5.7 CHLOROTHALONIL (081)

RESIDUE AND ANALYTICAL ASPECTS

Chlorothalonil (tetrachloroisophthalonitrile) was most recently evaluated by the JMPR in 2009 for toxicology and in 2010 for residues. For the parent compound, an ADI of 0–0.02 mg/kg bw and an ARfD of 0.6 mg/kg bw were established. In addition, the Meeting set an ADI of 0–0.008 mg/kg bw and an ARfD of 0.03 mg/kg bw for the metabolite SDS-3701.

The 2010 JMPR recommended the following residue definition for chlorothalonil:

Definition of the residue for compliance with MRL for plant commodities: *chlorothalonil*

Definition of the residue for estimation of dietary intake for plant commodities:

chlorothalonil

SDS-3701 (2,5,6-trichloro-4-hydroxyisophthalonitrile), all considered separately.

Definition of the residue for compliance with MRL and for estimation of dietary intake for animal commodities: *SDS-3701 (2,5,6-trichloro-4-hydroxyisophthalonitrile).*

The 2010 JMPR estimated maximum residue levels for numerous commodities, which were adopted as Codex MRLs by the Codex Alimentarius Commission in 2011. The compound was listed by the Forty-third Session of the CCPR for the review of additional MRLs. The 2012 JMPR received residue data for banana, chard, chicory, endive, spring onion, spinach, and peas.

Methods of residue analysis

The Meeting received information on the analytical methods used in the chlorothalonil field trials for bananas and vegetables. For banana, the samples were extracted with acidified acetone. After clean up, the residues were determined by GC-ECD with a resulting LOQ of 0.1 mg/kg in the trials from 2005. The trials conducted in 2008 made use of similar extraction and sample clean-up, together with GC/MSD analysis to obtain a LOQ of 0.01 mg/kg. Mean recoveries of 74–104% were reported in banana whole fruit and pulp samples spiked at the following levels: 0.01, 0.1, 4.0, and 10 mg/kg. Similar methods were used in the analysis of vegetables, with reported LOQs ranging from 0.01 to 0.05 mg/kg. Analytical methods used in the reported studies made appropriate use of sulphuric acid during sample homogenization to avoid degradation of chlorothalonil residues.

Stability of residues in stored analytical samples

No new information on storage stability was submitted. Detailed information from the 2010 JMPR showed that chlorothalonil residues are stable (> 70% remaining) in frozen storage for up to 12 months in most commodities: peaches, strawberries, oranges, potatoes, carrots, onions, cabbages, leeks, lentils, tomatoes, melons, sugar beet and barley forage.

The periods of demonstrated stability cover the frozen storage intervals in the residue studies.

Results of supervised residue trials on crops

The 2010 JMPR noted that metabolite SDS-3701 is found at negligible levels following direct crop treatments. In follow crops or after processing, the contribution of SDS-3701 should be accounted for in a separate dietary intake analysis, reflecting its different toxicological endpoint from chlorothalonil. Neither banana nor chard have processed commodities or are livestock feedstuffs. These commodities are not expected to increase the contribution of SDS-3701 included in the analysis conducted in 2010.

The OECD 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.

Bananas

In Brazil, chlorothalonil is registered for the use on banana at a rate of 1 kg ai/ha, a retreatment interval of 15 days, and a PHI of 0 days. Eight supervised field trials were conducted in Brazil. In four trials, whole fruit and pulp data were collected following 4 and 6 applications at the GAP rate. In the four other trials, only whole fruit data were collected after 6 applications at the GAP rate.

Chlorothalonil residues in whole fruits were (n=8): 0.11, 0.24, 0.28, 0.34, 0.59, 1.4, 1.8, and 10 mg/kg. In the pulp, residues were (n=4): 0.05, 0.07 (2), and 0.13 mg/kg. The mean of the ratios of the residue levels between the pulp and whole fruit in trials where both values were determined, was 0.071 (n=40).

Based on the data for whole fruits treated according to Brazilian GAP, the Meeting estimated a maximum residue level of 15 mg/kg for chlorothalonil in banana (whole fruit). Using the pulp/whole fruit ratio, the Meeting estimated an STMR value of 0.033 mg/kg (0.47 × 0.071) and an HR value of 0.71 mg/kg (10 × 0.071) for chlorothalonil in banana pulp.

Spring onion

Supervised trials data were available for spring onion from Australia.

In Australia, GAP for spring onion allows the use of chlorothalonil at 1.7 kg ai/ha with a 14-day retreatment interval and a 14-day PHI.

