INDOXACARB (216)

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EXPLANATION

Indoxacarb was first evaluated at the 2005 JMPR. It is an indeno-oxadiazine insecticide that is used for control of lepidoptera and other pests. The 2005 Meeting concluded that the residue definition for compliance with MRLs for all commodities and for estimation of dietary intake for plant commodities was sum of indoxacarb and its R enantiomer. For estimation of dietary intake for animal commodities, the residue was defined as sum of indoxacarb, its R enantiomer and methyl 7-chloro-2,5-dihydro-2-[[[4- (trifluoromethoxy)phenyl]amino]carbonyl] indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate (metabolite IN-JT333), expressed as indoxacarb. The 2005 JMPR established an ADI of 0-0.01 mg/kg bw and an ARfD of 0.1 mg/kg bw. Maximum residue levels were recommended for a number of plant and animal commodities. The 2007 JMPR re-evaluated head cabbage data due to short-term dietary intake concerns for children and estimated a new HR value of 2.0 mg/kg for that commodity.

The present Meeting received information on the residue analysis, storage stability, use pattern, supervised field trials, fate of residues during processing of plum and mint, and a laying hen feeding study. The supervised trial information included data on stone fruit (cherry, peach, and plum), cranberry, fruiting vegetables – cucurbits (cucumber, melons, and summer squash), cowpea (dry), and mints.

RESIDUE ANALYSIS

Analytical methods

For the determination of indoxacarb residues in plant materials, two single-residue methods (AMR 2712-93 and AMR 3493-95) and one multiresidue method AMR 4271-96 (modified DFG S19) for the determination of indoxacarb residues in plant materials were reported to the JMPR in 2005. These methods are briefly summarized below. Table 1 provides method validation and concurrent recoveries and LOQs obtained in supervised trial studies submitted to the present Meeting.

Method:	AMR 2712-93
(Reference)	Klemens *et al*., 1997, AMR 2712-93
Analytes:	Indoxacarb and its R enantiomer
LOQ:	typically 0.01 mg/kg (see Table 1 for individual commodities)
Determination:	HPLC-UV
Description:	Residues are extracted from homogenized samples with hexane-acetonitrile and the acetonitrile extract is concentrated and cleaned up by solid-phase extraction with a combination of silica and a strong anion exchange sorbent. The analytes are measured as a single peak by reversed-phase HPLC with UV detection at 310 nm.
Method:	AMR 3493-95
(Reference)	Gagnon and Guinivan, 1996, AMR 3493-95
Analytes:	Indoxacarb and its R enantiomer
LOQ:	typically 0.02 mg/kg (see Table 1 for individual commodities)
Determination:	GC-MS
Description:	Residues are extracted from homogenized samples with ethyl acetate after the addition of water. An aliquot of the extract is concentrated and cleaned up by solid-phase extraction with silica and carbon. The analysis is performed by GC-MS.
Method:	AMR 4271-96
(References)	Schmidt, 1997, AMR 4271-96; Kakkonen *et al*., 2006, DuPont-17240
Analytes:	Indoxacarb and its R enantiomer

LOQ:	typically 0.01 mg/kg (see Table 1 for individual commodities)
Determination:	GC-ECD, GC-MS or LC-MS/MS
Description:	Homogenized samples are extracted using acetone. Water is added before extraction to obtain water: acetone ratio of 2:1 (v/v). After addition of sodium chloride, analytes are partitioned into ethyl acetate:cyclohexane (1:1, v/v). The extract is cleaned by GPC, followed by a silica gel clean-up (not necessary for LC-MS/MS). The analysis is performed by GC-ECD, GC-MS or LC-MS/MS.

Table 1 Recoveries and LOQs obtained by analytical methods AMR 2712-93, AMR 3493-95, and AMR 4271-96 for determination of indoxacarb residues (sum of indoxacarb and its R enantiomer) in supervised trials on stone fruit, cranberry, cucurbits, cowpea (dry), and mint.

Commodity	Method	Conc. (mg/kg)	n	Mean recovery (%)	Range recovery (%)	RSD (%)	LOQ (mg/kg)	Ref.
Cherry	AMR 2712-93	0.02	6	113	108 - 118	3.5	0.02a (0.007)[b]	Corley 2005 IR-4 07235
		0.10	18	100	93 - 112	5.0		
		1.0	4	95	92 - 102	5.3		
	AMR 4271-96	0.01	2	93	92 - 93		0.01	Kakkonen *et al.* 2006 DuPont-17240
		0.10	2	110	110			
		0.20	1	113	113			
	AMR 4271-96	0.01	4	110	99 - 120	8.7	0.01	Old and Hansford 2007 DuPont-17244
		0.10	3	108	106 - 110	1.9		
		0.30	1	106	106			
Cowpea, dry	AMR 2712-93	0.01	12	84	72 - 110	13	0.01[a] (0.009)[b]	Corley 2004 IR-4 06984
		0.10	5	84	71 - 92	9.5		
		1.0	3	82	80 - 84	2.8		
Cranberry	AMR 3493-95	0.05	8	93	86 - 96	4.3	0.05[a] (0.02)[b]	Dorschner 2005 IR-4 08127
		0.20	6	97	78 - 110	13		
		0.50	9	91	82 - 105	10		
		0.70	2	109	107 - 110			
		5.0	3	91	86 - 93	4.0		
Cucumber	AMR 2712-93	0.01	17	101	80 -120	14	0.01[1] (0.008)[2]	Corley 2005 IR-4 06985
		0.10	4	105	83 - 113	13		
		1.0	15	104	89 - 119	8.7		
		2.0	3	98	94 - 109	10		
Melons	AMR 2712-93	0.01	14	94	80 - 110	11	0.01[a] (0.008)[b]	Corley 2005 IR-4 08339
		0.10	10	82	73 - 96	8.5		
		1.0	12	97	84 - 117	10		
Mint oil	AMR 4271-96	0.1	9	97	75 - 114	13	0.10[1] (0.11)[2]	Corley 2005 IR-4 08418
		1.0	3	107	105 - 113	4.9		
Mint tops	AMR 3493-95	0.05	6	95	76 - 104	11	0.05[a] (0.053)[b]	Corley 2005 IR-4 08418
		0.1	6	98	71 - 123	17		
		1.0	3	84	82 - 86	2.5		
		5.0	3	92	90 - 93	1.9		
		10	3	95	92 - 101	5.5		
Peach	AMR 2712-93	0.01	6	98	94 - 102	3.1	0.01[a] (0.003)[b]	Corley 2005 IR-4 07228
		0.10	18	94	84 - 100	4.3		
		1.0	3	93	92 - 93	1.1		
Plum	AMR 2712-93	0.01	11	93	84 - 118	10	0.01[a] (0.008)[b]	Corley 2005 IR-4 07234
		0.10	9	97	91 - 106	5.2		
		1.0	3	99	99 - 100	1.0		
	AMR 4271-96	0.01	3	102	99 - 106	3.4	0.01	Old and Hansford 2007 DuPont-19048
		0.02	2	105	102 - 107			
		0.10	3	96	93 - 99	3.2		
		0.20	2	100	99 - 100			

Commodity	Method	Conc. (mg/kg)	n	Mean recovery (%)	Range recovery (%)	RSD (%)	LOQ (mg/kg)	Ref.
		1.0	2	91	89 - 92			
Plum juice	AMR 4271-96	0.01	3	102	98 - 110	6.8	0.01	Old and Hansford 2007 DuPont-19048
		0.10	3	98	91 - 106	7.8		
Plum jam	AMR 4271-96	0.01	3	105	97 - 109	6.6	0.01	
		0.10	3	101	91 - 109	9.1		
Plum puree	AMR 4271-96	0.01	3	104	99 - 107	4.2	0.01	
		0.10	3	101	94 - 106	6.1		
Prune	AMR 2712-93	0.01	6	93	90 - 96	2.2	0.01[a] (0.003)[b]	Corley 2005 IR-4 07234
		0.10	4	104	97 - 115	7.7		
		1.0	3	94	91 - 96	3.2		
	AMR 4271-96	0.01	3	90	71 - 103	19	0.01	Old and Hansford 2007 DuPont-19048
		0.10	3	81	77 - 89	8.2		
		1.0	1	78	78			
Summer squash	AMR 2712-93	0.01	12	91	74 - 120	19	0.01[a] (0.014)[b]	Corley 2005 IR-4 08340
		0.10	6	97	93 - 100	3.1		
		1.0	3	92	91 - 93	1.1		

[a] lowest level of method validation (LLMV)

[b] calculated LOQ

The present Meeting received information on an analytical method AMR 12739 for indoxacarb, its R enantiomer and 5 metabolites, including IN-JT333, which was used in the laying hen feeding study (McLean and Swain, 2003, DuPont-8305) for the analysis of poultry muscle, fat, skin (with fat), liver and eggs. The method is briefly summarized below. Table 2 gives method validation and concurrent recoveries obtained for indoxacarb, its R enantiomer and metabolite IN-JT333 in the hen feeding study submitted to this Meeting. Results for the other four metabolites are not included in Table 2 because they are not part of the residue definition.

Method:	AMR 12739
(Reference)	McLean and Swain, 2003, DuPont-8305
Analytes:	Indoxacarb, its R enantiomer and 5 of its metabolites, including IN-JT333
LOQ:	0.01 mg/kg (LOD: 0.003 mg/kg)
Determination:	LC-MS/MS
Description:	Residues are extracted from homogenized samples with acidified acetonitrile. An aliquot of the extract is defatted with hexane and cleaned up by solid-phase extraction with Oasis sorbent. The analysis of indoxacarb and its metabolites is performed using LC-MS/MS, monitoring two MS/MS transitions for each analyte.

Table 2 Validation (at 0.01 and 0.10 mg/kg, n = 10) and concurrent recoveries of indoxacarb (and its enantiomer) and IN-JT333 metabolite obtained in poultry tissues and eggs using method ARM 12739 (McLean and Swain, 2003, DuPont-8305)

Analyte	Matrix	Validation recoveries		Concurrent recoveries			
		Mean recovery (%)	RSD (%)	Fortification levels (mg/kg)	n	Mean recovery (%)	RSD (%)
Indoxacarb and its R enantiomer	Whole egg	98	8.9	0.01 – 1.0	69	99	9.3
	Egg yolk	91	9.1	0.01 – 1.0	26	102	5.5
	Egg white	99	4.9	0.01 – 1.0	26	97	7.8
	Fat	90	7.0	0.01 – 2.0	12	97	8.7
	Muscle	91	9.9	0.01 – 0.10	10	94	17
	Liver	95	7.3	0.01 – 0.50	12	84	14

Analyte	Matrix	Validation recoveries		Concurrent recoveries			
		Mean recovery (%)	RSD (%)	Fortification levels (mg/kg)	n	Mean recovery (%)	RSD (%)
	Skin	94	9.7	0.01 – 0.50	9	94	9.8
IN-JT333	Whole egg	79	11	0.01 – 1.0	58	84	16
	Egg yolk	81	8.0	0.01 – 1.0	26	86	12
	Egg white	79	12	0.01 – 1.0	26	87	16
	Fat	73	12	0.01 – 2.0	12	88	11
	Muscle	85	14	0.01 – 0.10	7	90	16
	Liver	76	14	0.01 – 0.50	9	78	15
	Skin	74	11	0.01 – 0.50	9	88	9.2

Stability of pesticide residues in stored analytical samples

Freezer storage stability data for indoxacarb residues were evaluated in many commodities by the 2005 JMPR. The following are plant commodities and freezer storage duration for which indoxacarb residues were demonstrated to be stable: alfalfa forage (17 months), alfalfa hay (20 months), apple (530 days), apple juice (186 days), apple pomace (202 days), grapes (553 days), grape pomace (301), lettuce (365), peanut hay (11 months), peanut kernels (11 months), peanut meal (6 months), peanut oil (6 months), sweet corn (9 months), sweet corn forage (6 months), sweet corn stover (4 months), tomatoes (366 days), and wine (301 days). Table 3 provides freezer storage stability data and actual maximum duration of sample storage in supervised trials for the commodities evaluated by the present Meeting.

