DICOFOL (026)

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EXPLANATION

Dicofol is an organochlorine acaricide. It was evaluated by JMPR 1968 (T, R), 1992 (T,R), 1994 (R), 2011(T). It was evaluated for toxicological review by JMPR in 2011 as a periodic re-evaluation chemical. The ADI for dicofol was established as 0–0.002 mg/kg.bw and acute reference dose was 0.2 mg/kg bw. Dicofol was scheduled at the Forty-third Session of the CCPR (2011) for the periodic re-evaluation of residues by the 2012 JMPR.

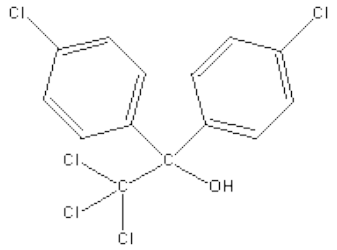
Dicofol is no longer supported by the original manufacturer. The plant metabolism and tea residue trial data were submitted by India; tea monitoring results were submitted by the Kingdom of Morocco.

IDENTITY

Chemical Names and Numbers

ISO common name: Dicofol

CAS No.: 115-32-2
IUPAC: 2,2,2-trichloro-1,1-bis(4-chlorophenyl)ethanol
Chemical Abstract: 4-chloro-α-(4-chlorophenyl)- α-(trichloromethyl) benzenemethanol
Other names: Kelthane
CIPAC Number: 123
Structural formula



Molecular formula: $C_{14}H_9Cl_5O$

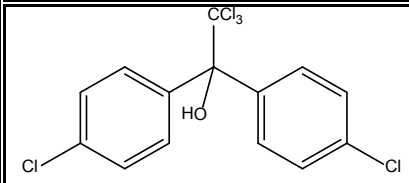
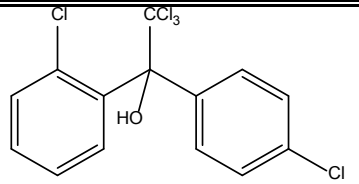
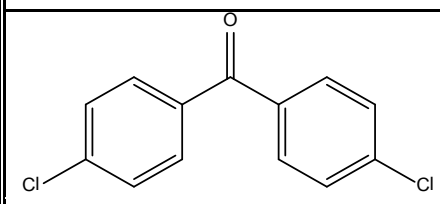
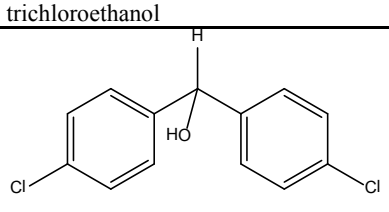
Structure Common name: Chemical name	Structure Common name: Chemical name
 p,p′-dicofol: 1,1-bis(4-chlorophenyl)-2,2,2-trichloroethanol	 o,p′-dicofol: 1-(2-chlorophenyl)-1-(4-chlorophenyl)-2,2,2-trichloroethanol
 DCBP: Dichlorobenzophenone	 DCBH: Dichlorobenzhydrol

Figure 1 The chemical structures of dicofol and metabolites

PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: Colourless solid
Vapour pressure	: 0.53 mPa (tech)
Melting point	: 78.5–79.5 °C
Log K_{ow}	: 4.3
Solubility (water and organic solvents at indicated temperature)	:In water, 0.8 mg/L (25 °C). In acetone, ethyl acetate toluene 400, methanol 36, hexane, isoproanol 30 (all in g/L).
Relative density	: 1.45 at 25 ºC
Hydrolysis	: Hydrolysed by alkaline media, DT_{50} 85 d (pH 5), DT_{50} 64–99 h (pH 7), (pH 9) 26 min.
Photolysis	: Photo-oxidation occurs in sunlight

Technical material

Minimum purity (in %)	: 95 % w/w (minimum), 80% dicofol and 20% o,p-dicofol
Main impurities	: DDT and related contaminants
Appearance	: Brown viscous oil

Plant metabolism

Information on plant metabolism was taken from the 1992 JMPR evaluation, supplemented by the original study reports. Summarized information on the metabolism of dicofol in/on the following crops were described: beans, cotton seed, grapefruit, and tomato.

Beans

Following treatment at a rate of 1.6 kg/ha, beans/pods and foliage were collected after 28 days. Dicofol comprised 50% TRR. No analysis of bound residues was attempted, and no other compounds were identified.

