5.17 METHOMYL (094) – ALTERNATIVE GAP

Methomyl was evaluated for residues and toxicology by the JMPR in 2001 under the periodic review programme, where MRLs for methomyl, arising from the use of either methomyl or thiodicarb on a number of commodities, were recommended.

The 2001 JMPR estimated short-term intakes that exceeded the ARfD of 0.02 mg/kg bw for apples, broccoli, Brussels sprouts, head cabbage, cauliflower, celery, water melon, grapes, kale, head lettuce, leaf lettuce, spinach, sweet corn and tomato.

At the 38th Session of the CCPR in 2006[38], the Committee requested JMPR to consider using alternative GAPs to recommend lower MRLs for apples, brassica vegetables, celery, fruiting vegetables, cucurbits, grapes, leafy vegetables and pears.

Information on current GAPs and new supervised trials data were submitted to the 2008 JMPR for cucurbits (cucumbers, courgettes and melons), grapes, lettuce and pears, and additional residue trials information was also provided for tomatoes. The Meeting also noted that the future of methomyl uses in EC Member States was uncertain.

No new residue data or information was available for brassica vegetables and celery and the Meeting agreed that the information evaluated by the 2001 JMPR was not sufficient to support the evaluation of an alternative GAP for these commodities.

Results of supervised residue trials on crops

Apples

Based on US GAP and residue data for thiodicarb and methomyl, the 2001 JMPR estimated a maximum residue level of 2 mg/kg, an STMR of 0.41 mg/kg and an HR (from the use of thiodicarb) of 1.6 mg/kg for methomyl in apples but indicated that the estimated short-term intakes for apples were 770% (children) and 260% (general population) of the ARfD (0.02 mg/kg bw).

The Meeting noted that the US GAP for thiodicarb, on which the 2001 JMPR had based its recommendations was no longer supported and that thiodicarb authorisations in EC Member States were also no longer supported.

Residue trials with methomyl, evaluated by the 2001 JMPR from trials in Europe matching the current GAP of Spain (0.05 kg ai/hL, PHI 7 days) and France (0.05–0.75 kg ai/hL) reported residues of 0.03, 0.05, 0.06, 0.06, 0.08, 0.08, 0.09, 0.09, 0.09, 0.1, 0.11, 0.13, 0.15, 0.16, and 0.17 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg for methomyl in apples and estimated an STMR of 0.09 mg/kg and an HR of 0.17 mg/kg. The Meeting withdrew its previous recommendation of 2 mg/kg.

Pears

Based on GAP for methomyl in France and Spain and using methomyl residue data on pears and apples from Europe, the 2001 JMPR estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.09 mg/kg and an HR of 0.18 mg/kg for methomyl in pears and indicated that the estimated short-

[38] Codex Alimentarius Commission. *Report of the 38th Session of the Codex Committee on Pesticides Residues, 3–8 April 2006, Fortaleza, Brazil,* (ALINORM 06/29/24)

term intakes for pears were 50% (children) and 30% (general population) of the ARfD (0.02 mg/kg bw).

The Meeting noted that a revised variability factor used in the IESTI calculations had been adopted since 2001 and based on a re-calculation of the short-term intake estimation, the Meeting estimated revised short-term intakes of 40% (children) and 20% (general population) of the ARfD.

The Meeting agreed that an alternate GAP evaluation was therefore not required for methomyl on pears and confirmed the maximum residue level of 0.3 mg/kg for pears, as recommended by the 2001 JMPR.

Grapes

Based on GAPs and residue data for methomyl and thiodicarb on grapes in USA and France, the 2001 JMPR estimated a maximum residue level of 7 mg/kg, an STMR of 0.86 mg/kg and an HR (from the use of methomyl) of 5.2 mg/kg for methomyl in grapes but indicated that the estimated short-term intakes for grapes were 1600% (children) and 470% (general population) of the ARfD (0.02 mg/kg bw).