Table 3 Freezer storage stability data for indoxacarb (and its R enantiomer) compared to actual maximum duration of sample storage in supervised trials on crops

Commodity	Stability study storage duration (days)	Residue remaining (%)	Concurrent recovery (%)	Max. trial sample storage duration (days)	Reference
Cherry	460	84 - 86	91	315	Corley 2005 IR-4 07235
Cowpea, dry	317	52 - 62 (77 - 87)a	71 - 80	267	Corley 2004 IR-4 06984
Cranberry	45	95 - 103	103 - 105	125	Dorschner 2005 IR-4 08127
Cucumber	724	73 - 84	80 - 109	697	Corley 2005 IR-4 06985
Melons	385	77 - 99	74 - 84	360	Corley 2005 IR-4 08339
Mint oil	167	99 - 103	107 - 114	166	Corley 2005 IR-4 08418
Mint tops	162	84 - 99	101 - 123	139	Corley 2005 IR-4 08418
Peach	168	92 - 98	97	119	Corley 2005 IR-4 07228
Plum	236	85 - 95	88	155	Corley 2005 IR-4 07234
Prune	190	101 - 102	97	189	Corley 2005 IR-4 07234
Summer squash	369	83 - 94	94 - 100	301	Corley 2005 IR-4 08340

[a] The residues measured were corrected for concurrent recoveries.

The Meeting received information on freezer storage stability (at -20 °C) of indoxacarb and its metabolites (including IN-JT333) in poultry tissues and eggs, which is summarized in Table 4. In the hen feeding study, egg samples were stored in a freezer for up to 12.7 months and tissues samples for up to 9.9 months, therefore the storage duration tested in the stability study covers the maximum storage duration of actual samples.

Table 4 Freezer storage stability data for indoxacarb, its R enantiomer and metabolite IN-JT333 in poultry tissues and whole eggs samples fortified at 0.10 mg/kg (McLean and Swain, 2003, DuPont-8305)

Analyte	Matrix	Storage duration (months)	Residue remaining (%)	Concurrent recoveries (%)	Mean normalized recovery (%)
Indoxacarb and its R enantiomer	Whole egg	16.9	74, 85	100, 97	81
	Fat	12.2	96, 78	101, 102	85
		16.4	85, 80	97, 86	90
	Liver	12.3	64, 83	90, 98	79
		16.6	84, 86	99, 101	85
	Muscle	12.5	80, 88	91, 97	89
		16.8	78, 75	95, 98	79
	Skin a	16.5	68, 58	97, 94	66
		16.9	73, 67	90, 89	78
			(86, 80)		(93)
IN-JT333	Whole egg	16.9	60, 74	86, 92	75
	Fat	12.2	72, 64	82, 80	84
		16.4	79, 72	79, 82	94
	Liver	12.3	57, 81	81, 104	71
		16.6	71, 71	84, 89	82
	Muscle	12.5	74, 100	98, 105	86
		16.8	66, 66	79, 79	84
	Skin a	16.5	60, 59	87, 82	70
		16.9	70, 68	80, 84	84
			(78, 76)		(94)

[a] The lower remaining residues in skin samples stored for 16.5 months were caused by lower extraction efficiency due to poorly ground stored samples. The analysis was repeated at 16.9 months of storage, resulting in higher recoveries. Also, the samples were extracted twice and the recovery found in the second fraction added to the first one (values in parentheses). There were no additional recoveries in the second fraction for the fresh fortifications (concurrent recoveries).

USE PATTERN

Indoxacarb is an indeno-oxadiazine insecticide that is registered for use against a large number of insect pests on a wide range of crops in many countries. It is used to control lepidoptera insect (e.g., budworm, armyworm, diamondback moth, loopers, codling moth, grape berry moth, and certain leafrollers) and a range of other insect pests, including Colorado potato beetle, cranberry weevil, leafhoppers, sawflies, and tarnished plant bug.

The Meeting received a copy of the official label providing information on registered uses of indoxacarb in the USA relevant to the supervised trial data. This information is summarized in Table 5. The Meeting was also informed that registration of indoxacarb on cherry and plum is pending in France and Italy.

Table 5 Registered uses of indoxacarb on cowpea (dry), cranberry, cucurbits, mint, and stone fruit in the USA using a foliar application of a WG formulation with 300 g ai/kg

Crop	Application				PHI, days
	Rate, kg ai/ha	Min. spray interval, days	Season max. rate, kg ai/ha	Max. number	
Cowpea (dry)[a]	0.073	3	0.29		7
Cranberry	0.12	7	0.49		30
Cucurbits[b]	0.05 – 0.12	5	0.49		3
Mints[c]	0.073	3	0.29		7
Stone fruit[d]	0.10 – 0.12	7	0.49	4	14

[a]Registration in the USA on southern pea (dry), which includes cowpea, blackeyed pea, callivance, cherry bean, Indian pea, cornfield pea, crowder pea, pois a vache, frijol de costa, niebe, caupi, costeno, rabizo.

[b]Cucurbits group in the USA includes chayote (fruit), Chinese waxgourd (Chinese preserving melon), citron melon, cucumber, gherkin, edible gourd (including hyotan, cucuzza, hechima and Chinese okra), Momordica species (including balsam apple, balsam pear, bitter melon and Chinese cucumber), muskmelon (including true cantaloupe, cantaloupe, casaba, crenshaw melon, golden pershaw melon, honeydew melon, honey balls, mango melon, Persian melon, pineapple melon, Santa Claus melon and snake melon), pumpkin, summer squash (including crookneck squash, scallop squash, straightneck squash, vegetable marrow and zucchini), winter squash (including butternut squash, calabaza, hubbard squash, acorn squash and spaghetti squash) and watermelon.

[c] Peppermint and spearmint.

[d]Stone fruit group in the USA includes apricot, sweet cherry, tart cherry, nectarine, peach, plum, chicksaw plum, damson plum, Japanese plum, plumcot and prune.

RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS

The Meeting received information on indoxacarb supervised trials on the following crops:

Commodity	Commodity Group	Country	Table No.
Cherry	Stone fruit	Canada, USA	6
		France, Italy	7
Peach		Canada, USA	8
Plum		Canada, USA	9
		France, Italy	10
Cranberry	Berries and small fruit	USA	11
Cucumber	Fruiting vegetables, cucurbits	USA	12
Melons		Canada, USA	13
Summer squash		Canada, USA	14
Cowpea, dry	Pulses	USA	15
Mints	Herbs	USA	16

All trials were conducted using a 30 WG formulation containing 300 g/kg of indoxacarb (S enantiomer) and 100 g/kg inactive R enantiomer ("indoxacarb 3S+1R"). In the tables, the application rate and spray concentration are expressed in terms of the active ingredient, indoxacarb. Residues were measured and expressed as sum of indoxacarb and its R enantiomer.

Trials were generally well documented with laboratory and field reports. Laboratory reports included method validation results with procedural recoveries of samples fortified at levels similar to those occurring in samples from the supervised trials. In general, data on procedural recoveries were within the acceptable range 70–120%, with RSDs of < 20%. Dates of analyses and duration of residue sample storage prior to analyses were also provided. Field reports included data on the dates of spray applications, methods used and sampling dates. Although trials included control plots, no control data are recorded in the summary tables below unless residues in control samples exceeded the LOQ. Results reported have not been corrected for concurrent method recoveries unless indicated.

Trials conducted within the same study at the same location, time, and on the same crop variety were generally considered replicate trials. In most trials, duplicate or multiple field samples from replicate plots were taken at each sampling period and were analysed separately. Each value is reported in the tables and the highest value was taken as the best estimate of the residues in the replicate plots or replicate trials used in the estimation of the maximum residue levels. Highest residue values from the trials conducted according to maximum GAP are underlined.

When residues were not detected they are shown as below the LOQ (e.g., < 0.01 mg/kg). Residues, application rates and spray concentrations have generally been rounded to two significant figures or, for residues near the LOQ, to one significant figure.

Table 6 Indoxacarb residues (expressed as sum of indoxacarb and its R enantiomer) resulting from foliar application on cherry in Canada and the USA (spray interval 6–8 days)

CHERRY Location Year (variety)	Application					PHI days	Indoxacarb residues, mg/kg	Author, Date Study No.
	Form g ai/kg	kg ai/ha	Water L/ha	No.	Total kg ai/ha			
Canada (BC) 2003 (Cristalina)	WG 300	0.12	982	4	0.50	14	0.07, 0.07	Corley 2005 IR-4 07235
Canada (BC) 2003 (Santina)	WG 300	0.12	963	4	0.49	14	0.07, 0.07	Corley 2005 IR-4 07235
USA (CA) 2004 (Rainier)	WG 300	0.13	1207	4	0.51	13	0.15, 0.15	Corley 2005 IR-4 07235
USA (CA) 2004 (Bing)	WG 300	0.12	1122	4	0.50	5	0.45, 0.45	Corley 2005 IR-4 07235
USA (CO) 2002 (Montmorency)	WG 300	0.13	1150	4	0.52	13	0.22, 0.21	Corley 2005 IR-4 07235
USA (ID) 2003 (Montmorency)	WG 300	0.12	935	4	0.49	14	0.19, 0.19	Corley 2005 IR-4 07235
USA (MI) 2003 (Montmorency)	WG 300	0.12	926	4	0.49	14	0.15, 0.15	Corley 2005 IR-4 07235
USA (MI) 2002 (Montmorency)	WG 300	0.12	945	4	0.50	14	0.16, 0.15	Corley 2005 IR-4 07235
		0.12	935	4	0.49	14	0.30, 0.32	
		0.12	926	4	0.49	14	0.51, 0.51	
		0.12	926	4	0.50	12	0.24, 0.28	
USA (NJ) 2002 (North Star)	WG 300	0.12	1094	4	0.50	14	0.12, 0.15	Corley 2005 IR-4 07235
Canada (ON) 2003 (North Star)	WG 300	0.12	804	4	0.50	14	0.26, 0.26	Corley 2005 IR-4 07235
Canada (ON) 2003 (Montmorency)	WG 300	0.13	823	4	0.50	14	0.31, 0.32	Corley 2005 IR-4 07235
Canada (ON) 2003 (Montmorency)	WG 300	0.12	786	4	0.49	13	0.13, 0.13	Corley 2005 IR-4 07235
USA (WA) 2002 (Montmorency)	WG 300	0.12	767	4	0.50	12	0.62, 0.64	Corley 2005 IR-4 07235

