

## 5.10 DIMETHOATE (027)

### Dimethoate (027) – Alternative GAP

Dimethoate was evaluated by the JMPR in several years from 1965–1994 and under the CCPR periodic review programme in 1998. The compound was re-evaluated in 2003 for residues and toxicology. The 2003 Meeting recommended a number of MRLs and established an acute reference dose (ARfD) of 0.02 mg/kg bw. In 2006 the JMPR evaluated a pending request from CCPR about residues in barley and decided that the MRL for barley was acceptable. The 39th session of the CCPR in 2007 decided to retain draft MRLs for head lettuce (3 mg/kg) and sweet peppers (5 mg/kg) at Step 7 because of short-term dietary intake concerns and requested that an evaluation of alternative GAP for these commodities be undertaken by the JMPR at its 2008 Meeting (ALINORM 07/30/24). The draft MRL for cabbage, head (2 mg/kg) was deleted.

New GAP data were submitted by the manufacturer for the consideration of alternative GAP for lettuce, utilising supervised residue trial data, previously submitted to the 2003 JMPR. On sweet peppers, new residue and GAP data for dimethoate following foliar treatment were submitted by Australia and information on GAP by Japan.

#### *Results of supervised residue trials on crops*

The toxicological evaluation of omethoate, the major plant metabolite of dimethoate, indicated a greater level of toxicity than dimethoate, i.e., by a factor of 10. Since consumers are exposed to both dimethoate and omethoate residues at the time of consumption, the difference in toxicity was taken into account (1998 JMPR residue evaluations, p. 510) by multiplying the omethoate residues by a factor of 10 for calculation of the sum of the residues. The total toxicologically significant residues, calculated in this way, were used for the estimation of dietary exposure. The present Meeting followed the same practice. The sum ( $C_T$ ) of dimethoate ( $C_D$ ) and omethoate ( $C_O$ ) residue concentrations reported for the specific commodities was calculated as  $C_T = C_D + (10 \times C_O \times 1.075^{37})$ . The HRs and STMRs were estimated on the basis of the calculated  $C_T$  values.

In the case of undetectable residues, the concentration of omethoate residues was calculated by taking into account the average ratio of dimethoate to omethoate in the edible portions of the crop at the specified pre-harvest interval.

#### *Peppers, sweet*

Dimethoate is approved in Australia for use in vegetables, and capsicums (Sweet peppers) for the control of aphids, thrips, leafhoppers, mites, bugs, wingless grasshoppers and fruit fly with a foliar spray concentration of 0.03 kg ai/hL. The pre-harvest interval is either 7 days (all States) or 3 days (against fruit fly in Queensland, Western Australia and New South Wales only). The labels were submitted for consideration as alternative GAPs.

Data from two new Australian supervised residue trials and the residue data reported by JMPR 2003 were evaluated according to Australian GAP for pre-harvest foliar spray applications at 0.03 kg ai/hL and a PHI of 3 days or of 7 days. The residues found 3 days after the last treatment of  $3 \times 0.03$  kg ai/hL were 0.04, 0.08, 0.14, 0.19 and 0.42 mg/kg for dimethoate and < 0.02, 0.02, < 0.04, 0.06 and 0.15 mg/kg for omethoate. After 7 days, the residues found were 0.03, 0.03, 0.06, 0.14 and 0.26 mg/kg for dimethoate and < 0.02, 0.02, 0.02, < 0.04 and 0.1 mg/kg for omethoate.

Based on the ratio of omethoate to dimethoate residues at 3 or 7 days after application, factors of 0.32, 0.33, 0.36, 0.38, 0.5, 0.67 were estimated. In the case of the two Australian trials with

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<sup>37</sup> The molecular mass of dimethoate is 229.28 and for omethoate 213.19, resulting in a factor of 1.075

omethoate residues at LOQ ( $< 0.02$ ,  $< 0.04$  mg/kg) an average factor of 0.4 was included:  $C_T = C_D + (LOQ \times 10 \times 1.075 \times 0.4)$ .

