5.15 INDOXACARB (216)

RESIDUE AND ANALYTICAL ASPECTS

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 <u>cherries</u>, <u>peach</u> and <u>plum</u> 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, <u>0.15</u> (3), <u>0.19</u>, 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)						1.02[a]
			0.039	0.015	0.030	1.07[b]
[22.5, 75]			[< 0.01,			[0.54, 1.9][a]
			0.093]	[0.013, 0.019]	[0.020, 0.049]	[0.57, 2.0][b]
MRL Dairy Cattle	mean	mean				
(33)		0.92[a]				
	0.084	0.96[b]				
[22.5, 75]		[0.60, 2.2][a]				
	[0.058, 0.19]	[0.62, 2.3][b]				
STMR Beef Cattle			mean	mean	mean	mean
(17)			< 0.01	0.01	0.014	0.38

Dietary burden (ppm) Feeding level [mg/kg]	Milk	Cream	Muscle	Liver	Kidney	Fat
[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) [7.5, 22.5]	0.037 [0.021, 0.058]	0.39 [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.

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 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 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.