Table 7 Indoxacarb residues (expressed as sum of indoxacarb and its R enantiomer) resulting from foliar application on cherry in southern Europe (Italy and southern France)

CHERRY Location Year (variety)	Application					PHI days	Indoxacarb residues, mg/kg	Author, Date Study No.
	Form g ai/kg	kg ai/ha	kg ai/hl	Water L/ha	No.			
Italy 2005 (Cordia)	WG 300	0.076	0.005	1523	2	14	0.18	Kakkonen *et al.* 2006 DuPont-17240
France 2005 (Stark)	WG 300	0.076	0.005	1524	2	BLA 0	0.10 0.17	Kakkonen *et al.* 2006 DuPont-17240
		0.075	0.005	1502	2	3	0.12	
		0.075	0.005	1507	2	7	0.13	
		0.075	0.005	1500	2	14	0.10	
		0.075	0.005	1502	2	21	0.04	
Italy 2006 (Cordia)	WG 300	0.076	0.005	1521	2	14	0.12	Old and Hansford 2007 DuPont-17244
France 2006 (Reinier)	WG 300	0.076	0.005	1515	2	BLA 0	0.10 0.26	Old and Hansford 2007 DuPont-17244
		0.075	0.005	1503	2	3	0.29	
		0.075	0.005	1502	2	7	0.27	
		0.076	0.005	1509	2	14	0.21	
		0.076	0.005	1516	2	21	0.30	
France 2006 (Van)	WG 300	0.075	0.005	1509	2	14	0.15	Old and Hansford 2007 DuPont-17244
France 2006 (Stark)	WG 300	0.075	0.005	1479	2	14	0.04	Old and Hansford 2007 DuPont-17244
France 2006 (Sweeter)	WG 300	0.075	0.005	1493	2	15	0.09	Old and Hansford 2007 DuPont-17244

Table 8 Indoxacarb residues (expressed as sum of indoxacarb and its R enantiomer) resulting from foliar application on peach in Canada and the USA (spray interval 6-8 days).

PEACH Location Year (variety)	Application					PHI days	Indoxacarb residues, mg/kg	Author, Date Study No.
	Form g ai/kg	kg ai/ha	Water L/ha	No.	Total kg ai/ha			
Canada (BC) 2003 (Glohaven)	WG 300	0.12	580	4	0.50	14	<u>0.07</u>, 0.06	Corley 2005 IR-4 07228
USA (CA) 2003 (Champagne)	WG 300	0.12	1169	4	0.50	14	0.26, <u>0.29</u>	Corley 2005 IR-4 07228
USA (CA) 2003 (Angelos)	WG 300	0.12	1291	4	0.49	14	0.13, <u>0.13</u>	Corley 2005 IR-4 07228
USA (CA) 2003 (Fairtime)	WG 300	0.12	1216	4	0.50	14	0.03, <u>0.04</u>	Corley 2005 IR-4 07228
USA (CA) 2003 (O'Henry)	WG 300	0.12	599	4	0.50	14	0.04, <u>0.04</u>	Corley 2005 IR-4 07228

PEACH Location Year (variety)	Application					PHI days	Indoxacarb residues, mg/kg	Author, Date Study No.
	Form g ai/kg	kg ai/ha	Water L/ha	No.	Total kg ai/ha			
USA (MI) 2003 (Elberta)	WG 300	0.12	935	4	0.49	14	0.10, <u>0.10</u>	Corley 2005 IR-4 07228
USA (NC) 2003 (Contender)	WG 300	0.12	963	4	0.49	14	0.09, <u>0.09</u>	Corley 2005 IR-4 07228
USA (NC) 2003 (Emery)	WG 300	0.12	954	4	0.49	14	0.09, <u>0.10</u>	Corley 2005 IR-4 07228
USA (NJ) 2003 (Ernie's Choice)	WG 300	0.12	701	4	0.50	13	0.10, <u>0.10</u>	Corley 2005 IR-4 07228
USA (NJ) 2003 (Flamin'fury)	WG 300	0.12	701	4	0.49	13	0.09, <u>0.09</u>	Corley 2005 IR-4 07228
USA (NY) 2003 (Harrow Beauty)	WG 300	0.12	468	4	0.49	14	0.30, <u>0.30</u>	Corley 2005 IR-4 07228
Canada (ON) 2003 (Virgil)	WG 300	0.13	823	4	0.50	14	0.16, <u>0.16</u>	Corley 2005 IR-4 07228
Canada (ON) 2003 (Red Haven)	WG 300	0.12	795	4	0.50	14	0.19, <u>0.20</u>	Corley 2005 IR-4 07228
Canada (ON) 2003 (Canadian Harmony)	WG 300	0.12	804	4	0.49	13	0.58, <u>0.59</u>	Corley 2005 IR-4 07228
USA (TN) 2003 (Bell of Georgia)	WG 300	0.12	458	4	0.47	7	0.07, 0.07	Corley 2005 IR-4 07228
USA (TX) 2003 (Harvester)	WG 300	0.12	580	5	0.62	15	<u>0.50</u>, 0.48	Corley 2005 IR-4 07228

Table 9 Indoxacarb residues (expressed as sum of indoxacarb and its R enantiomer) resulting from foliar application on plum in Canada and the USA (spray interval 6-8 days).

PLUM Location Year (variety)	Application					PHI days	Indoxacarb residues, mg/kg	Author, Date Study No.
	Form g ai/kg	kg ai/ha	Water L/ha	No.	Total kg ai/ha			
USA (CA) 2003 (Red Beaut)	WG 300	0.12	982	4	0.50	13	0.02, <u>0.02</u>	Corley 2005 IR-4 07234
USA (CA) 2003 (Casselman)	WG 300	0.12	711	4	0.49	14	0.01, <u>0.01</u>	Corley 2005 IR-4 07234
USA (CA) 2003 (Hiromi)	WG 300	0.12	1160	4	0.49	14	0.02, <u>0.02</u>	Corley 2005 IR-4 07234
USA (CA) 2003 (Fortune)	WG 300	0.12	1309	4	0.50	14	0.02, <u>0.02</u>	Corley 2005 IR-4 07234

PLUM Location Year (variety)	Application					PHI days	Indoxacarb residues, mg/kg	Author, Date Study No.
	Form g ai/kg	kg ai/ha	Water L/ha	No.	Total kg ai/ha			
USA (CA) 2003 (Angelenos)	WG 300	0.12	1019	4	0.49	14	0.02, 0.02	Corley 2005 IR-4 07234
USA (ID) 2003 (Friar)	WG 300	0.13	954	4	0.50	13	0.03, 0.03	Corley 2005 IR-4 07234
USA (MI) 2003 (Early Golden)	WG 300	0.12	935	4	0.49	14	0.07, 0.07	Corley 2005 IR-4 07234
Canada (NS) 2003 (Empress)	WG 300	0.12	1038	4	0.50	14	0.04, 0.04	Corley 2005 IR-4 07234
Canada (ON) 2003 (Early Golden)	WG 300	0.12	804	4	0.48	15	0.07, 0.07	Corley 2005 IR-4 07234
Canada (ON) 2003 (Italian Blue)	WG 300	0.13	823	4	0.50	13	0.19, 0.18	Corley 2005 IR-4 07234
USA (OR) 2003 (Brooks)	WG 300	0.13	571	4	0.50	14	< 0.01, < 0.01	Corley 2005 IR-4 07234

Table 10 Indoxacarb residues (expressed as sum of indoxacarb and its R enantiomer) resulting from foliar application on plum in France and Italy.

PLUM Location Year (variety)	Application					PHI days	Indoxacarb residues, mg/kg	Author, Date Study No.
	Form g ai/kg	kg ai/ha	kg ai/hl	Water L/ha	No.			
Italy 2006 (Stanley)	WG 300	0.15	0.010	1489	2	14	0.16	Old and Hansford 2007 DuPont-19048
France 2006 (Mirabelle)	WG 300	0.15	0.010	1503	2	14	0.06	Old and Hansford 2007 DuPont-19048

Table 11 Indoxacarb residues (expressed as sum of indoxacarb and its R enantiomer) resulting from foliar application on cranberry in the USA (spray interval 6-8 days).

CRANBERRY Location Year (variety)	Application					PHI days	Indoxacarb residues, mg/kg	Author, Date Study No.
	Form g ai/kg	kg ai/ha	Water L/ha	No.	Total kg ai/ha			
USA (MA) 2002 (Early Blacks)	WG 300	0.12	419	4	0.49	14	0.16, 0.22	Dorschner 2005 IR-4 08127
						30	0.09, 0.15	
USA (MA) 2002 (Howes)	WG 300	0.12	422	4	0.49	14	0.17, 0.21	Dorschner 2005 IR-4 08127
						30	0.15, 0.15	
USA (NJ) 2003 (Early Blacks)	WG 300	0.13	270	4	0.51	13	0.11, 0.11	Dorschner 2005 IR-4 08127
						28	0.10, 0.11	

CRANBERRY Location Year (variety)	Application					PHI days	Indoxacarb residues, mg/kg	Author, Date Study No.
	Form g ai/kg	kg ai/ha	Water L/ha	No.	Total kg ai/ha			
USA (WI) 2003 (Ben Lear)	WG 300	0.12	347	4	0.49	15	0.36, 0.28	Dorschner 2005 IR-4 08127
						29	0.19, 0.16	
USA (WI) 2003 (Ben Lear)	WG 300	0.12	343	4	0.49	15	0.30, 0.17	Dorschner 2005 IR-4 08127
						29	0.13, 0.11	
USA (OR) 2003 (Stevens)	WG 300	0.12	373	4	0.50	15	0.39, 0.23	Dorschner 2005 IR-4 08127
						30	0.57, 0.69	

Table 12 Indoxacarb residues (expressed as sum of indoxacarb and its R enantiomer) resulting from foliar application on cucumber in the USA (spray interval 4-6 days).