Grapefruit

Following treatment with ^{14}C-dicofol, grapefruit were sampled at intervals of 7 days; 1, 2, 3, 4, and 5 months after application. Analysis showed that > 98 % TRR was in the peel, and 1.5% in the pulp. Dichlorobenzophenone (DCBP) was the only metabolite identified, but its level was not specified.

Cotton seed

Cotton plants were treated twice with ^{14}C-dicofol at a total rate of 2.9 kg/ha. The first application was made just after first bloom and the second 30 days later when approximately10% of the bolls were open. Cotton was harvested 72 days after the initial application. Experiments using radiolabelled p,p'-dicofol found 59% TRR as dicofol and 13% as DCBP. Experiments using radiolabelled o,p'-dicofol found 24% dicofol and 27% DCBP.

Tomato

Two applications of ^{14}C-dicofol were made to tomato plants at 8-day intervals at a total rate of 2.7 kg/ha. Applications of radiolabelled o,p'-dicofol and p,p'-dicofol were made to separate plants. Ripe tomatoes were collected at intervals ranging from 17 to 28 days after the first application. Parent dicofol accounted for 90 and 50% TRR, following p,p'-dicofol and o,p'-dicofol treatments, respectively. Identified metabolites were p,p'-DCBP (< 1% TRR from p,p'-dicofol), o,p'-DCBP (4%

TRR from o,p'-dicofol) and o,p'-dichlorobenzhydrol (DCBH) (7% TRR from o,p'-dicofol). The major component of the residue is parent dicofol and, over time, the residue becomes strongly associated by either covalent or non-covalent binding to lignin. Table 1 summarizes the findings of the dicofol tomato metabolism study.

Table 1 Distribution of radioactivity in tomatoes sampled 21 days after the second application of ^{14}C-dicofol.

	TRR = 0.70 mg/kg	TRR = 0.65 mg/kg
Component	% TRR, ^{14}C-p,p' label study	% TRR, ^{14}C-o,p' label study
Dicofol	89	65
DCBP	0.9	4.1
DCBH	0.0	6.6
Aqueous unknown	3.7	6.9
Organic unknown	3.7	10
Non-extractable	2.9	7.6
Total	100	100

The studies indicate that dicofol is primarily a surface residue, and that parent is the predominant residue in plants. Since 80% of technical dicofol is the p,p' isomer, the results from the tomato ^{14}C-p,p' label experiment are most relevant. These show < 1% TRR is comprised of DCBP and DCBH after 21 days.

Methods of residue analysis

The method involves re-hydration of the dry tea leaves (10 g) with distilled water (40 mL) and extraction with 200 mL mixture of n-hexane and acetone (4:1, v/v) by blending at high speed using a top mounted blender. The contents were allowed to stand (5 min.) and an aliquot (50 mL) of extract was washed with aqueous sodium chloride solution. Residues were partitioned into hexane, and extracts were cleaned with alumina. Residues in the cleaned extract were quantified by GLC-ECD using a fused silica open tubular wide bore capillary column coated with DB-5. The method LOQ was 0.02 mg/kg.

USE PATTERN

Dicofol is registered for use as an EC (emulsifiable concentrate) formulation in India. The use patterns relevant for this evaluation are summarized in Table 1.

Table 2 GAP use pattern for dicofol use on tea

Crop	F or G [a]	Formulation		Application			Application rate per treatment			PHI (days)
		Type [b]	Conc. of ai	method	growth stage [c]	number	kg ai/hL	water L/ha	kg ai/ha	
Tea	F	EC	185g/L	High volume spraying, foliar sprays	Active vegetative growth stage	1	0.046	400	0.185	7

[a] Outdoor or field use (F), or glasshouse application (G)
[b] emulsifiable concentration (EC)
[c] Growth stage at last treatment

RESIDUES RESULTING FROM SUPERVISED TRIALS

Tea

Eight supervised dicofol residue trials were conducted in India using foliar application of EC formulations, as summarized below.

Results from the supervised trials are shown in Table 3. Residues of dicofol were determined by GLC/ECD, with a LOQ of 0.02 mg/kg. The LOD was 0.01 mg/kg for all analytes in all matrices.