The results of new methomyl residue trials in France, Greece, Italy and Spain were made available to the Meeting. The Meeting noted that thiodicarb authorisations in the EC were also no longer supported and that the use of thiodicarb on grapes was also no longer supported in USA.

GAP for methomyl in France is 0.5 kg ai/ha (max), PHI 7 days for wine grapes and 28 days for table grapes. Residues in trials matching the GAP for wine grapes in France (at a PHI of 7 days) in trials evaluated by the 2001 JMPR and in the more recent trials were: 0.01, 0.04, 0.05, 0.07, 0.08, 0.09, 0.09, 0.09, 0.1, 0.14 and 0.2 mg/kg (n = 11).

In trials matching the GAP for table grapes in France (at a PHI of 28 days), residues were: < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, 0.02, 0.02, 0.03, 0.05 and 0.08 mg/kg (n = 11).

The Meeting agreed it was appropriate to use the data supporting the GAP for table grapes to determine an STMR and HR for dietary intake estimation and the data supporting the GAP for wine grapes to determine an STMR-P for wine and to estimate a maximum residue level.

The Meeting estimated a maximum residue level of 0.3 mg/kg for methomyl in grapes based on the results matching the wine grape GAP and estimated an STMR of 0.01 mg/kg and an HR of 0.08 mg/kg based on the results matching the table grape GAP.

Fruiting vegetables, Cucurbits

Based on GAPs in France and Netherlands and using residue data for methomyl on cucumbers, summer squash and melons in Europe and based on US GAP and residue data on watermelons, the 2001 JMPR estimated a maximum residue level of 0.1 mg/kg, an STMR of 0.02 mg/kg and an HR of 0.07 mg/kg for methomyl in cucurbit vegetables but indicated that the estimated short-term intake for watermelon was 140% of the ARfD (0.02 mg/kg bw) for children.

The Meeting noted that a revised variability factor used in the IESTI calculations had been adopted since 2001 and based on a re-calculation of the short-term intake estimation, the Meeting decided that the recommendations from the 2001 JMPR did not result in any dietary intake concern with the highest short-term intake being for watermelons, at 80% of the ARfD for children.

The Meeting agreed that an alternate GAP evaluation was therefore not required for methomyl on cucurbit vegetables and confirmed the maximum residue level of 0.1 mg/kg for cucurbit vegetables, as recommended by the 2001 JMPR.

Tomato

Based on GAPs and residue data for thiodicarb on protected tomatoes in Australia and Spain, the 2001 JMPR estimated a maximum residue level of 1 mg/kg, an STMR of 0.16 mg/kg and an HR (from the use of thiodicarb) of 0.73 mg/kg for methomyl in tomatoes but estimated that the short-term intake for tomatoes was 190% of the ARfD (0.02 mg/kg bw) for children.

The Meeting noted that a revised variability factor used in the IESTI calculations had been adopted since 2001 and based on a re-calculation of the short-term intake estimation; the Meeting decided that the recommendations from the 2001 JMPR did not result in any dietary intake concern, with the highest short-term intake being 100% of the ARfD for children.

The Meeting agreed that an alternate GAP evaluation was therefore not required for methomyl on tomato and confirmed the maximum residue level of 1 mg/kg for tomato, as recommended by the 2001 JMPR.

Leafy vegetables

Based on GAPs for methomyl and/or thiodicarb on lettuce, spinach and collards in USA and on residue data from USA on head lettuce (thiodicarb), leaf lettuce (thiodicarb), collards (thiodicarb) and spinach (methomyl and thiodicarb), the 2001 JMPR estimated a maximum residue level of 30 mg/kg, an STMR of 1.4 mg/kg and an HR (from the use of thiodicarb) of 25 mg/kg for methomyl in leafy vegetables but estimated that the respective short-term intakes for head lettuce, leaf lettuce and spinach were 3000%, 3800% and 7200% of the ARfD (0.02 mg/kg bw) for children and 2000%, 1500% and 2800% of the ARfD for the general population.