CUCUMBER Location Year (variety)	Application					PHI days	Indoxacarb residues, mg/kg	Author, Date Study No.
	Form g ai/kg	kg ai/ha	Water L/ha	No.	Total kg ai/ha			
USA (CA) 2002 (Conquistador)	WG 300	0.13	271	4	0.50	3	0.02, 0.02	Corley 2005 IR-4 06985
USA (CO) 2002 (Thunderbird)	WG 300	0.12	374	4	0.46	1	0.03, 0.03	Corley 2005 IR-4 06985
						3	0.02, 0.02	
						6	0.01, 0.01	
						12	< 0.01, < 0.01	
USA (FL) 2002 (Supersett FL)	WG 300	0.13	337	4	0.50	3	0.03, 0.03	Corley 2005 IR-4 06985
USA (GA) 2002 (XP 3501217)	WG 300	0.12	187	4	0.49	3	0.03, 0.01	Corley 2005 IR-4 06985
USA (MD) 2002 (General Lee)	WG 300	0.12	374	4	0.50	3	< 0.01, < 0.01	Corley 2005 IR-4 06985
USA (NC) 2002 (Calypso)	WG 300	0.12	365	4	0.49	1	0.03, 0.03	Corley 2005 IR-4 06985
						3	0.02, 0.02	
						6	0.02, 0.01	
						12	< 0.01, < 0.01	
USA (NJ) 2002 (Wisconsin SMR 58)	WG 300	0.14	421	4	0.52	3	0.04, 0.07	Corley 2005 IR-4 06985
USA (TX) 2002 (Poinset 76)	WG 300	0.12	355	4	0.50	3	0.03, 0.03	Corley 2005 IR-4 06985
USA (WI) 2002 (Marketmore 56)	WG 300	0.12	290	4	0.50	3	0.01, 0.01	Corley 2005 IR-4 06985
USA (WI) 2002 (Marketmore 76)	WG 300	0.12	299	4	0.50	3	0.02, 0.02	Corley 2005 IR-4 06985

Table 13 Indoxacarb residues (expressed as sum of indoxacarb and its R enantiomer) resulting from foliar application on cantaloupe melon in Canada and the USA (spray interval 4-6 days).

MELONS Location Year (variety)	Application					PHI days	Indoxacarb residues, mg/kg	Author, Date Study No.
	Form g ai/kg	kg ai/ha	Water L/ha	No.	Total kg ai/ha			
USA (CA) 2003 (Hymark)	WG 300	0.13	402	4	0.51	3	0.03, 0.06	Corley 2005 IR-4 08339
USA (CA) 2003 (M-80)	WG 300	0.13	281	4	0.50	3	0.25, 0.20	Corley 2005 IR-4 08339
USA (CA) 2003 (Western Sunrise)	WG 300	0.12	281	4	0.50	3	0.13, 0.17	Corley 2005 IR-4 08339
USA (MD) 2003 (Athena F1)	WG 300	0.13	327	4	0.50	3	0.39, 0.23	Corley 2005 IR-4 08339
USA (NJ) 2003 (Ambrosia)	WG 300	0.12	215	4	0.52	3	0.09, 0.07	Corley 2005 IR-4 08339
USA (NM) 2003 (Topmark SR)	WG 300	0.12	234	4	0.49	3	0.03, 0.02	Corley 2005 IR-4 08339
USA (OH) 2003 (Peto)	WG 300	0.12	355	4	0.50	3	0.05, 0.06	Corley 2005 IR-4 08339
Canada (ON) 2003 (Pulsar)	WG 300	0.12	196	4	0.49	3	0.04, 0.04	Corley 2005 IR-4 08339
Canada (QC) 2003 (Anthena)	WG 300	0.13	224	4	0.53	4	0.05, 0.05	Corley 2005 IR-4 08339
USA (TX) 2003 (Primo)	WG 300	0.12	224	4	0.49	1	0.13, 0.12	Corley 2005 IR-4 08339
						3	0.12, 0.12	
						5	0.09, 0.14	
						12	0.05, 0.04	
USA (TX) 2003 (Cruiser)	WG 300	0.12	262	4	0.49	3	0.02, 0.02	Corley 2005 IR-4 08339

Table 14 Indoxacarb residues (expressed as sum of indoxacarb and its R enantiomer) resulting from foliar application on summer squash in Canada and the USA (spray interval 4-6 days).

SUMMER SQUASH Location Year (variety)	Application					PHI days	Indoxacarb residues, mg/kg	Author, Date Study No.
	Form g ai/kg	kg ai/ha	Water L/ha	No.	Total kg ai/ha			
Canada (BC) 2003 (Senator)	WG 300	0.13	383	4	0.50	2	0.12, 0.08	Corley 2005 IR-4 08340
USA (CA) 2003 (Monet F1)	WG 300	0.13	299	4	0.52	3	0.01, 0.01	Corley 2005 IR-4 08340
USA (CO) 2003 (Ambassador)	WG 300	0.13	290	4	0.49	2	0.11, 0.05	Corley 2005 IR-4 08340

SUMMER SQUASH Location Year (variety)	Application					PHI days	Indoxacarb residues, mg/kg	Author, Date Study No.
	Form g ai/kg	kg ai/ha	Water L/ha	No.	Total kg ai/ha			
USA (FL) 2003 (Yellow Straight)	WG 300	0.12	281	4	0.51	2	0.04, 0.03	Corley 2005 IR-4 08340
USA (GA) 2003 (Goldbar)	WG 300	0.13	196	4	0.51	4	< 0.01, < 0.01	Corley 2005 IR-4 08340
USA (MD) 2003 (Liberator III)	WG 300	0.13	337	4	0.50	3	0.02, 0.03	Corley 2005 IR-4 08340
Canada (ON) 2003 (Aristocrat)	WG 300	0.12	309	4	0.48	2	0.04, 0.03	Corley 2005 IR-4 08340
Canada (QC) 2003 (Spineless beauty)	WG 300	0.12	196	4	0.47	3	0.01, 0.01	Corley 2005 IR-4 08340
USA (TX) 2003 (Multipik)	WG 300	0.12	215	4	0.49	3	0.03, 0.03	Corley 2005 IR-4 08340
USA (WA) 2003 (Early Summer Crookneck)	WG 300	0.12	318	4	0.50	2	< 0.01, < 0.01	Corley 2005 IR-4 08340
USA (WI) 2003 (General Patton)	WG 300	0.13	309	4	0.51	3	< 0.01, 0.02	Corley 2005 IR-4 08340
USA (NY) 2003 (Yellow Crookneck)	WG 300	0.13	290	5	0.61	3	< 0.01, < 0.01	Corley 2005 IR-4 08340

Table 15 Indoxacarb residues (expressed as sum of indoxacarb and its R enantiomer) resulting from foliar application on cowpea, dry (southern pea, dry) in the USA (spray interval 2-4 days).

COWPEA, DRY Location Year (variety)	Application					PHI days	Indoxacarb residues, mg/kg	Author, Date Study No.
	Form g ai/kg	kg ai/ha	Water L/ha	No.	Total kg ai/ha			
USA (CA) 2002 (California Blackeye)	WG 300	0.073	696	4	0.29	7	0.07, 0.06	Corley 2004 IR-4 06984
USA (GA) 2002 (Texas Cream 40)	WG 300	0.075	478	4	0.30	7	< 0.01, < 0.01	Corley 2004 IR-4 06984
USA (MD) 2002 (Queen Ann)	WG 300	0.074	658	4	0.29	7	0.01, 0.01	Corley 2004 IR-4 06984
USA (NC) 2002 (Colosus)	WG 300	0.071	298	4	0.29	7	< 0.01, < 0.01	Corley 2004 IR-4 06984
USA (TN) 2002 (Miss Silver)	WG 300	0.071	271	4	0.29	6	0.01, 0.01	Corley 2004 IR-4 06984
		0.073	278	4	0.29	7	0.03, 0.02	

COWPEA, DRY Location Year (variety)	Application					PHI days	Indoxacarb residues, mg/kg	Author, Date Study No.
	Form g ai/kg	kg ai/ha	Water L/ha	No.	Total kg ai/ha			
USA (WI) 2002 (California Blackeye)	WG 300	0.074	279	4	0.30	6	0.01, <u>0.03</u>	Corley 2004 IR-4 06984

Table 16 Indoxacarb residues (expressed as sum of indoxacarb and its R enantiomer) resulting from foliar application on mints in the USA (spray interval 2-4 days).

MINTS Location Year (variety)	Application					PHI days	Indoxacarb residues, mg/kg	Author, Date Study No.
	Form g ai/kg	kg ai/ha	Water L/ha	No.	Total kg ai/ha			
USA (ID) 2002 (Peppermint Black Mitcham)	WG 300	0.073	186	4	0.29	8	<u>6.8</u>, 5.9	Corley 2005 IR-4 08418
USA (WA) 2002 (Scotch Native)	WG 300	0.073	430	4	0.29	7	5.3, <u>6.8</u>	Corley 2005 IR-4 08418
USA (WA) 2002 (Native Spearmint)	WG 300	0.073	294	4	0.29	7	<u>3.6</u>, 2.6	Corley 2005 IR-4 08418
USA (WI) 2002 (Peppermint Black Mitcham)	WG 300	0.074	239	4	0.29	8	2.2, <u>2.7</u>	Corley 2005 IR-4 08418
USA (WI) 2002 (Roberts Black Mitcham Peppermint)	WG 300	0.077	246	4	0.30	8	<u>2.2</u>, 2.1	Corley 2005 IR-4 08418
USA (WI) 2002 (Scotch Spearmint)	WG 300	0.078	251	4	0.30	8	2.8, <u>3.4</u>	Corley 2005 IR-4 08418

FATE OF RESIDUES IN STORAGE AND PROCESSING

In processing

The Meeting received information on the fate of incurred residues of indoxacarb during the processing of plums and mints.

Processing of plums

In a processing study conducted in the USA according to commercial practices (Corley, 2005, IR-4 07234), fresh plums were placed on trays lined with paper and dried for two days in a fruit dryer set at 60 °C to produce prunes. Table 17 provides the supervised trial information and indoxacarb residues determined in fresh plums and prunes.

Table 17 Indoxacarb residues (expressed as sum of indoxacarb and its R enantiomer) in plums and prunes obtained in a trial in the USA (Corley, 2005, IR-4 07234)

PLUM Location Year (variety)	Application					PHI days	Commodity	Indoxacarb residues, mg/kg	PF [a]
	Form g ai/kg	kg ai/ha	Water L/ha	No.	Total kg ai/ha				
USA (CA) 2003 (Casselman)	WG 300	0.12	711	4	0.49	14	Fresh fruit Prunes	0.01, 0.01 0.04	 4.0

[a] PF = processing factor

In two processing studies conducted in southern Europe according to commercial practices (Old and Hansford, 2007, DuPont-19048), fresh plums were washed and processed to plum juice, canned plums, jam, puree, and prunes. In plum juice processing, the plums were stoned, crushed, and put into an automatic sieve to separate the juice from pomace. The pH of juice was adjusted with citric acid to 3.5 and the juice was pasteurized at 82–85 °C for 1 minute. For canned plums, the plums were blanched in boiling water for 1 min, stoned, and placed in cans. Sugar syrup was added and pH adjusted to 3.5 with citric acid. Canned plums were pasteurized at 90–95 °C for 1 min. In plum jam processing, the plums were stoned and crushed. Sugar was added to the crushed plums and the mixture was reduced in a double jacketed saucepan until the Brix degree reached 62%. The pH was adjusted to 3.5 with citric acid. For plum puree, the plums were stoned, crushed, and put into an automatic sieve to separate the puree from waste. Sugar was added to sieved plums and the mixture was reduced in a double jacketed saucepan until the Brix degree reached 24%. The pH was adjusted to 3.5 with citric acid. In prune processing, the plums were stoned and put in an oven on shelves or drawers covered with siliconized baking paper. The drying was conducted at 60 °C until considered visually complete (18-38 hours). Table 18 provides the supervised trial information and indoxacarb residues determined in RAC and processed plum commodities.

