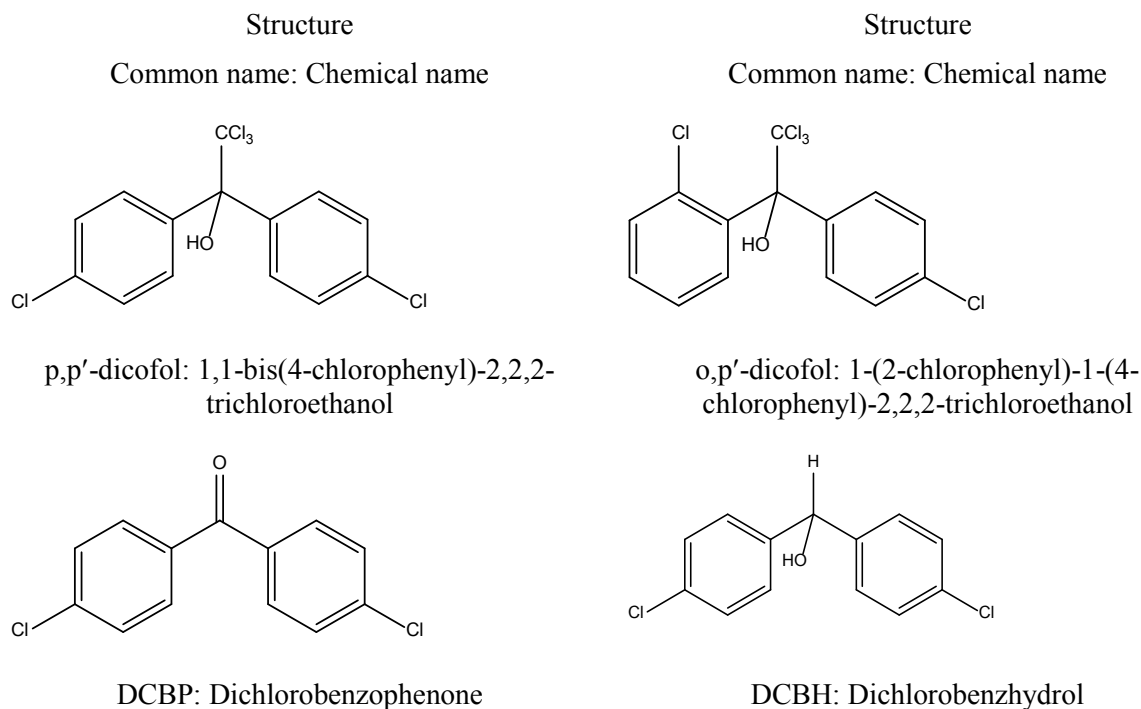


5.12 DICOFOL (026)

RESIDUE AND ANALYTICAL ASPECTS

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 for the periodic re-evaluation of residues by the 2012 Meeting of the JMPR.



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 ¹⁴C-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 totaled 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.

Definition of the residue

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)*

Results of supervised residue trials on crops

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.

Fate of residues during processing

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

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. 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. 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.