The dimethoate equivalents of the sum of dimethoate and omethoate residues in sweet peppers 3 days after the final application were 0.17, 0.26, 0.31, 0.84 and 2.03 mg/kg. Using the value of 2.03 mg/kg as HR for the short-term dietary intake calculation, the ARfD was exceeded for children (130%). Therefore, the JMPR could not estimate a maximum residue level based on the GAP with a PHI of 3 days following a final foliar spray of 0.03 kg ai/hL.

The dimethoate equivalents of the sum of dimethoate and omethoate residues in sweet peppers 7 days after the final application were 0.03 kg ai/hl 0.12, 0.25, 0.28, 0.31 and 1.3 mg/kg. The trials match the second alternative GAP submitted by Australia. Based on the dimethoate residue data for a 7 day PHI, the Meeting estimated a maximum residue level of 0.5 mg/kg for sweet peppers and proposed to withdraw the previous recommendation of 5 mg/kg. According to the residue definition for risk assessment of dimethoate and 10 times omethoate, an STMR value of 0.28 mg/kg and HR value of 1.3 mg/kg were estimated.

#### *Dried chilli peppers*

Based on the residues in sweet peppers and a default concentration factor of 10, the Meeting estimated a maximum residue level of 3 mg/kg for dried chilli peppers and withdrew its previous recommendation of 50 mg/kg. According to the residue definition for risk assessment of dimethoate and 10 times omethoate, an STMR value of 2.8 mg/kg and HR value of 13 mg/kg were estimated.

#### *Lettuce, head*

The residue data on lettuce reported by JMPR 2003 were evaluated according to new information on GAP.

As described above, the dimethoate equivalents of dimethoate and omethoate residues were calculated as follows:  $C_T = C_D + (C_O \times 10 \times 1.075)$ . Based on the ratio of omethoate to dimethoate residues 14 or 28 days after application, factors of 0.18, 0.27, 0.25, 0.29, 0.5, 0.5, 0.55, 1.3, 1.5 were estimated. Because of the wide range, the LOQ values for omethoate were not corrected by a factor.

The 2003 JMPR evaluated outdoor residue trials data on head lettuce from Greece (1), Spain (4) and Italy (4) with application of 0.04 kg ai/hL and 14 days PHI against Italian GAP. The residues at 14 days, in ranked order, were:  $< 0.01$  (6), 0.03, 0.07 and 0.11 mg/kg for dimethoate, and  $< 0.01$  (5), 0.01, 0.02, 0.04 and 0.06 for omethoate. For dietary risk assessment purposes, the dimethoate equivalents of the sum of dimethoate and omethoate residues were estimated as follows:  $< 0.12$  (4), 0.12, 0.18, 0.23, 0.46 and 0.76 mg/kg.

Eight outdoor trials on head lettuce from the UK submitted to the 2003 JMPR were evaluated against Irish GAP ( $6 \times 0.34$  kg ai/ha, PHI 14 days). The residues at 14 days, in ranked order were: 0.01, 0.02, 0.02, 0.02, 0.04, 0.07, 0.07 and 0.11 mg/kg for dimethoate and  $< 0.01$  (5), 0.02, 0.03 and 0.03 mg/kg for omethoate. For dietary risk assessment purposes, the dimethoate equivalents of the sum of dimethoate and omethoate residues were estimated as follows: 0.12, 0.13, 0.13, 0.15, 0.18, 0.29, 0.34 and 0.43 mg/kg.

The 2003 JMPR evaluated eleven residue trials conducted in glasshouses in the UK completed in 1996 and 1998. Dimethoate EC 400 g/L was applied once at 0.34 kg ai/ha (0.17 kg ai/hL) with a PHI of 28 days. GAP for glasshouse use was reported from Ireland (0.34 kg ai/ha, repeated as necessary with a 28-day PHI). The 2008 JMPR was informed that the Irish GAP had been modified as follows: spraying, up to and including 9th leaf unfolded stage or before the head starts to form (up to and including BBCH 19). Eight from eleven supervised trials complied with new Irish glasshouse GAP. The residues in ranked order were  $< 0.01$ , 0.01, 0.01, 0.02, 0.02, 0.06, 0.16 and 0.17 mg/kg for dimethoate and  $< 0.01$  (4), 0.01, 0.03, 0.03 and 0.04 mg/kg for

omethoate. For dietary risk assessment purposes, the dimethoate equivalents of the sum of dimethoate and omethoate residues were estimated as follows: 0.12 (3), 0.13, 0.13, 0.38, 0.49 and 0.59 mg/kg.