Table 18 Indoxacarb residues (expressed as sum of indoxacarb and its R enantiomer) in RAC and processed plum commodities obtained in trials in southern Europe (Old and Hansford, 2007, DuPont-19048)

PLUM Location Year (variety)	Application					PHI days	Commodity	Indoxacarb residues, mg/kg	PF [a]
	Form g ai/kg	kg ai/ha	kg ai/hl	Water L/ha	No.				
Italy 2006 (Stanley)	WG 300	0.15	0.010	1489	2	14	Fresh fruit Washed fruit Juice Wet pomace Canned plums Jam Puree Prunes	0.16 0.06 0.07 0.09 0.08 0.12 0.17 0.43	 0.39 0.43 0.58 0.50 0.75 1.1 2.7
France 2006 (Mirabelle)	WG 300	0.15	0.010	1503	2	14	Fresh fruit Washed fruit Juice Wet pomace Canned plums Jam Puree Prunes	0.06 0.08 0.02 0.07 0.05 0.08 0.09 0.52	 1.2 0.31 1.1 0.77 1.2 1.5 8.5

[a] PF = processing factor

Processing of mints

In two trials on mints conducted in the USA (Corley, 2005, IR-4 08418), mint tops were distilled to mint oil according to commercial practices. Table 19 provides the supervised trial information and indoxacarb residues determined in mint tops and mint oil.

Table 19 Indoxacarb residues (expressed as sum of indoxacarb and its R enantiomer) in mint tops and oil obtained in two trials in the USA (Corley, 2005, IR-4 08418)

MINT Location Year (variety)	Application					PHI days	Commodity	Indoxacarb residues, mg/kg	PF [a]
	Form g ai/kg	kg ai/ha	Water L/ha	No.	Total kg ai/ha				
USA (WA) 2002 (Scotch Native)	WG 300	0.073	430	4	0.29	7 8	Mint tops Mint oil	5.3, 6.8 < 0.1	< 0.015
USA (WI) 2002 (Peppermint Black Mitcham)	WG 300	0.074	239	4	0.29	8 8	Mint tops Mint oil	2.2, 2.7 < 0.1	< 0.037

[a] PF = processing factor

RESIDUES IN ANIMAL COMMODITIES

Farm animal feeding studies

The Meeting received information on a laying hen feeding study (McLean and Swain, 2003, DuPont-8305) on sixty laying White Leghorn hens (initial body weight of 1.35–1.93 kg), which were randomized into 6 groups (10 birds each): a control/untreated group and 5 treatment groups. Four groups were dosed daily via gelatine capsule with indoxacarb (3S+1R) at 1.75, 7, 21, and 70 ppm in the dry-weight diet, for 28 consecutive days. Ten animals were included in a second 70 ppm treatment group to evaluate depuration of residues after 29 consecutive days of dosing. No treatment-related changes in food consumption or egg production were observed in any of the study animals during the course of the study. No adverse reaction to the test substance was seen.

Birds from the control group and the four treatment groups were slaughtered on Day 29 (23 h after the last dosing). The depuration study group was slaughtered on Day 57 (28 days after the last dosing). In each case, muscle, liver, abdominal fat pad and skin with fat samples were collected for the analysis using method ARM 12739, which was validated with an LOQ of 0.01 mg/kg and LOD of 0.003 mg/kg for all tested poultry matrices and target analytes (indoxacarb, its R enantiomer and 5 metabolites, including IN-JT333).

Eggs were collected twice daily. On Days 7, 14, 21, and 28, the whole eggs were separated into yolk and egg white. Residues of indoxacarb and its R enantiomer in eggs (Table 20) reached a plateau at about 7 days (and declined < LOQ within 10 days after withdrawal of the 70 ppm dose). Residues of IN-JT333 in eggs (Table 21) reached a plateau at about 14 days (and declined < LOQ within 17 days after withdrawal of the 70 ppm dose).

Table 22 summarizes indoxacarb (and its R enantiomer) and IN-JT333 residues in eggs and tissues obtained at 1.75, 7, 21, and 70 ppm dosing levels in the diet.

No detectable residues (< 0.003 mg/kg) of indoxacarb and its R enantiomer were found in the tissues after 28 days of withdrawal of the 70 ppm daily dose. In the same tissues, metabolite IN-JT333 was detected only in fat at 0.006 mg/kg, which is below the method LOQ.

Table 20 Indoxacarb (and its R enantiomer) residues in whole eggs, egg white and yolk (3 pooled samples on each day) obtained at 1.75, 7, 21 and 70 ppm dosing levels in the diet (NS = no sample)

Day	Dosing level			
	1.75 ppm	7 ppm	21 ppm	70 ppm
Whole eggs				
1	< 0.003, < 0.003, < 0.003	< 0.003, < 0.003, < 0.003	< 0.003, < 0.003, < 0.003	< 0.003, < 0.003, < 0.003
2	< 0.003, < 0.003, < 0.003	< 0.003, 0.011, 0.010	0.083, 0.046, 0.020	0.16, 0.16, 0.18
3	< 0.003, < 0.003, < 0.003	0.014, 0.008, 0.016	0.031, 0.031, 0.031	0.10, 0.12, 0.10
4	0.003, 0.005, < 0.003	0.047, 0.010, 0.021	0.059, 0.028, 0.036	0.21, 0.18, 0.18
5	0.005, < 0.003, < 0.003	< 0.003, 0.005, 0.020	0.072, 0.051, 0.024	0.18, 0.18, 0.18
6	0.006, 0.006, < 0.003	0.006, 0.020, 0.025	0.072, 0.074, 0.039	0.11, 0.21, 0.29
7	0.004, NS, < 0.003	0.009, 0.019, 0.016	0.065, 0.048, 0.057	0.18, 0.27, 0.18
10	< 0.003, 0.004, 0.010	0.020, 0.014, 0.009	0.056, 0.032, 0.040	0.26, 0.12, 0.23
12	0.004, 0.006, 0.012	0.016, 0.012, 0.006	0.061, 0.065, 0.057	0.12, 0.17, 0.22
14	0.004, 0.004, 0.015	0.018, 0.012, 0.005	0.061, 0.074, 0.092	0.22, 0.24, 0.35
16	< 0.003, 0.003, 0.011	0.017, 0.013, 0.018	0.068, 0.073, 0.049	0.14, 0.31, 0.29
18	0.005, < 0.003, 0.006	0.023, 0.017, 0.021	0.078, 0.041, 0.061	0.40, 0.26, 0.17
21	0.006, 0.004, 0.005	0.017, 0.013, 0.019	0.071, 0.074, 0.12	0.21, 0.21, 0.38
23	0.004, 0.005, 0.003	0.011, 0.018, 0.026	0.080, 0.084, 0.075	0.19, 0.31, 0.22
25	0.004, 0.005, 0.003	0.010, 0.018, 0.028	0.064, 0.072, 0.081	0.22, 0.30, 0.22
28	0.004, 0.004, 0.004	0.017, 0.020, 0.019	0.058, 0.068, 0.073	NS, 0.28, 0.26
Egg white				
7	0.003, NS, < 0.003	0.008, 0.022, 0.016	0.063, 0.045, 0.063	0.18, 0.30, 0.15
14	0.004, 0.004, 0.017	0.018, 0.011, 0.004	0.068, 0.078, 0.097	0.20, 0.27, 0.39
21	0.005, 0.004, < 0.003	0.016, 0.012, 0.017	0.074, 0.059, 0.13	0.16, 0.15, 0.34
28	0.004, 0.004, 0.004	0.018, 0.021, 0.016	0.057, 0.060, 0.067	NS, 0.28, 0.22
Egg yolk				
7	0.005, NS, < 0.003	0.012, 0.012, 0.017	0.069, 0.055, 0.056	0.19, 0.20, 0.26
14	0.004, 0.004, 0.010	0.017, 0.014, 0.008	0.048, 0.065, 0.080	0.25, 0.18, 0.26
21	0.006, 0.005, 0.009	0.019, 0.015, 0.024	0.063, 0.11, 0.087	0.32, 0.32, 0.45
28	0.004, 0.004, 0.004	0.015, 0.019, 0.026	0.061, 0.088, 0.061	NS, 0.27, 0.34

Table 21 IN-JT333 residues in whole eggs, egg white and yolk (3 pooled samples on each day) obtained at 1.75, 7, 21 and 70 ppm dosing levels in the diet (NS = no sample)

Day	Dosing level			
	1.75 ppm	7 ppm	21 ppm	70 ppm
Whole eggs				
1	< 0.003, < 0.003, < 0.003	< 0.003, < 0.003, < 0.003	< 0.003, < 0.003, < 0.003	< 0.003, < 0.003, < 0.003
2	< 0.003, < 0.003, < 0.003	< 0.003, < 0.003, < 0.003	< 0.003, < 0.003, < 0.003	0.005, 0.004, 0.005
3	< 0.003, < 0.003, < 0.003	< 0.003, < 0.003, < 0.003	0.004, 0.004, 0.005	0.014, 0.014, 0.021
4	< 0.003, < 0.003, < 0.003	< 0.003, < 0.003, < 0.003	0.009, 0.009, 0.006	0.050, 0.032, 0.029
5	< 0.003, < 0.003, < 0.003	0.004, 0.004, 0.007	0.016, 0.024, 0.014	0.035, 0.052, 0.033
6	< 0.003, < 0.003, < 0.003	NS, 0.006, 0.007	0.029, 0.031, 0.020	0.036, 0.079, 0.071
7	0.004, NS, 0.004	0.007, 0.010, 0.011	0.028, 0.036, 0.028	0.084, 0.098, 0.11
10	< 0.003, 0.003, 0.005	0.015, 0.014, 0.012	0.038, 0.048, 0.025	0.092, 0.089, 0.095
12	0.003, 0.004, 0.008	0.012, 0.012, 0.009	0.036, 0.044, 0.040	0.098, 0.12, 0.13
14	0.010, 0.007, 0.006	0.016, 0.019, 0.011	0.038, 0.060, 0.052	0.11, 0.10, 0.11
16	0.004, 0.004, 0.013	0.013, 0.014, 0.006	0.038, 0.047, 0.043	0.096, 0.15, 0.14
18	0.004, 0.003, 0.011	0.014, 0.015, 0.007	0.045, 0.055, 0.050	0.13, 0.14, 0.13
21	0.010, 0.007, 0.010	0.021, 0.022, 0.017	0.037, 0.057, 0.058	0.21, 0.20, 0.12
23	0.004, 0.004, 0.005	0.012, 0.015, 0.015	0.050, 0.055, 0.046	0.11, 0.18, 0.16
25	0.005, 0.005, 0.005	0.020, 0.020, 0.020	0.057, 0.064, 0.058	0.12, 0.18, 0.19
28	0.007, 0.007, 0.007	0.019, 0.019, 0.023	0.061, 0.070, 0.062	NS, 0.17, 0.19
Egg white				
7	< 0.003, NS, < 0.003	< 0.003, < 0.003, < 0.003	< 0.003, < 0.003, < 0.003	< 0.003, 0.006, < 0.003

