5.7 DIMETHOMORPH (225)

RESIDUES AND ANALYTICAL ASPECTS

Dimethomorph was first evaluated by JMPR in 2007 (T, R) and subsequently evaluated in 2014 for residues. The 2007 Meeting established an ADI of 0–0.2 mg/kg bw and an ARfD of 0.6 mg/kg bw, and defined the residue (for compliance with the MRL and for the estimation of dietary intake) for plant and animal commodities as dimethomorph (sum of isomers).

In the 2014 Meeting, a short-term dietary intake concern for children from consumption of leaf lettuce was identified and the 47th Session of the CCPR (2015) scheduled the evaluation of an alternative GAP and of additional MRLs for dimethomorph by 2016 JMPR. This Meeting re-considered residue trials on lettuce using provided and previous information.

Methods of analysis

Method 575/0 or 535/1 was used in lettuce residue trials. In contrast to previous JMPR Meetings, it was noted that in some supervised field trials used for the analysis of samples from greenhouse trials (Ref. 2005/1027640) the method used gave inadequate mean procedural analytical recoveries (< 70%) for head lettuce and lambs lettuce. The results from these trials were not suitable for an assessment.

Validation data reported in all other supervised field trial study reports demonstrated acceptable analytical recoveries and were considered suitable for the determination of dimethomorph in various plant matrices.

Stability of pesticide residues in stored analytical samples

In all residue trials, the samples were stored at below -18 °C until analysis within a storage period known as stable up to 18–24 months in crops.

Results of supervised residue trials on crops

The Meeting received the Italian GAP and the supporting lettuce residue trials (head lettuce and lambs lettuce) cultivated in outdoor and under greenhouse conditions. The greenhouse trials were evaluated by 2007 JMPR and re-submitted to this Meeting. Leaf lettuce trials were not submitted.

This Meeting re-evaluated residue trial data on lettuce (head, lambs and leaf) against Italy GAP, using newly and previously submitted data.

Leafy vegetables (including Brassica leafy vegetables)

Lettuce, head

Eight field trials and four greenhouse trials from Southern European countries matched Italian GAP (3 × 0.144 kg ai/ha on a 7-10 day interval and with a 3-day PHI).

The residues in outdoor head lettuce were (n = 8): 0.14, 0.16, 0.27, 0.33, 0.36, 0.85, 1.2 and 1.3 mg/kg.

The residues in greenhouse head lettuce were (n = 4): 0.79, 4.0, 4.5 and 7.1 mg/kg.

Based on the residues observed in the field and the greenhouse lettuce trials, the greenhouse trials resulted in the highest residues (7.1 mg/kg). As there were only four greenhouse trials reflecting

the critical GAP in Italy, the Meeting considered these trials insufficient to recommend a maximum residue level for head lettuce.

Leaf lettuce

No new residue data supporting the Italian GAP were submitted. The Meeting considered the global data approach and decided to use residue data from the US supporting the GAP. Nine trials of eighteen outdoor trials from USA (evaluated by 2014 Meeting) could be scaled to match the Italian GAP (3 × 0.144 kg ai/ha on a 7–10 day interval and with a 3-day PHI). The trials were carried out at a higher rate of 0.225 kg ai/ha and then a scaling factor of 0.64 was used to estimate a maximum residue level.

The residues in outdoor leaf lettuce were (n = 9): 0.26, 0.43, 0.45, 1.1, 1.2, 1.3, 2.6, 3.2 and 9.7 mg/kg. The scaled residues were: 0.17, 0.28, 0.29, 0.70, 0.77, 0.83, 1.7, 2.0 and 6.2 mg/kg.

The Meeting estimated a maximum residue level of 9 mg/kg, an STMR of 0.77 mg/kg and an HR of 6.2 mg/kg.

Corn salad (Lambs lettuce)

Four new outdoor trials and three greenhouse trials from Southern European countries matched the Italian GAP (3 ×0.144 kg ai/ha on a 7-10 day interval and with a 3-day PHI).

The residues in outdoor Lambs lettuce were (n = 4): 0.35, 0.37, 3.5 and 9.7 mg/kg.

For the greenhouse Lambs lettuce trials, inadequate analytical recoveries were observed (< 70%). Therefore, residues found (6.8, 9.8 and 10 mg/kg) probably underestimated the actual residues.

Noting the use of dimethomorph on greenhouse Lambs lettuce is the critical GAP for Italy, the Meeting considered these greenhouse trials insufficient upon which to base a maximum residue level recommendation for Lambs lettuce.

Residues in animal commodities

No feed items were evaluated by the present Meeting.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue level listed in Annex 1is appropriate for establishing a maximum residue limit and for IEDI and IESTI assessment.

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: *dimethomorph (sum of isomers)*

The residue is not fat soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The International Estimated Daily Intakes (IEDIs) of dimethomorph were calculated for the 17 GEMS/Food cluster diets using STMRs/STMR-Ps estimated by the current and previous Meeting. The results are shown in Annex 3 to the 2016 JMPR Report.

The ADI is 0–0.2 mg/kg bw and the calculated IEDIs were 0–2% of the maximum ADI. The Meeting concluded that the long-term dietary exposure to residues of dimethomorph resulting from the use considered by the JMPR is unlikely to present a public health concern.

Short-term dietary exposure

The International Estimated Short Term Intakes (IESTIs) of dimethomorph were calculated for the food commodity using the HR estimated by the current Meeting. The results are shown in Annex 4 to the 2016 JMPR Report.

The ARfD is 0.6 mg/kg bw and the calculated IESTIs were 0–20% for general population and 0–60% for children. On the basis of the information provided, the Meeting concluded that the short-term dietary exposure to residues of dimethomorph, from uses considered by the Meeting is unlikely to present a public health concern.