## 5.18 FLUDIOXONIL (211)

### RESIDUE AND ANALYTICAL ASPECTS

Fludioxonil (4-(2,2-difluoro-1,3-benzodioxol-4-yl)pyrrole-3-carbonitrile) was first evaluated by the 2004 JMPR. The 2004 JMPR recommended 48 maximum residue levels for a variety of commodities and an ADI of 0–0.4 mg/kg bw. ARfD was considered unnecessary. The 2004 JMPR recommended the residue definition for plant commodities (for both compliance with the MRL and estimation of dietary intakes) should be fludioxonil. Fludioxonil is considered fat-soluble.

Fludioxonil was reviewed also by the 2006 and 2010 JMPR which together recommended six additional maximum residue levels and withdrew two previous maximum residue levels. At the Forty-third Session, CCPR included fludioxonil in the Priority List for review by the current Meeting for an additional MRL.

After the 2010 JMPR, a post-harvest use of fludioxonil on mango was approved and the label was available to the current Meeting from South Africa. The current Meeting received information on residue trials conducted in Australia and South Africa to support this use, along with information on methods of analysis for fludioxonil in mango.

#### *Methods of analysis*

The Meeting received information on validation of three methods of analysis used in the supervised field trial studies, HPLC/UV method already reviewed by the 2008 JMPR and two new methods, GC/MS method and HPLC/MS/MS method, for determination of fludioxonil in mango. These methods were satisfactorily validated for determination of fludioxonil in mango pulp and peel with mean recoveries within a range of 70–110% and RSD less than 20%.

#### *Stability of residues in stored analytical samples*

The 2004, 2006 and 2010 JMPR concluded that fludioxonil is stable when stored frozen for at least the following periods: 24 months in apple and grape; 14 months in grapefruit; and 10 months in lemon pulp and potato. In supervised trials, samples were stored deep-frozen for a maximum of 8 months.

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

The Meeting received information on supervised post-harvest trials of fludioxonil on mango.

The OECD MRL calculator was used as a tool to assist in the estimation of maximum residue levels from the selected residue data set obtained from the supervised residue trials. As a first step, the Meeting reviewed trial conditions and other relevant factors related to each data set to arrive 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, a brief explanation of the derivation was supplied.

*Mango*

A number of trials were conducted in Australia and South Africa. The registered post-harvest use of fludioxonil on mango in South Africa allows hot dip at 52 °C for a minimum of 30 seconds to a maximum of 5 minutes at the maximum rate of 34.5 g ai/hL. As the intended use was post-harvest application, the trials conducted in Australia and those in South Africa using post-harvest application were considered together.

Residues in whole fruit (including stone) from trials conducted in Australia and South Africa using post-harvest application following GAP in South Africa were in rank order (14): 0.29, 0.31, 0.34, 0.36, 0.37, 0.42, 0.49, 0.59, 0.62, 0.66, 0.67, 0.74, 1.1 and 1.2 mg/kg.

Corresponding residues in pulp, in rank order were (n = 14): < 0.01 (6), < 0.02(4), 0.02, 0.04(2), and 0.09 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg and an STMR of 0.02 mg/kg.

## DIETARY RISK ASSESSMENT

### *Long-term intake*

The International Estimated Daily Intakes (IEDIs) of fludioxonil were calculated for the 13 GEMS/Food cluster diets using STMRs and STMRPs estimated by the 2004, 2006, 2010 and current Meetings (Annex 3). The ADI is 0–0.4 mg/kg bw and the calculated IEDIs were 0–2% of the maximum ADI. The Meeting concluded that the long-term intake of residues of fludioxonil resulting from the uses considered by the 2004, 2006, 2010 and current JMPR is unlikely to present a public health concern.

### *Short-term intake*

The 2004 JMPR concluded that an ARfD for fludioxonil is unnecessary. The Meeting therefore concluded that the short-term intake of fludioxonil residues is unlikely to present a public health concern.