Table 3 Results of residue trials conducted with 1 application of dicofol 185 g ai/L EC in/on tea (Reference 1)

Country Year	Variety	Application g ai/hL	 g ai/ha	 L/ha	Dry vs. Wet season	PHI	Portion	Residues (mg/kg) Dicofol
Tocklai, Assam India 4/1994	Multiple cultivars	46	185	400	Dry	0 7 14 21	Black tea	108.7 15.53 8.03 1.30
Tocklai ,Assam India 7/1994	Multiple cultivars	46	185	400	Wet	0 7 14 21	Black tea	19.2 1.90 0.26 <0.02
Nagrakata, West Bengal India 11/1994	Multiple cultivars	46	185	400	Dry	0 7 14 21	Black tea	47.0 9.66 7.06 4.20
Nagrakata, West Bengal India 7/1994	Multiple cultivars	46	185	400	Wet	0 7 14 21	Black tea	59.6 4.13 1.10 0.72
Darjeeling, West Bengal India 5/1994	Multiple cultivars	46	185	400	Dry	0 7 14 21	Black tea	51.07 12.56 8.86 1.70
Darjeeling, West Bengal India 8/1994	Multiple cultivars	46	185	400	Wet	0 7 14 21	Black tea	37.8 9.2 1.13 0.21
UPASI, Valparai, Tamilnadu 2/1997	Multiple cultivars	46	185	400	Dry	0 7 14	Black tea	91.40 15.56 1.18
UPASI, Valparai, Tamilnadu 10/1998	Multiple cultivars	46	185	400	Wet	0 7 14	Black tea	88.34 14.37 6.69

Further, the Kingdom of Morocco submitted the results of monitoring data collected for imported tea samples over the years 2000-2011. The majority (85–95%) of the imported green tea originated from China, while the remainder originated from India or Sri Lanka. The number of samples containing detectable levels of dicofol and the values measured are presented in Table 4.

Table 4 Summary of monitoring program results from the Kingdom of Morocco over the years 2000–2011 (Reference 2)

No of samples containing dicofol	Dicofol residues determined in tea (mg/kg) Year											
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
1	1.2	0.2	1.45	1	0.18	0.2	0.14	0.02	0.08	0.14	0.05	0.12
2		1.7	0.03	0.28	0.4	0.1	0.53	0.1	0.05	0.25	0.24	0.14
3		1.3	0.26	0.53	0.07	0.15	0.88	0.12	0.05	0.14	0.15	0.06
4		0.3	0.13	0.14	0.07	0.08	0.4	0.12	0.54	0.24		0.08
5		0.3	0.18	0.09	0.06	0.09	0.22	0.04	0.09	0.02		0.28
6		0.2	0.3	0.68	0.2	0.15	0.17	0.2	0.14	0.15		0.22
7		0.8	0.17	0.67	0.4	0.25	0.27	0.12	0.14	0.01		0.58

No of samples containing dicofol	Dicofol residues determined in tea (mg/kg)											
	Year											
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
8		0.2	0.11	0.95	0.12	0.09	0.17	0.06	0.29	0.03		0.19
9		0.18	0.08	0.66	0.05	0.13	0.15	0.01	0.05	0.06		0.1
10		0.15	0.1	0.2	0.1	0.29	0.11	0.08	0.06	0.05		0.28
11		0.2	0.06	0.4	0.2	0.5	0.54	0.05	0.22	0.07		0.33
12		0.36	0.04	0.3	0.1	0.19	0.18	0.02	0.06			0.27
13		0.25	0.06	1.1	0.11	0.41	0.14	0.1	0.07			0.25
14		0.3	0.1	0.2	0.3	0.22	0.27	0.04	0.35			0.46
15		0.21	0.02	0.4	0.16	0.42	0.11	0.01	0.08			0.1
16		0.34	0.1	0.1	0.17	0.57	0.05	0.03				0.25
17		0.15	0.11	0.5	0.1	0.11	0.49	0.06				0.19
18		0.2	0.1	1.3	0.1	0.24	0.05	0.03				0.16
19		2.2	0.12	0.12	0.11	0.37	0.18	0.06				0.32
20		0.04	0.2	0.05	0.1	0.58	0.28	0.09				0.33
21		0.14	0.2	0.54	0.1	0.2	0.14	0.05				0.27
22		0.03	0.04	0.1	0.15	0.08	0.08	0.05				0.08
23		0.03	0.03	0.24	0.2	0.1	0.37	0.07				0.19
24			0.06	2.5	0.01	0.06	0.98	0.1				0.04
25			0.02	0.1	0.15	0.08	0.09	0.02				0.19
26			0.12	0.17	0.1	0.1	0.16	0.02				0.11
27			0.38	1.5	0.13	0.2	0.1	0.05				0.1
28			0.4	0.08	0.12	0.1	0.1	0.06				0.13
29			0.4	0.06	0.15	0.09	0.15	0.02				0.4
30			0.14	0.2	0.1	0.06	0.15	0.05				0.16
31			0.3	0.1	0.03	0.24	0.18	0.05				0.02
32			0.1	0.18	0.14	0.1	0.42	0.02				0.38
33			0.8	0.12	0.3	0.2	0.17	0.03				0.09
34			0.6	0.48	0.07	0.07	0.2	0.08				0.15
35			0.6	0.22	0.06	0.2	0.11	0.05				0.33
36				0.12	0.04	0.15	0.06					0.24
37				0.08	0.06	0.33	0.18					0.19
38				0.15	0.04	0.96	0.18					0.47
39				0.11	0.04	1.3	0.19					0.05
40				0.4	0.16	1.3	0.2					0.17
41				0.1	0.1	0.3	0.22					0.09
42				0.45	0.2	0.06	0.46					1.96
43				0.5	0.05	0.4	0.07					0.36
44				3	1.75	0.7	0.2					1.14
45				3	0.21	0.3	0.1					0.06
46				0.2	0.11	0.9	0.36					0.13

