kg for propamocarb in Brussels sprouts.

Head cabbage

In 12 trials conducted in Europe matching the GAP of Spain (three foliar applications at 1.0 kg ai/ha, 14 days PHI), residue were 0.02, 0.03, 0.06, 0.08, 0.13, 0.18, 0.21, 0.23, 0.24, 0.28, 0.32 and 0.36 mg/kg. The meeting estimated a maximum residue level of 1 mg/kg, a STMR of 0.195 mg/kg and a HR of 0.36 mg/kg for propamocarb in head cabbage.

Leafy Vegetables

Kale

In nine trials conducted in Europe matching the GAP of Belgium (three foliar applications of 1.0 kg ai/ha, 14 days PHI), residues were 0.33, 0.39, 0.46, 3.9, 4.0, 4.0, 5.2, 10.7 and 11.8 mg/kg. The meeting estimated a maximum residue level of 20 mg/kg, a STMR of 4.0 mg/kg and a HR of 11.8 mg/kg for propamocarb in kale.

Legume vegetables

Lima Beans

In three trials conducted in the United States according to US GAP (four foliar applications at 1.0 kg ai/ha, 0 days PHI), residues in seed without pods were 0.26, 0.42 and 0.43 mg/kg, residues in forage were 40.6, 83.6 and 47.4 mg/kg. As only three trials were conducted according to GAP the meeting could not recommend a maximum residue level for propamocarb in lima bean seed without pods.

FATE OF RESIDUES DURING PROCESSING

The Meeting received information on the fate of propamocarb residues during the processing of tomatoes, spinach and lettuce, and a study on the nature of residues in processed commodities. Propamocarb hydrochloride was stable under all conditions of processing tested (pasteurisation, baking, brewing, boiling and sterilisation). Processing factors based on the residue of propamocarb are listed in table below. Using the $STMR_{RAC}$ obtained from propamocarb use, the Meeting estimated STMR-P values for processed commodities to be used in dietary intake calculations and/or livestock dietary burden calculations.

Summary of the processing studies in tomato, spinach and lettuce

Commodity	Processed commodity	Processing factors Residue: PCB	Processing factor(PF) (Mean or best estimate)	STMR-P= STMRRAC X PF(mg/kg)
Tomato 0.515 mg/kg [a]	Juice	0.43, 0.44, 0.46, 0.53, 0.59, 0.68, 0.86	0.53	0.27
	Preserve	0.27, 0.31, 0.34, 0.40, 0.41,0.50, 0.59	0.40	0.21
	Puree	0.32, 0.40, 0.64, 0.65, 0.71, 0.83, 1.1 [a], 1.4 [a], 1.4 [a], 2.6	0.77	0.40
	Paste a	3.0, 3.2, 3.0	3.1	1.54
Spinach 11.2 mg/kg [a]	Leaf, cooked	0.86, 0.87, 0.88, 0.93	0.88	9.9

[a] Data from 2006 JMPR evaluation

Farm animal feeding studies

The meeting received information on feeding studies with lactating cows and laying hens.

Dairy cow feeding study

No measurable residues of propamocarb or its metabolites 2-hydroxy-propamocarb, propamocarb-N-oxide, and oxazolidine-2-one propamocarb were detected in milk or edible tissues of cattle exposed to propamocarb at levels of 0.8, 2.4 or 8 ppm administrated daily for 28 days, except for milk, where levels of up to 0.019 mg/kg of 2-hydroxy-propamocarb were found in the highest dose group (8 ppm).These residues were equally distributed between the milk fat and the skim milk. LOQs were 0.01 mg/kg (milk) and 0.05 mg/kg (tissues).

Laying hen feed study

A residue transfer study of propamocarb was conducted in laying hens. Hens were dosed orally for 35 consecutive days at the rates of 1.2 ppm (0.3×), 4.1 ppm (1×), 12.3 ppm (3×), and 41.1 ppm (10×) in the feed.

The mean (maximum) propamocarb residues in the egg samples from 1× and 0.3× feeding levels were: 0.0047 mg/kg (0.005 mg/kg) and 0.012 mg/kg (0.013 mg/kg) at Day 35.

In fat, the mean (maximum) propamocarb residues at Day 35 were < LOD (0.0014 mg/kg) in 1× and 0.3× dose groups.

In liver, the mean (maximum) propamocarb residues at Day 35 were 0.0037 mg/kg (0.0055 mg/kg) in the 1× dose group, and 0.0019 mg/kg (0.0021 mg/kg) in the 0.3× dose group.

In muscle, the mean (maximum) propamocarb residues at Day 35 were 0.0022 mg/kg (0.0028 mg/kg) in the 1× dose group, and 0.001 mg/kg (0.001 mg/kg) in the 0.3× dose group.

Animal commodity maximum residues levels

The dietary burdens were estimated using the OECD diets listed in Appendix IX of the 2009 Edition of FAO Manual. Potential cattle feed items include: cabbage, kale and potatoes (including by-products). Dietary burden calculations for beef cattle and dairy cattle and poultry are provided below.