In five spring onion trials in Australia matching GAP, chlorothalonil residues in spring onion were (n=5): 0.13, 0.44, 0.95, 1.2, and 2.8 mg/kg.

Following recommendations from the 2010 JMPR, there is an existing spring onion MRL of 10 mg/kg, based on two applications at a rate of 1 kg ai/ha and a 14-day PHI, and four trials from the United Kingdom. The Meeting agreed that the existing MRL accommodates the GAP used in Australia.

Leafy vegetables

Supervised trial data were available for chard, chicory, endive, and spinach.

Chard (Silverbeet)

In Australia, chlorothalonil is registered for use on chard for up to 4 treatments at a rate of 1.7 kg ai/ha, with a PHI and a retreatment interval of 7 days. Three supervised field trials are available at this GAP from Australia.

Rank-order chlorothalonil residues in Swiss chard were (n=3): 8.5, 16, and 19 mg/kg.

The Meeting estimated a maximum residue level of 50 mg/kg for chlorothalonil in/on chard, an STMR value of 16 mg/kg, and an HR value of 19 mg/kg.

Chicory

In Australia, GAP for chicory specifies the use of chlorothalonil with a maximum of two foliar applications at 0.75 kg ai/ha, a 7-day retreatment interval, and a 7-day PHI.

One trial matching GAP from Australia was submitted, showing a residue of 4.4 mg/kg chlorothalonil.

The Meeting agreed that one trial is insufficient to base maximum residue estimates for chicory.

Endive

In Australia, GAP for endive specifies the use of chlorothalonil with a maximum of two foliar applications at 0.75 kg ai/ha, a 7-day retreatment interval, and a 7-day PHI.

One trial matching GAP from Australia was submitted, showing a residue of 6.6 mg/kg chlorothalonil.

The Meeting agreed that one trial is insufficient to base maximum residue estimates for endive.

Spinach

In Australia, GAP for spinach allows the use of chlorothalonil with a maximum of four foliar applications at 1.7 kg ai/ha, a 7-day retreatment interval, and a 7-day PHI.

Four trials matching GAP were available from Australia.

Rank-order chlorothalonil residue concentrations in spinach were: 2.8, 38, 42, and 66 mg/kg.

The Meeting agreed that 4 trials are insufficient to base maximum residue estimates for spinach.

Peas (pods and succulent = immature seeds)

Supervised trials data were available for garden and snow peas.

In Australia, GAP for peas allows the use of chlorothalonil with four foliar applications at 1.3 kg ai/ha, a 7-day retreatment interval, and a 7-day PHI.

A total of four trials on garden peas and two trials on snow peas were submitted from Australia. However, the Meeting noted that the garden pea trials were not independent; hence, only two trials match GAP for garden peas and snow peas, respectively.

Chlorothalonil residue concentrations in garden peas were: 5.4 and 7.3 mg/kg.

Chlorothalonil residue concentrations in snow peas were: 2.5 and 5.1 mg/kg.

The Meeting determined that insufficient trials were available to support maximum residue estimates for peas.

Beetroot

In Australia, chlorothalonil is registered for use on beetroot for up to 4 treatments at a rate of 1.7 kg ai/ha, with a PHI and retreatment interval of 7 days. Supervised field trials are available at this GAP.

A total of three trials on beetroot were conducted in Australia according to GAP.

Rank-order chlorothalonil residues in beetroot were (n=3): < 0.05 (2), and 2.1 mg/kg.

The Meeting determined that insufficient trials were available to support maximum residue estimates for beetroot.

DIETARY RISK ASSESSMENT

Long-term intake

The ADI for chlorothalonil is 0–0.02 mg/kg bw. The International Estimated Daily Intakes (IEDI) for chlorothalonil was estimated for the 13 GEMS/Food cluster diets using the STMR or STMR-P values estimated by the current Meeting in addition to those determined by the 2010 JMPR. The results are shown in Annex 3. The IEDI ranged from 8–50% of the maximum ADI. The Meeting concluded that the long-term intake of residues of chlorothalonil, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

Short-term intake

The ARfD for chlorothalonil is 0.6 mg/kg bw. The International Estimated Short Term Intake (IESTI) for chlorothalonil was calculated for the plant commodities for which STMRs and HRs were estimated (banana and chard). The results are shown in Annex 4. The IESTI calculated for chlorothalonil represented 7–70% of the ARfD. The Meeting concluded that the short-term intake of residues of chlorothalonil, from uses that have been considered by the JMPR, is unlikely to present a public health concern.