No of samples containing dicofol	Dicofol residues determined in tea (mg/kg)											
	Year											
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
47				2.6	0.25	1.1	0.25					0.11
48					0.3	0.7	0.14					0.4
49					0.75	0.7	0.21					0.16
50					0.55	0.9	0.09					0.02
51					0.08	0.3	0.13					0.38
52					0.49	0.1	0.1					0.09
53					1.05	0.06	0.1					0.15
54					1.1	0.08	0.1					0.33
55					1	0.2	0.1					0.24
56					1	0.16	0.01					0.19
57					0.4	0.05	0.1					0.47
58					0.75	0.25	0.14					0.05
59					0.7	0.4	0.02					0.17
60					0.6	0.5	0.08					0.09
61					0.22	0.16	0.35					1.96
62					0.07	0.3	0.04					0.36
63					1.2	0.14	0.04					1.14
64					0.15	0.48	0.12					0.06
65					0.08	0.22	0.22					0.13
66					0.4	0.11	0.05					0.11
67					0.3	0.14	0.01					1.33
68						0.32	0.1					2.5
69						0.34	0.14					2.49
70						0.05	0.13					4.36
71						0.19						3.85
72						0.48						4.06
73						0.11						5.73
74						0.11						6.21
75						0.15						5.79
76						0.21						5
77						0.33						5.02
78						0.19						6.36
79						0.1						4.85
80						0.18						6.71
81						0.17						3.45
82						0.37						3.23
83						0.3						2.54
84						0.15						6.1
85						0.37						0.14

No of samples containing dicofol	Dicofol residues determined in tea (mg/kg)											
	Year											
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
86						0.05						0.08
87												0.1
88												0.5
89												0.17
90												2.57
91												0.17
92												2.57

Table 5 presents a summary of dicofol residue levels found in imported green tea samples to Morocco over the years 2000–2011. The highest residue found was 6.7 mg/kg in a sample from 2011.

Table 5 Summary of dicofol monitoring program results from the Kingdom of Morocco over the years 2000–2011 (Reference 2)

	Year												Total
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	
No of Samples analysed	60	79	66	86	108	100	96	50	71	53	76	104	949
% > LOQ	1.7	29.1	53.0	54.7	62.0	86.0	72.9	70.0	21.1	20.8	3.9	88.5	51.1
Minimum (mg/kg)	1.2	0.03	0.02	0.05	0.01	0.05	0.01	0.01	0.05	0.01	0.05	0.02	0.01
Maximum (mg/kg)	1.2	2.2	1.45	3.0	1.75	1.3	0.98	0.2	0.54	0.25	0.24	6.71	6.71
Average (mg/kg)	1.2	0.43	0.23	0.57	0.29	0.29	0.20	0.06	0.15	0.11	0.15	0.43	0.44

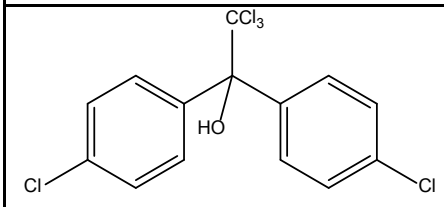
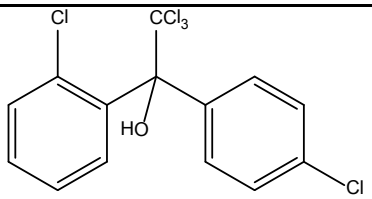
FATE OF RESIDUES IN PROCESSING

Processing studies

The transfer of dicofol residues from made tea to tea brews was studied. The transfer of residues was reported to be 1.6%.