14	< 0.003, < 0.003, < 0.003	< 0.003, < 0.003, < 0.003	< 0.003, < 0.003, < 0.003	0.004, 0.005, 0.006
21	< 0.003, 0.004, < 0.003	< 0.003, < 0.003, < 0.003	< 0.003, < 0.003, 0.004	0.005, 0.004, 0.007
28	< 0.003, < 0.003, < 0.003	< 0.003, < 0.003, < 0.003	< 0.003, < 0.003, < 0.003	NS, 0.004, 0.005
Egg yolk				
7	0.007, NS, 0.006	0.016, 0.026, 0.032	0.091, 0.12, 0.096	0.28, 0.32, 0.36
14	0.013, 0.015, 0.027	0.044, 0.045, 0.027	0.11, 0.19, 0.16	0.34, 0.32, 0.34
21	0.023, 0.013, 0.027	0.053, 0.062, 0.050	0.11, 0.19, 0.18	0.40, 0.56, 0.63
28	0.015, 0.016, 0.014	0.047, 0.051, 0.068	0.18, 0.23, 0.19	NS, 0.54, 0.55

Table 22 Indoxacarb (and its R enantiomer) and IN-JT333 residues in eggs and tissues obtained at 1.75, 7, 21 and 70 ppm dosing levels in the diet for 28 consecutive days

Dose (ppm)	Matrix	Indoxacarb and its R enantiomer		IN-JT333	
		Residues [a] (mg/kg)	Mean residue [b] (mg/kg)	Residues [a] (mg/kg)	Mean residue [b] (mg/kg)
1.75	Whole eggs	< 0.003 – 0.012	0.005	< 0.003 – 0.013	0.007
	Egg white	0.008, 0.004, 0.004	0.005	< 0.003, 0.003, < 0.003	0.003
	Egg yolk	0.006, 0.007, 0.004	0.006	0.018, 0.021, 0.015	0.018
	Muscle	< 0.003 (3)	< 0.003	< 0.003 (3)	< 0.003
	Liver	< 0.003 (3)	< 0.003	< 0.003 (3)	< 0.003
	Fat	< 0.003, 0.008, < 0.003	0.005	0.051, 0.045, 0.037	0.044
	Skin with fat	< 0.003 (3)	< 0.003	0.009, 0.014, 0.016	0.013
7	Whole eggs	< 0.003 – 0.047	0.016	< 0.003 – 0.023	0.016
	Egg white	0.011, 0.015, 0.018	0.015	< 0.003 (3)	< 0.003
	Egg yolk	0.013, 0.019, 0.020	0.018	0.039, 0.055, 0.055	0.050
	Muscle	< 0.003 (3)	< 0.003	< 0.003 (3)	< 0.003
	Liver	< 0.003 (3)	< 0.003	0.005 (3)	0.005
	Fat	0.045, 0.042, 0.045	0.044	0.19, 0.21, 0.21	0.20
	Skin with fat	0.013, 0.007, 0.006	0.009	0.051, 0.031, 0.030	0.037
21	Whole eggs	0.020 – 0.12	0.067	< 0.003 – 0.070	0.052
	Egg white	0.081, 0.088, 0.061	0.077	< 0.003, 0.003, < 0.003	0.003
	Egg yolk	0.064, 0.087, 0.078	0.076	0.15, 0.16, 0.20	0.17
	Muscle	0.006, < 0.003, < 0.003	0.004	0.011, 0.015, 0.007	0.011
	Liver	< 0.003 (3)	< 0.003	0.010, 0.019, 0.009	0.014
	Fat	0.12, 0.16, 0.16	0.15	0.67, 0.81, 0.65	0.71
	Skin with fat	0.045, 0.078, 0.055	0.059	0.29, 0.28, 0.12	0.23
70	Whole eggs	0.10 – 0.40	0.24	0.004 – 0.21	0.15
	Egg white	0.29, 0.22, 0.25	0.25	0.005, 0.005, 0.004	0.005
	Egg yolk	0.23, 0.36, 0.29	0.29	0.33, 0.53, 0.48	0.45
	Muscle	0.007, 0.005, < 0.003	0.005	0.015, 0.017, 0.022	0.018
	Liver	< 0.003 (3)	< 0.003	0.028, 0.086, 0.057	0.057
	Fat	0.76, 0.45, 0.67	0.63	1.3, 1.8, 2.0	1.7
	Skin with fat	0.25, 0.14, 0.20	0.20	0.28, 0.57, 0.44	0.43

[a] For whole eggs, the range of residues obtained on Days 2-28 is included in the table. For tissues, residues from 3 pooled samples for each tissue are listed. For egg white and yolk, mean results obtained on Days 14, 21 and 28 are listed.

[b] For whole eggs, the mean residue obtained at the plateau (Days 7-28 for indoxacarb and its enantiomer and Days 14-28 for IN-JT333) is included in the table.

APPRAISAL

Indoxacarb is an indeno-oxadiazine insecticide that is used for control of lepidoptera and other insect pests. It was first evaluated by the 2005 JMPR. The 2007 JMPR then re-evaluated data for head cabbage, due to short-term dietary intake concerns for children. The present Meeting received information on the residue analysis, storage stability, use pattern, supervised field trials, fate of residues during processing of plum and mint and a laying hen feeding study. The supervised trial information included data on stone fruit (cherry, peach and plum), cranberry, fruiting vegetables – cucurbits (cucumber, melons and summer squash), cowpea (dry), and mints.

Methods of analysis

The Meeting received information on an analytical method (AMR 12739) for indoxacarb, its R enantiomer and five metabolites, which was used in the laying hen feeding study for the analysis of poultry muscle, fat, skin (with fat), liver and eggs. The metabolites included compound IN-JT333 (methyl 7-chloro-2,5-dihydro-2-[[[4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno-[1,2-e][1,3,4] oxadiazine-4a(3H)-carboxylate), which is part of the residue definition for estimation of dietary intake of indoxacarb in animal commodities. The method is based on extraction with acidified acetonitrile, de-fatting with hexane, solid-phase extraction clean-up and LC-MS/MS analysis. The method validation and concurrent recoveries were typically ranging between 70–120%. The method LOQ was 0.01 mg/kg (LOD of 0.003 mg/kg) for all target poultry matrices.

For plant commodities, two single-residue methods and one multiresidue method (modified DFG S19) for the determination of indoxacarb residues (sum of indoxacarb and its R enantiomer) were reported to the JMPR in 2005. The 2005 Meeting concluded that these methods were adequate for gathering data in supervised trials and other studies and for monitoring and enforcing indoxacarb MRLs in samples of plant origin. These three methods were also used for the analysis of indoxacarb residues in supervised trials submitted to the present Meeting. The method validation and concurrent recoveries were typically ranging between 70–120%. The typical LOQ was 0.01 mg/kg, except for cranberry and mint tops (0.05 mg/kg), and mint oil (0.10 mg/kg).

Stability of pesticide residues in stored analytical samples

Freezer storage stability data for indoxacarb residues were available for the hen feeding study results, e.g. eggs, poultry fat, liver, meat and skin, and all commodities, for which supervised trial data were made available to the present Meeting, e.g., cherry, cowpea, cranberry, cucumber, melons, mint tops and oil, peach, plum, prune, and summer squash. Indoxacarb residues (sum of indoxacarb and its R enantiomer) were stable (less than 30% disappearance) during the storage stability study with the storage intervals generally covering the actual duration of sample storage in the supervised trials. The only exception was cranberry trials, in which samples were held in freezer storage for up to 125 days, whereas the duration of the stability study was only 45 days. Based on the stability data in other plant commodities (storage intervals significantly longer than 125 days) evaluated by this and the 2005 JMPR, the Meeting concluded that indoxacarb residues in the evaluated cranberry trials can be considered stable.

Results of supervised trials on crops

The Meeting received supervised trials data for indoxacarb on stone fruits (cherry, peach and plum), cranberry, fruiting vegetables – cucurbits (cucumber, melons and summer squash), cowpea (dry), and mints. All trials were conducted using a 30 WG formulation containing 300 g/kg of indoxacarb (S enantiomer) and 100 g/kg inactive R enantiomer ("indoxacarb 3S+1R").

The NAFTA calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the NAFTA calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was supplied. Some common factors, that may lead to rejection of the statistical estimate include when the number of data points in a data set is < 15 or when there are a large number of values < LOQ.

Stone fruits

The GAP on stone fruit in the USA is 4 × 0.12 kg ai/ha (maximum seasonal application rate of 0.49 kg ai/ha) and a PHI of 14 days.

The Meeting received supervised trial data on cherries, peach and plum from Canada and the USA. Results from supervised trials on cherries and plum in Italy and France were also submitted, however the Meeting received no GAP information for southern Europe to support the trials.

Twelve trials on cherries were conducted in Canada and the USA at the US GAP rate with a PHI of 12–14 days. Indoxacarb residues in cherries, in ranked order (n = 12), were: 0.07 (2), 0.13, 0.15 (3), 0.19, 0.22, 0.26, 0.32, 0.51, and 0.64 mg/kg.

Fifteen trials on peaches were conducted in Canada and the USA at the US GAP rate with a PHI of 13–15 days. Indoxacarb residues in peaches, in ranked order (n = 15), were: 0.04 (2), 0.07, 0.09 (2), 0.10 (3), 0.13, 0.16, 0.20, 0.29, 0.30, 0.50, and 0.59 mg/kg.

Eleven trials on plums were conducted in Canada and the USA at the US GAP rate with a PHI of 13–15 days. Indoxacarb residues in plums, in ranked order (n = 11), were: < 0.01, 0.01, 0.02 (4), 0.03, 0.04, 0.07 (2), and 0.19 mg/kg.

The 2005 JMPR received results from supervised trials on peaches from southern Europe (France, Greece and Italy) and on apricot, nectarine and peaches from Australia. The Australian data was insufficient to support a recommendation. The results from trials on peaches in Greece, matching Greek GAP (0.1 kg ai/ha, 3 applications, and a PHI of 7 days), and in France and Italy, matching Italian GAP (0.075 kg ai/ha, 4 applications, and a PHI of 7 days), were used as a basis for estimation of a maximum residue level, STMR and HR values for peach by the 2005 JMPR. Based on the highest values from replicate field samples, indoxacarb residues in peach from European trials, in ranked order (n = 9), were: 0.05, 0.07, 0.08, 0.11, 0.13 (2), 0.15, 0.16, and 0.18 mg/kg.

The Meeting agreed that the data on cherries, peaches and plums obtained in Canada and the USA, matching the US GAP for stone fruit, could be used to support a commodity group maximum residue level estimate. Based on the residues obtained on cherries, the Meeting estimated a maximum residue level for indoxacarb in stone fruit of 1 mg/kg and STMR and HR values of 0.17 and 0.64 mg/kg, respectively.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 0.94 mg/kg. The normal JMPR procedure is to use one significant figure for maximum residue levels below 10 mg/kg. With rounding up the value derived from use of the calculator was in good agreement with the Meeting's estimate.

The Meeting agreed to withdraw its previous recommendation of a maximum residue level of 0.3 mg/kg for indoxacarb in peach.

Cranberry

Supervised trials were available inform the USA. The GAP of the USA specifies 0.12 kg ai/ha per application with maximum seasonal rate of 0.49 kg ai/ha and a PHI of 30 days.