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

	US-Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	0.38	0.20	16.16	5.58	0.11	0.05	0.00	0.00
Dairy cattle	0.13	0.07	16.11	5.53	31.55a, b	10.70c, d	0.00	0.00
Poultry-broiler	0.00	0.00	0.10	0.04	0.00	0.00	0.00	0.00
Poultry-layer	0.00	0.00	4.03e	1.37f	0.00	0.00	0.00	0.00

[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 mammalian milk

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

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

The propamocarb dietary burden for animal commodity MRL and STMR estimation (residue levels in animal feed expressed on dry weight) are 31.55 and 10.7 ppm for mammalian products (based primarily on the new use on kale), and the maximum and mean dietary burdens are 4.03 and 1.37 ppm for poultry products.

Mammalian products

The Meeting noted that the maximum cattle dietary burden was about 3–4 times higher than the dose level (8 ppm) in the feeding study and the metabolism study of lactating cow (11.5 ppm), and could not estimate maximum residue levels for mammalian commodities. The Meeting agreed to withdraw the previous MRLs of 0.01* mg/kg for milk, meat from mammals other than marine mammals, and edible offal, mammalians.

Poultry products

The MRLs for poultry products were estimated using the maximum dietary burden and the highest residues obtained from the laying hen feeding study. For the estimation of the STMRs, the mean dietary burden and mean residues on poultry products from the feeding study were used.

The maximum dietary burden of 4.03 ppm DM matches the 1× dose level of the laying hen feeding study. Therefore, the residue levels reported in the feeding study were used as a direct estimate of the residue levels in poultry muscle, fat, liver and eggs resulting from the dietary burden. Similarly, the STMR of 1.37 ppm approximates the lowest dose level of the feeding study (1.2 ppm). Therefore, as an estimate for the STMR in the poultry products, the mean residue levels from the feeding study at this level were used. The estimated MRLs and STMRs are summarized in following table.

	Feed level	Residues	Feed level	Residues (mg/kg) in		
	(ppm) for egg residues	(mg/kg) in egg	(ppm) for tissue residues	Muscle	Liver	Fat
MRL poultry						
Feeding study [a]	4.1	0.005	4.1	0.0028	0.0055	< LOD [c]
Dietary burden and high residue	4.03	0.005	4.03	0.0028	0.0055	< LOD [c]
STMR poultry						
Feeding study [b]	1.2	0.0012	1.2	0.0010	0.0019	< LOD [c]
Dietary burden and residue estimate	1.37	0.0012	1.37	0.0010	0.0019	< LOD [c]

[a] Highest residues for tissues and highest residues for eggs

[b] Mean residues for tissues and mean residues for eggs

[c] LOD in fat was 0.0014 for propamocarb

The meeting estimated the following STMR values: eggs 0.001 mg/kg, muscle 0.001 mg/kg, liver 0.002 mg/kg and fat 0.001 mg/kg. The following HR values are also estimated: eggs of 0.005 mg/kg, muscles of 0.003 mg/kg, liver of 0.006 mg/kg and fat of 0.001 mg/kg.

The meeting recommended the maximum residue levels of 0.01* mg/kg for poultry fat, and confirmed it previous recommendation for maximum residue levels of 0.01* mg/kg for eggs, poultry meat, and poultry, edible offal of.

RECOMMENDATIONS

Summary of the recommendations for the MRL, STMR and HR for propamocarb:

Commodity		Recommended MRL (mg/kg)		STMR (mg/kg)	HR (mg/kg)
CCN	Name	New	Previous		
VA0385	Onion	2		0.050	1.4
VB0400	Broccoli	3		0.290	1.7
VB0404	Cauliflower	2	0.2	0.035	0.82
VB0402	Brussels sprouts	2		0.47	1.3
VB0041	Cabbage, Head	1		0.195	0.36
VL0480	Kale	20		4.00	11.8
VA0384	Leek	30		2.50	15.0
PF0111	Poultry fat	0.01*		0.001	0.001
PM0110	Poultry meat	0.01*	0.01*	0.001	0.003
PO0111	Poultry, edible offal of	0.01*	0.01*	0.002	0.006
PE0112	Eggs	0.01*	0.01*	0.001	0.005

Commodity		Recommended MRL (mg/kg)		STMR (mg/kg)	HR (mg/kg)
CCN	Name	New	Previous		
ML0106	Milk	W	0.01*		
MM0095	Meat from mammals other than marine mammals	W	0.01*		
MO0515	Edible offal, mammalians	W	0.01*		

DIETARY RISK ASSESSMENT

Long-term intake

The long-term dietary intake for propamocarb (ADI 0–0.4 mg/kg bw) was calculated for the 17 regional diets on the basis of the STMRs estimated by the JMPR in 2006 and the current meeting. The results are shown in Annex 3 of the 2014 Report.

The International Estimated Daily Intakes (IEDI) of propamocarb were 0–1% of the maximum ADI (0.4 mg/kg bw). The Meeting concluded that the long-term intake of residues of propamocarb from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The ARfD for propamocarb is 2 mg/kg bw. The International Estimated Short Term Intake (IESTI) of propamocarb was calculated for the commodities for the commodities for which residue levels were estimated. The results are shown in Annex 4 of the 2014 Report.

The IESTI of propamocarb calculated were up to 20% of the ARfD (2 mg/kg bw) for children and general population. The Meeting concluded that the short-term intake of residues of propamocarb resulting from uses that have been considered by current meeting is unlikely to present a public health concern.

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M-349882-02-1	Melrose I.; Portet, M.,	2010	Determination of the residues of Fosetyl and Propamocarb in/on carrot, lettuce and wheat, winter after spraying of Fosetyl & Propamocarb SL 840 in the Field in Netherlands
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