APPRAISAL

Dicofol is an organochlorine acaricide. It was evaluated by JMPR 1968 (T, R), 1992 (T, R), 1994 (R), 2011(T). It was evaluated for toxicological review by JMPR in 2011 as a periodic re-evaluation chemical. The ADI for dicofol was established as 0–0.002 mg/kg.bw and acute reference dose was 0.2 mg/kg bw. Dicofol was scheduled at the Forty-third Session of the CCPR (2011) for the periodic re-evaluation of residues by the 2012 Meeting of the JMPR.

Structure Common name: Chemical name	Structure Common name: Chemical name
	
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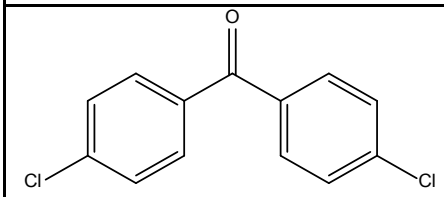	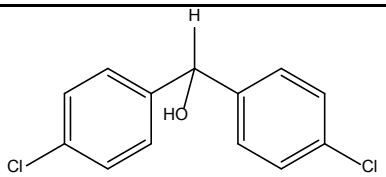
DCBP: Dichlorobenzophenone	DCBH: Dichlorobenzhydrol

Technical dicofol is a 80:20 mixture of p,p'-dicofol and o,p'-dicofol. The major impurities are DDT and related contaminants. No information was provided regarding the level of these impurities.

Plant Metabolism

Information on plant metabolism was taken from the 1992 JMPR evaluation, supplemented by the original plant metabolism study reports. Translocation studies were provided for bean and grapefruit, and metabolism studies were provided for tomato and cotton. The studies indicate that dicofol is primarily a surface residue that does not translocate in plants, and that parent is the predominant residue, comprising 50% TRR in grapefruit five months after treatment.

The tomato metabolism study involved treatment of ^{14}C-labeled p,p′-dicofol and o,p′-dicofol in separate experiments. The metabolites DCBP and DCBH were detected in tomatoes 21 days after treatment, but less was formed from the major dicofol isomer, p,p′-dicofol, than from o,p′-dicofol. Less than 1% TRR was comprised on DCBP and DCBH in the p,p′-dicofol experiment, while the sum of DCBP and DCBH totalled about 11% TRR in the o,p′-dicofol experiment.

Similar results were obtained in the cotton metabolism studies, although these experiments involved sampling 72 days after treatment and demonstrated relatively more conversion of dicofol into its DCBP and DCBH metabolites than observed in the tomato metabolism studies.

Methods of residue analysis

The method involves re-hydration of the dry tea leaves with distilled water and extraction with a 4:1 v/v mixture of n-hexane and acetone. Residues were partitioned into hexane and extracts cleaned with alumina. Quantitation of the cleaned extracts was by GLC-ECD using a fused silica open tubular wide bore capillary column coated with DB-5. The limit of quantitation was 0.02 mg/kg. Method validation was demonstrated up to 5 mg/kg.

Stability of residues in stored analytical samples

Residues in stored samples were demonstrated to be stable over the storage intervals involved in the magnitude of the residue studies.

Residue definition

The available plant metabolism and translocation studies demonstrate that dicofol is primarily a surface residue that does not translocate. Dicofol comprised the major portion of the residue, with some conversion to the metabolites DCBP and DCBH over time. In tomato experiments with a 21 day

PHI, < 1% TRR was found as DCBP and DCBH in the p,p'-dicofol experiment, while DCBP and DCBH comprised approximately 11% TRR in the o,p'-dicofol experiment. As the GAP for tea in India lists a 7 day PHI, less conversion to the dicofol metabolites is expected in tea than observed in the tomato metabolism studies. The Meeting agreed that parent dicofol is the appropriate residue for enforcement and dietary risk assessment.

Dicofol has a log K_{ow} of 4.3.

No animal metabolism data were submitted. As tea is not a livestock feedstuff, the Meeting agreed that a residue definition for animals is not currently required. However, for future uses on plant commodities that are livestock feedstuffs, animal metabolism studies will be necessary.