Six trials on cranberry were conducted matching the US GAP rate with a PHI of 28–30 days. Indoxacarb residues in cranberry, in ranked order (n = 6), were: 0.11, 0.13, 0.15 (2), 0.19, and 0.69 mg/kg.

The Meeting estimated a maximum residue level for indoxacarb in cranberry of 1 mg/kg and STMR and HR values of 0.15 and 0.69 mg/kg, respectively.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 0.91 mg/kg, which when rounded up corresponded to the Meeting’s estimation.

Fruiting vegetables, Cucurbits

The Meeting received results from supervised trials on cucumber, melons and summer squash in Canada and the USA. The GAP of the USA for cucurbits specifies 0.12 kg ai/ha with maximum seasonal application rate of 0.49 kg ai/ha and a PHI of 3 days.

Ten trials on cucumber were conducted according to the US GAP. Indoxacarb residues in cucumber, in ranked order (n = 10), were: < 0.01, 0.01, 0.02 (4), 0.03 (3), and 0.07 mg/kg.

Eleven trials on cantaloupe melons were conducted according to the US GAP. Indoxacarb residues in whole melons, in ranked order (n = 11), were: 0.02, 0.03, 0.04, 0.05, 0.06 (2), 0.09, 0.14, 0.17, 0.25, and 0.39 mg/kg.

Twelve trials on summer squash were conducted according to the US GAP with a PHI of 2–4 days. Indoxacarb residues in summer squash, in ranked order (n = 12), were: < 0.01 (3), 0.01 (2), 0.02, and 0.03 (2), 0.04 (2), 0.11, and 0.12 mg/kg.

The 2005 JMPR received results from supervised trials on cucumber, melons, and summer squash from southern Europe (France, Greece, Italy and Spain). The summer squash data was considered insufficient to support a recommendation.

Results from greenhouse trials on cucumber matching Hungarian GAP for greenhouse use (0.051 kg ai/ha and a PHI of 1 day) were used as a basis for estimation of a maximum residue level and STMR and HR values for cucumber by the 2005 JMPR. Based on the highest values from replicate field samples, indoxacarb residues in cucumber from European greenhouse trials, in ranked order (n = 13), were: < 0.02 (6), 0.02 (2), 0.03 (3), 0.05, and 0.10 mg/kg.

Results from field and greenhouse trials on melons matching Spanish GAP (0.038 kg ai/ha and a PHI of 1 day) were used as a basis for estimation of a maximum residue level and STMR and HR values for melons by the 2005 JMPR. Indoxacarb residues in melons (whole fruit) from European trials (n = 18), in ranked order, were: 0.02 (4), 0.03 (8), 0.04 (4), 0.05, and 0.09 mg/kg. Indoxacarb residues were below LOQ of 0.02 mg/kg in every sample of pulp in all trials (PHI 0–7 days). The 2005 JMPR concluded that indoxacarb residues are unlikely to occur in melon pulp.

The Meeting agreed that the data on cucumber, melons and summer squash obtained in Canada and the USA according to the US GAP for cucurbits could be used to support a commodity group maximum residue level estimate. Based on the residues obtained on whole melons, the Meeting estimated a maximum residue level for indoxacarb in fruiting vegetables, cucurbits, of 0.5 mg/kg and STMR and HR values of 0.06 and 0.39 mg/kg, respectively.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 0.37 mg/kg. This was below the HR value of 0.39 mg/kg. As noted by the Meeting, the number of data points was insufficient to minimize the errors of the statistical extrapolation to the required high percentile values.

Based on the pulp data for melon from the European trials, the Meeting estimated STMR and HR values of 0.02 mg/kg for indoxacarb in cucurbits with inedible peel.

The Meeting agreed to withdraw its previous recommendations of indoxacarb maximum residue levels of 0.2 mg/kg in cucumber and 0.1 mg/kg in melon, except watermelon.

Cowpea, dry

The Meeting received results from supervised trials data on dry cowpea (southern pea, dry) in the USA. The GAP of the USA for southern pea, dry (including cowpea and other similar kinds of southern peas) specifies an application rate of 0.073 kg ai/ha with maximum seasonal rate of 0.29 kg ai/ha with a PHI of 7 days.

Six trials on cowpeas were conducted at the US GAP rate with PHIs of 6–7 days. Indoxacarb residues in dry cowpea, in ranked order (n = 6), were: < 0.01 (2), 0.01, 0.03 (2), and 0.07 mg/kg.

The Meeting estimated a maximum residue level for indoxacarb in cowpea, dry of 0.1 mg/kg and an STMR value of 0.02 mg/kg.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 0.13 mg/kg, which when rounded down corresponded to the Meeting's estimation.

Mints

The Meeting received results from supervised trials on mint in the USA. The GAP of the USA for mint specifies an application rate of 0.073 kg ai/ha with seasonal maximum of 0.29 kg ai/ha and a PHI of 7 days.

Six trials on mint were conducted at the US GAP rate with PHIs of 7–8 days. Indoxacarb residues in mints, in ranked order (n = 6), were: 2.2, 2.7, 3.4, 3.6, and 6.8 (2) mg/kg.

The Meeting estimated a maximum residue level for indoxacarb in mint of 15 mg/kg and STMR and HR values of 3.5 and 6.8 mg/kg, respectively.

The normal JMPR procedure is to round up the value to the nearest 5 for maximum residue levels between 10 and 30 mg/kg. The maximum residue level estimate derived from use of the NAFTA statistical calculator was 11.6 mg/kg. With rounding up, the value derived from use of the calculator corresponded to the Meeting's recommendation.

Fate of residues during processing

The Meeting received information on the fate of incurred residues of indoxacarb during commercial-type processing of plums and mints. The processing factors and STMR-P and HR-P values are summarized in the table below.

Processing (Transfer) factors from the processing of Raw Agricultural Commodities (RACs) with field-incurred residues from foliar treatment with indoxacarb

RAC			Processed commodity					
					Processing factor			
Name	STMR (mg/kg)	HR (mg/kg)	CCN	Name	Calculated values	Median or best estimate	STMR-P (mg/kg)	HR-P (mg/kg)
Plum [a]	0.17	0.64	DF 0014	Prunes	2.7, 4.0, 8.5	4.0	0.68	2.6
				Plum juice	0.31, 0.43	0.37	0.06	
				Plum pomace, wet	0.58, 1.1	0.84	0.14	
				Canned plums	0.50, 0.77	0.64	0.11	
				Plum jam	0.75, 1.2	0.98	0.17	
				Plum puree	1.1, 1.5	1.3	0.22	
Mints	3.5	6.8		Mint oil	< 0.015, < 0.037	< 0.015	0.052	

[a] STMR and HR values for stone fruit commodity group.

Based on the HR-P value of 2.6 mg/kg, the Meeting estimated a maximum residue level of 3 mg/kg for indoxacarb in prunes.

Farm animal dietary burden

The Meeting estimated the dietary burden of indoxacarb in farm animals on the basis of the diets listed in Annex 6 of the 2006 JMPR Report (OECD Feedstuffs Derived from Field Crops), using previously estimated highest residues and STMR/STMR-P values for feed commodities and an STMR value for cowpea (dry) estimated by the present Meeting. Calculation from the highest residue and

STMR/STMR-P (some bulk commodities) values provides the levels in feed suitable for estimating maximum residue levels, while calculation from STMR and STMR-P values for feed is suitable for estimating STMR values for animal commodities.

The table below shows estimated maximum and mean dietary burdens for beef cattle, dairy cattle, broilers, and laying poultry based on the animal diets from the United States/Canada, the European Union, and Australia. The calculations are provided in Annex 6.

		Indoxacarb, Animal dietary burden (ppm of dry matter diet)		
		US-Canada	EU	Australia
Beef cattle	Maximum	30	23	41[a]
	Mean	12	13	17[b]
Dairy cattle	Maximum	20	20	33[c]
	Mean	8.1	8.0	14[d]
Poultry - broiler	Maximum	0.047	0.027	0.024
	Mean	0.047	0.027	0.024
Poultry - layer	Maximum	0.027	1.5[e]	0.024
	Mean	0.027	0.80[f]	0.024

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

[b] Highest mean beef cattle dietary burden suitable for STMR estimates for mammalian meat.

[c] Highest maximum dairy cattle dietary burden suitable for MRL estimates for milk.

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

Farm animal feeding studies

The Meeting received information on a laying hen feeding study. Sixty laying White Leghorn hens were randomized into six groups. Each group was fed for 28 consecutive days with a nominal dose rate of 0, 1.75, 7, 21, 70 and 70 ppm of indoxacarb (3S+1R) in the dry-weight diet. The second 70 ppm treatment group was used to evaluate depuration of residues after 29 consecutive days of dosing. This group was slaughtered 28 days after withdrawal. The other birds were slaughtered on Day 29. In each case, muscle, liver, abdominal fat pad and skin with fat samples were collected for the analysis of indoxacarb, its R enantiomer and metabolites, including metabolite IN-JT333.

Eggs were collected twice daily. Residues of indoxacarb and its R enantiomer in eggs reached a plateau at about 7 days (and declined < LOQ of 0.01 mg/kg within 10 days after withdrawal of the 70 ppm dose). Residues of IN-JT333 reached a plateau at about 14 days (and declined < 0.01 mg/kg within 17 days after withdrawal of the 70 ppm dose). Residue levels were approximately proportional to the dose. The highest residues obtained during the dosing period for indoxacarb and its enantiomer in whole eggs were 0.01 mg/kg (1.75 ppm), 0.05 mg/kg (7 ppm), 0.12 mg/kg (21 ppm), and 0.40 mg/kg (70 ppm). For metabolite IN-JT333, these values were 0.01, 0.02, 0.07, and 0.21 mg/kg, respectively.

Residue levels in egg yolk and white were similar for indoxacarb and its enantiomer, whereas metabolite IN-JT333 concentrated in egg yolk (0.45 mg/kg vs. 0.005 mg/kg in egg yolk and white, respectively, at 70 ppm dosing level).

As concluded by the 2005 JMPR, the indoxacarb residue is fat soluble. For indoxacarb and its R enantiomer, residues above LOQ were found only in fat or skin with fat, at higher dosing levels. The highest residues in abdominal fat (higher residues than in skin with fat) were < 0.01 (1.75 ppm), 0.05 mg/kg (7 ppm), 0.16 mg/kg (21 ppm), and 0.76 mg/kg (70 ppm).

Metabolite IN-JT333 gave generally higher residues in the tissues than indoxacarb and its enantiomer. The highest residues of IN-JT333 in fat were 0.05 (1.75 ppm), 0.21 mg/kg (7 ppm), 0.81 mg/kg (21 ppm), and 2.0 mg/kg (70 ppm). The corresponding highest IN-JT333 residues in muscle were < 0.01, < 0.01, 0.02, and 0.02 mg/kg, respectively; and in liver: < 0.01, < 0.01, 0.02, and 0.09 mg/kg, respectively.

No detectable residues (< 0.003 mg/kg) of indoxacarb and its R enantiomer were found in the tissues after 28 days of withdrawal of the 70 ppm daily dose. In the same tissues, metabolite IN-JT333 was detected only in fat at 0.006 mg/kg, which is below the method LOQ.