The Meeting noted that no additional information had been received to support consideration of an alternative GAP for thiodicarb on leafy vegetables and agreed to evaluate an alternative GAP for methomyl alone.

Lettuce

The Meeting received results of new residue trials with methomyl on lettuce in France, Italy. In Spain, GAP for lettuce is 0. 5 kg ai/ha, maximum 2 applications/season (at least 14 days apart), PHI 14 days and in trials in France and Spain matching this GAP, residues were: < 0.01, < 0.01, < 0.01 < 0.01, 0.03, 0.03, 0.04 and 0.07 mg/kg.

Residues following treatments matching the GAP of Spain but involving a single application were: < 0.01, < 0.01, < 0.01, < 0.01, 0.01, 0.02, 0.02 and 0.02 mg/kg.

The Meeting agreed that the residues from these two data sets could be combined because the residues from the initial application, at least 28 days before harvest would not contribute significant to the final residue. The combined data set was: < 0.01 (8), 0.01, 0.02, 0.02, 0.02, 0.025, 0.03, 0.04 and 0.07 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg for methomyl in lettuce, head and lettuce, leaf and estimated an STMR of 0.01 mg/kg and an HR of 0.07 mg/kg for lettuce.

The Meeting also agreed to withdraw the previous recommendation for a maximum residue level of 30 mg/kg for methomyl on leafy vegetables.

Fate of residues during processing

The Meeting estimated STMR-Ps for apples juice and tomato paste using the methomyl processing factors reported for these commodities by the 2001 JMPR.

Using the processing factor of 0.29 for apple juice and the STMR of 0.09 mg/kg proposed for apples, the Meeting estimated an STMR-P of 0.026 mg/kg for apple juice.

Using the processing factor of 0.053 for tomato paste and the STMR of 0.16 mg/kg confirmed for tomatoes, the Meeting estimated an STMR-P of 0.0085 mg/kg for tomato paste.

The Meeting received information on the fate of incurred residues of methomyl during the processing of grapes. Based on the results of four processing studies conducted in France, processing factors were calculated for a range of processing fractions including red wine (0.96), white wine (0.22), grape juice (0.19), raisins (< 0.2) and grape pomace (1).

Based on the STMR value of 0.09 mg/kg for wine grapes (estimated from the results matching the GAP for wine grapes) and the median processing factors of 0.59 (red and white wine combined), 0.22 for grape juice, < 0.2 for raisins and 1 for wet pomace, the STMR-Ps for methomyl residues were 0.053 mg/kg in wine, 0.0198 mg/kg in grape juice, 0.018 mg/kg in dried grapes and 0.09 mg/kg in grape pomace, wet.

Based on the HR of 0.2 mg/kg estimated for table grapes (estimated from the results that matched the table grape GAP) and the processing factor of 0.2 for raisins, the Meeting estimated an HR-P of 0.04 mg/kg for methomyl in dried grapes.

DIETARY RISK ASSESSMENT

Long-term intake

This evaluation of methomyl has resulted in revised recommendations for MRLs and STMRs for raw and processed commodities based on the evaluation of alternative GAPs leading to lower maximum residue levels. Consumption data were available for 40 food commodities and were used in the dietary intake calculation. The results are shown in Annex 3.

The International Estimated Daily Intakes in the 13 GEMS/Food cluster diets, based on the estimated STMRs were in the range 0–3% of the maximum ADI of 0.02 mg/kg bw (Annex 3). The Meeting concluded that the long-term intake of residues of thiodicarb and methomyl 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) for methomyl was calculated for the food commodities (and their processing fractions) for which maximum residue levels and HRs were estimated and for which consumption data were available. The results are shown in Annex 4.

The IESTI varied from 0–50% of the ARfD (0.02 mg/kg bw) for the general population. The IESTI varied from 0–100% of the ARfD for children 6 years and below. The Meeting concluded that the short-term intake of residues of methomyl from used considered by the Meeting was unlikely to present a public health concern.