The Meeting recommended the following residue definition for dicofol

For plants: Definition of the residue (for compliance with the MRL and for estimation of dietary intake): *dicofol (sum of o,p' and p,p' isomers)*

Residues resulting from supervised trials

The Meeting received supervised field trial data for dicofol uses on tea from India; and tea monitoring data from Morocco. The Meeting noted that no information regarding the levels of DDT in tea, as a result of its possible presence as a contaminant in the technical grade dicofol, was provided in the residue trials.

The OECD MRL 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 proposed 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 OECD 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 provided.

Tea

The GAP in India for tea allows the use of dicofol as one foliar treatment at a rate of 0.19 kg ai/ha, and harvest of fruit 7 days after application (7-day PHI). Trials were conducted at four sites in India during both the dry and wet seasons.

Rank-order dicofol residue concentrations in tea from dry season Indian trials were: 9.7, 13, 15.5, and 15.6 mg/kg.

Rank-order dicofol residue concentrations in tea from wet season Indian trials were: 1.9, 4.1, 9.2, and 14.4 mg/kg.

Residue data with suitable GAP were available for tea. Noting the overlap between the residue levels in tea samples, the Meeting decided to combine the results for the purposes of estimating dicofol residue levels in tea. Thus, the rank-order dicofol residue concentrations in tea were: 1.9, 4.1, 9.2, 9.7, 12.6, 14.4, 15.5, and 15.6 mg/kg.

The Meeting estimated a maximum residue level of 40 mg/kg for residues of dicofol in tea, green and black. The Meeting estimated STMR and HR values of 11.2 and 15.6 mg/kg, respectively, for dicofol residues in tea. The Meeting withdraws its previous maximum residue level recommendation of 50 mg/kg for dicofol in tea, green and black.

Green Tea Monitoring Data from Morocco

The highest dicofol level found in green tea samples from Morocco over the years 2000–2011 was 6.7 mg/kg.

Processing studies

The transfer of dicofol residues from made tea to tea brew was studied. The tea brew processing factor was 0.016.

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 and dietary risk assessment for plant commodities): *dicofol (sum of o,p' and p,p' isomers).*

Commodity		MRL, mg/kg		STMR or STMR-P, mg/kg	HR, mg/kg
CCN	Name	New	Previous		
	Beans (dry)	W	0.1		
	Cattle meat	W	3 (fat)		
	Cattle, Edible offal of	W	1		
	Cherries	W	5		
	Citrus fruits	W	5		
	Common bean (pods and/or immature seeds)	W	2		
	Cotton seed	W	0.1		
	Cotton seed oil, Crude	W	0.5		
	Cotton seed oil, Edible	W	0.5		
	Cucumber	W	0.5		
	Eggs	W	0.05		
	Grapes	W	5		
	Hops, Dry	W	50		
	Melons, except watermelon	W	0.2		
	Milks	W	0.1		
	Peach	W	5		
	Pecan	W	0.01		
	Peppers	W	1		
	Peppers, Chili, dried	W	10		
	Plums (including prunes)	W	1		
	Poultry meat	W	0.1 (fat)		
	Poultry, Edible offal of	W	0.05		
	Prunes	W	3		
	Squash, summer	W	1		
DT 1114	Tea, green, black (black, fermented and dried)	40[a]	50	11.2	15.6
	Walnuts	W	0.01		

[a] DDT may be present in tea as a result of its presence as a contaminant in the technical grade dicofol.

DIETARY RISK ASSESSMENT

Long-term intake

The ADI for dicofol is 0–0.002 mg/kg bw. The International Estimated Daily Intake (IEDI) for dicofol was estimated for the 13 GEMS/Food cluster diets using the STMR values estimated by the current Meeting. The results are shown in Annex 3 of the 2012 JMPR Report. The IEDI ranged from 1–30% of the maximum ADI. The Meeting concluded that the long-term intake of residues of dicofol, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

Short-term intake

The ARfD for dicofol is 0.2 mg/kg bw. The International Estimated Short Term Intake (IESTI) for dicofol was calculated for the plant commodities for which STMRs and HRs were estimated and for which consumption data were available. The results are shown in Annex 4 of the 2012 JMPR Report. The IESTI calculated for dicofol represented 0 and 20% of the ARfD for brewed tea and tea leaf, respectively. The Meeting concluded that the short-term intake of residues of dicofol, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

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