The 2005 Meeting received information on a lactating dairy cattle feeding study, which was conducted at the equivalent of 7.5, 22.5, and 75 ppm of indoxacarb in the dry-weight diet for 28 consecutive days. Indoxacarb, its R enantiomer and metabolite IN-JT333 were analysed in milk, cream and tissues (muscle, liver, kidney and fat).

Animal commodity maximum residue levels

The dietary burdens for the estimation of maximum residue levels for indoxacarb in animal commodities are 41 ppm for beef cattle, 33 ppm for dairy cattle and 1.5 ppm for poultry. The dietary burdens for the estimation of STMR values for animal commodities are 17 ppm for beef cattle, 14 ppm for dairy cattle and 0.80 ppm for poultry.

In the table below, dietary burdens for cattle are shown in round brackets (), feeding levels and resulting residue concentrations in square brackets [], and estimated (interpolated) indoxacarb concentration related to the dietary burdens are shown without brackets. The MRL estimations are based on sum of indoxacarb and its R enantiomer. For STMR and HR estimation, the concentrations of metabolite IN-JT333 were expressed as indoxacarb and added to the concentration of indoxacarb and its R enantiomer, which caused a slight change in concentrations in cream and fat, but not in milk or the other tissues. Therefore, the residue concentrations listed below include the IN-JT333 metabolite unless noted otherwise.

Summary of residues corresponding to the estimated dietary burden

Dietary burden (ppm) Feeding level [mg/kg]	Milk	Cream	Muscle	Liver	Kidney	Fat
MRL Beef Cattle			highest	highest	highest	highest
(41)			0.039	0.015	0.030	1.02[a] 1.07[b]
[22.5, 75]			[< 0.01, 0.093]	[0.013, 0.019]	[0.020, 0.049]	[0.54, 1.9][a] [0.57, 2.0][b]
MRL Dairy Cattle	mean	mean				
(33)	0.084	0.92[a] 0.96[b]				
[22.5, 75]	[0.058, 0.19]	[0.60, 2.2][a] [0.62, 2.3][b]				
STMR Beef Cattle			mean	mean	mean	mean
(17)			< 0.01	0.01	0.014	0.38
[7.5, 22.5]			[< 0.01, < 0.01]	[< 0.01, 0.01]	[< 0.01, 0.017]	[0.22, 0.48]
STMR Dairy Cattle	mean	mean				
(14)	0.037	0.39				
[7.5, 22.5]	[0.021, 0.058]	[0.21, 0.62]				

[a] Indoxacarb residue for MRL estimation: sum of indoxacarb and its R enantiomer.

[b] Indoxacarb residue for HR estimation: sum of indoxacarb, its R enantiomer and metabolite IN-JT333, expressed as indoxacarb.

Based on the highest indoxacarb residues (sum indoxacarb, its R enantiomer and metabolite IN-JT333, expressed as indoxacarb) at the dosing levels of 22.5 and 75 ppm, the interpolated (estimated) highest residues for the maximum beef cattle dietary burden of 41 ppm were 0.039 mg/kg in muscle, 0.015 mg/kg in liver, 0.030 mg/kg in kidney, and 1.07 mg/kg in fat. Estimated highest residue concentration of indoxacarb and its R metabolite in fat was 1.02 mg/kg.

On the fat basis, the Meeting estimated a maximum residue level of 2 mg/kg for indoxacarb in meat (fat) from mammals (other than marine mammals) to replace the previous recommendation of 1 mg/kg. The Meeting estimated a maximum residue level of 0.05 mg/kg for indoxacarb in edible offal (mammalian), which confirms the previous recommendation made by the 2005 JMPR.

Based on the mean indoxacarb residues (sum indoxacarb, its R enantiomer and metabolite IN-JT333, expressed as indoxacarb) at the dosing levels of 7.5 and 22.5 ppm, the interpolated (estimated) mean residues for the mean beef cattle dietary burden of 17 ppm were < 0.01 mg/kg in muscle, 0.01 mg/kg in liver, 0.014 mg/kg in kidney, and 0.38 mg/kg in fat.

The Meeting estimated STMR values for indoxacarb in mammalian meat, fat and edible offal of 0.01, 0.38 and 0.014 mg/kg, respectively, with corresponding HR values of 0.039, 1.07 and 0.030 mg/kg, respectively.

Based on the mean indoxacarb residues (sum indoxacarb, its R enantiomer and metabolite IN-JT333, expressed as indoxacarb) at the dosing levels of 22.5 and 75 ppm, the interpolated (estimated) highest residues for the maximum dairy cattle dietary burden of 33 ppm were 0.084 mg/kg in milk and 0.96 mg/kg in cream. Estimated highest residue concentration of indoxacarb and its R metabolite in cream was 0.92 mg/kg. Similarly, based on the mean indoxacarb residues (sum indoxacarb, its R enantiomer and metabolite IN-JT333, expressed as indoxacarb) at the dosing levels of 7.5 and 22.5 ppm, the interpolated (estimated) mean residues for the mean dairy cattle dietary burden of 14 ppm were 0.037 mg/kg in milk and 0.39 mg/kg in cream. On the assumption of 50% milk fat in cream, the highest and mean residues in milk fat were 1.92 and 0.78 mg/kg, respectively. For indoxacarb and its R metabolite, the estimated highest residue concentration of in milk fat was 1.84 mg/kg.

The Meeting estimated maximum residue levels of 0.1 and 2 mg/kg for indoxacarb in milk and milk fat, respectively, which confirms the previous maximum residue level recommendations made by the 2005 JMPR.

The Meeting estimated STMR values of 0.037 and 0.78 mg/kg for indoxacarb in milk and milk fat, respectively.

For poultry, the maximum dietary burden of 1.5 ppm is close to the dose level of 1.75 ppm in the hen feeding study. At 1.75 ppm, residues of indoxacarb and its R enantiomer were < 0.01 mg/kg in muscle, liver and fat (only one sample of fat had detectable residues above the LOD of 0.003 mg/kg). In eggs, the highest residue at 1.75 ppm dose was 0.012 mg/kg, which by estimation gives 0.010 mg/kg at 1.5 ppm.

The Meeting estimated maximum residue level of 0.01(*) mg/kg for indoxacarb in poultry meat (fat) and poultry offal, which confirms the previous recommendation made by the 2005 JMPR.

The Meeting estimated maximum residue level of 0.02 mg/kg for indoxacarb in eggs to replace the previous recommendation of 0.01(*) mg/kg.

Based on the highest indoxacarb residues (sum indoxacarb, its R enantiomer and metabolite IN-JT333, expressed as indoxacarb) at the dosing level of 1.75 ppm and maximum poultry dietary burden of 1.5 ppm, the Meeting estimated HR values of 0, 0.05, 0 and 0.02 for indoxacarb in poultry meat, fat, offal and eggs, respectively.

Based on the mean indoxacarb residues (sum indoxacarb, its R enantiomer and metabolite IN-JT333, expressed as indoxacarb) at the dosing level of 1.75 ppm and mean poultry dietary burden of 0.8 ppm, the Meeting estimated STMR values of 0, 0.025, 0 and 0.01 for indoxacarb in poultry meat, fat, offal and eggs, respectively.

RECOMMENDATIONS

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

Definition of the residue for compliance with the MRL for all commodities and for estimation of dietary intake for plant commodities: *sum of indoxacarb and its R enantiomer*.

Definition of the residue for estimation of dietary intake for animal commodities: s*um of indoxacarb, its R enantiomer and methyl 7-chloro-2,5-dihydro-2-[[[4-(trifluoromethoxy)phenyl] amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate, expressed as indoxacarb.*

The residue is fat soluble.

Commodity		MRL (mg/kg)		STMR or STMR-P (mg/kg)	HR or HR-P (mg/kg)
CCN	Name	New	Previous		
VD 0527	Cowpea, dry	0.1		0.02	
FB 0265	Cranberry	1		0.15	0.69
VC 0424	Cucumber	W [a]	0.2		
MO 0105	Edible offal (mammalian)	0.05	0.05	0.014	0.030
PE 0112	Eggs	0.02	0.01*	0.01	0.02
VC 0045	Fruiting vegetables, cucurbits	0.5		0.06[b] 0.02[c]	0.39[b] 0.02[c]
MM 0095	Meat (from mammals other than marine mammals)	2 (fat)	1 (fat)	0.01 muscle 0.38 fat	0.039 muscle 1.07 fat
VC 0046	Melons, except watermelons	W a	0.1		
FM 0183	Milk fats	2	2	0.78	
ML 0106	Milks	0.1	0.1	0.037	
HH 0738	Mints	15		3.5	6.8
FS 0247	Peach	W[d]	0.3		
PM 0110	Poultry meat	0.01* (fat)	0.01* (fat)	0 muscle 0.025 fat	0 muscle 0.05 fat
PO 0111	Poultry, Edible offal of	0.01*	0.01*	0	0
DF 0014	Prunes	3		0.68	2.6
FS 0012	Stone fruit	1		0.17	0.64
	Mint oil			0.052	
	Plum jam			0.17	
	Plum juice			0.06	
	Plum pomace, wet			0.14	
	Plum puree			0.22	
	Plums, canned			0.11	

[a] The recommendations for cucumber and melon, except watermelon were replaced by a commodity group recommendation for fruiting vegetables, cucurbits.

[b] STMR and HR values for fruiting vegetables, cucurbits with edible peel, *i.e.* in whole fruit.

[c] STMR and HR for fruiting vegetables, cucurbits with inedible peel, *i.e.* in edible portion (pulp).

[d] The recommendation for peach was replaced by a commodity group recommendation for stone fruit.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of indoxacarb based on STMR and STMR-P values estimated by the 2005 JMPR and the present Meeting for 46 commodities and commodity groups for the thirteen GEMS/Food Consumption Cluster Diets were 1–30% of the maximum ADI (0.01 mg/kg bw). The results are shown in Annex 3 of the 2009 JMPR Report. The Meeting concluded that the long-term dietary intake of indoxacarb residues resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short Term Intake (IESTI) of indoxacarb calculated on the basis of the recommendations made by the present Meeting represented for the general population 0–10% and for children 0–20% of the ARfD (0.1 mg/kg bw). The results are shown in Annex 4 of the 2009 JMPR Report.

The 2005 Meeting was not able to calculate the IESTI for leaf lettuce at the time because unit weight data were not available for leaf lettuce. Based on the new consumption data, the current Meeting calculated the IESTI for leaf lettuce and obtained 60% and 150% of the ARfD for the general population and for children, respectively.

The Meeting concluded that the short-term intake of residues of indoxacarb resulting from uses that have been considered by the JMPR, except the use on leaf lettuce, is unlikely to present a public health concern.

The Meeting also considered ways in which the short-term dietary intake for leaf lettuce could be refined. The Meeting noted that leaf lettuce is consumed as a raw commodity and that there was no alternative GAP available. Furthermore, the basis upon which the ARfD was set, a single-dose study, by the JMPR in 2005 meant that refinement was not possible. Consequently, the Meeting concluded that the information provided to the JMPR precludes an estimate that the dietary intake would be below ARfD for consumption of leaf lettuce by children.

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Reference	Author(s)	Year	Study Title
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