The Meeting was aware that the three data sets (outdoor Southern Europe, outdoor UK and indoor UK) are based on different GAPs but recognized no observable difference in the estimation of a maximum residue level between the data sets. The maximum dimethoate value of 0.17 mg/kg results from the UK indoor data set and the highest omethoate residue of 0.06 mg/kg (which leads to an HR of 0.76 mg/kg dimethoate equivalents) from the outdoor European data set. The Meeting concluded that the data can be combined. Residues in rank order ( $n = 25$ ) were: < 0.01 (7), 0.01 (3), 0.02 (5), 0.03, 0.04, 0.06, 0.07 (3), 0.11 (2), 0.16 and 0.17 mg/kg for dimethoate and < 0.01 (14), 0.01, 0.01, 0.02, 0.02, 0.03 (4), 0.04, 0.04 and 0.06 mg/kg for omethoate.

The dimethoate equivalents, of the sum of dimethoate and omethoate residues, in head lettuce were: < 0.12 (4), 0.12 (5), 0.13 (4), 0.15, 0.18 (2), 0.23, 0.29, 0.34, 0.38, 0.43, 0.46, 0.49, 0.59 and 0.76 mg/kg. Based on the dimethoate residue data, the Meeting estimated a maximum residue level of 0.3 mg/kg for head lettuce and withdrew its previous recommendation of 3 mg/kg. According to the residue definition for risk assessment of dimethoate and 10 times omethoate, an STMR value of 0.13 mg/kg and an HR value of 0.76 mg/kg were estimated.

## DIETARY RISK ASSESSMENT

### *Long-term intake*

The International Estimated Daily Intakes (IEDI) of dimethoate including its metabolite omethoate were estimated for the 13 GEMS/Food cluster diets based on 22 commodities. The results are shown in Annex 3.

The IEDI of dimethoate including its metabolite omethoate was calculated on the basis of the STMRs and STMR-Ps estimated by the JMPR in 2003/2008 for globe artichoke, Brussels sprouts, cauliflower, celery, citrus fruits, head lettuce, mango, olives, olive oil, sweet peppers, wheat (except flour and wholemeal), wheat flour and wheat wholemeal as sum of dimethoate and omethoate residues, considering the ten times higher toxicity of omethoate. The 1998 JMPR estimated separate STMRs for dimethoate and omethoate, arising from the use of dimethoate, for asparagus, barley, Savoy cabbage, cherries, peas (pods and succulent, immature seeds), potato, sugar beet, and garden turnip. Because no sum STMR was calculated by the 1998 JMPR, the sum of the separate STMRs of omethoate (multiplied by 10) and dimethoate was used in the IEDI calculation by the current Meeting.

The IEDI for the 13 GEMS/Food cluster diets was 20–100% of the maximum ADI of 0.002 mg/kg bw. The Meeting concluded that the long-term intake of residues of dimethoate 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 dimethoate and its metabolite omethoate was calculated for the food commodities for which maximum residue levels, STMRs and HRs were estimated by the current Meeting and for which consumption data was available: i.e., sweet peppers and head lettuce. The results are shown in Annex 4.

For head lettuce, an IESTI of 40% of the ARfD (0.02 mg/kg bw) was calculated for the general population and 80% for children 6 years and below. For sweet peppers, an IESTI of 30% of the ARfD was calculated for the general population and 80% for children 6 years and below.

The Meeting concluded that the short-term intake of residues of dimethoate (including its metabolite omethoate) from uses considered by the current Meeting is unlikely to present a public health concern.