5.16 FLUDIOXONIL (211)

RESIDUE AND ANALYTICAL ASPECTS

Fludioxonil, a fungicide to control plant-pathogenic fungi such as *Botrytis cinerea,* was first evaluated at the 2004 JMPR Meeting. That Meeting established an ADI of 0–0.4 mg/kg bw and considered that an ARfD was unnecessary. The Meeting concluded that the residue definition for plant commodities for compliance with the MRL and for consumer risk assessment was fludioxonil only. A number of maximum residue levels were proposed, but in 2004, no maximum residue level was recommended for the post-harvest use on pomegranate or yam. At that time no GAP was available for pomegranate and the number of trials at the critical GAP for yams was insufficient. A maximum residue level for citrus fruit was recommended based on post-harvest uses. However, since the last evaluation a new GAP has been introduced for post-harvest applications of fludioxonil to citrus fruits, in which the maximum application rate has been doubled and further residue studies have been carried out. Furthermore, additional data has been submitted by the manufacturer to support the use of fludioxonil on pomegranate and root & tuber vegetables.

Methods of analysis

In the newly submitted supervised residue trials, fludioxonil (parent only) was analysed by either method REM 133.04 or AG-597B, or slight modifications thereof. JMPR 2004 concluded the following on these methods: 'Methods REM-133/AG631A and AG-597 are suitable for the determination of fludioxonil in samples of plant origin. The methods are fully validated for a range of crops and crop types.'

In the current trials, the methods were validated for the range of LOQ to at least the highest residue value measured, with an LOQ of 0.02 mg/kg for citrus fruits, sweet potato and pomegranate, 0.03 mg/kg for older pomegranate studies and 0.04 mg/kg for yams.

Stability of pesticide residues in stored analytical samples

The 2004 Meeting concluded that fludioxonil is stable in an array of stored frozen commodities. No degradation of fludioxonil was observed in any frozen commodity throughout the duration of the studies. Fludioxonil is stable for at least 24 months in frozen samples of the following commodities: cereal grains, cereal straw, apple, tomato, grape, pea, rape-seed, maize grain, maize meal, sorghum hay, potato tuber and potato flake. Fludioxonil is stable for at least 12 months in frozen broccoli, cabbage and carrots and for 9 months in frozen chives. Fludioxonil is also stable for at least 3 months in frozen peach, plum, cherry and blueberry.

Additional storage stability studies on citrus, sweet potato and yam were available to the Meeting. Fludioxonil is stable for at least 14 months in frozen samples of citrus, and at least 10 months in lemon juice and pulp. Fludioxonil is also stable for at least 10 months in sweet potato and for 5 months in yam. Based on these data, the Meeting concluded, that no storage stability problems are to be expected in these commodities since samples were stored for less than the period tested for in the storage stability studies. Storage of pomegranate samples is covered by results for citrus fruits.

Results of supervised trials on crops

Supervised trials with fludioxonil were conducted with post-harvest treatment of citrus fruit, pomegranate, sweet potato and yam.

Citrus fruits

Since 2004, 27 new trials have been carried out in the USA and in the EU. Citrus fruit was treated with fludioxonil in post-harvest residue trials in oranges (10), lemons (5), grapefruit (4) and mandarins (8). Citrus fruits were treated once, twice or three times by post-harvest dip or drench (30-240 g ai/hL) or spray (1-4 g ai/tonne fruit).

The critical GAP in the US is 2 applications of dip or drench at 120 g ai/hL and/or spray at 4 mg ai/kg fruit. No minimum time for interval between applications is given. As residue decline studies show that the residue is stable in time, interval duration does not significantly influence final residue values. For compliance with worst case GAP, all trials conducted with two applications at worst case GAP-rate (± 25% of overall application rate) were considered, regardless the length of interval between applications.

The selected residue levels on orange (seven trials; two treatments at GAP rate) in ranked order, were: 2.9, 3.5, 4.0, 4.4, 4.6, 5.0 and 7.2 mg/kg. The levels on mandarin (seven trials; two treatments at GAP rate) were: 2.9, 5.6 (2), 5.8, 7.0, 7.3 and 7.8 mg/kg. The residue level on lemon (two trials at 75% of GAP rate) were: 2.5 and 3.9 mg/kg.

No trials that were summarised in JMPR 2004 complied with the newly introduced critical GAP. The Meeting decided to estimate a maximum residue level based on the data from mandarin; the data from orange and lemon are used for support. The Meeting estimated a maximum residue level for whole citrus of 10 mg/kg. In the selected trials, residue in the pulp was not measured. However, in 47 of the other citrus trials residues in peel and pulp were determined and a processing factor of 0.07 for residue in citrus pulp could be derived. An STMR-P of 0.41 (5.8×0.07) mg/kg was estimated, for citrus pulp.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 11 mg/kg. Since the total dose is 8 mg/kg (post-harvest), the Meeting considered that 10 mg/kg was sufficient.

Pomegranates

Since 2004, four post-harvest trials on pomegranate have been conducted according to the critical GAP in the USA, i.e. a single dip or drench application at 60 g ai/hL. Another two trials with the same applications were summarised in JMPR 2004. All trials are considered appropriate to be included in MRL setting and calculation of STMR.

The residue levels on pomegranate (six trials) in ranked order, were: 0.65, 0.80, 0.95, 1.1, 1.2 and 1.3 mg/kg. The Meeting estimated a maximum residue level for pomegranate 2 mg/kg and an STMR of 1 mg/kg.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 2 mg/kg.

Root and tuber vegetables

Four post-harvest trials on sweet potato tubers have been conducted in the USA and two trials on yam tubers have been conducted in Puerto Rico (also summarised in JMPR 2004, but with some errors). All trials were conducted according to the range specified in the recommended GAP. Two sweet potato trials in the USA (2.5 and 2.8 mg/kg) and two yam trials in Puerto Rico (4.2 and 5.7 mg/kg) comply with the critical GAP, i.e., a single application at 60 g ai/hL.

The residue levels on yams and sweet potatoes (four trials) were used in mutual support. The Meeting estimated a maximum residue level for yams and sweet potatoes of 10 mg/kg and an STMR of 3.5 mg/kg.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 9 mg/kg,

Fate of residues during processing

Post-harvest treatments are normally reserved for high value commodities and it is therefore unlikely that treated crops will undergo industrial processing. However, information on the fate of incurred residues of fludioxonil during the processing of citrus fruits was submitted to the Meeting for completeness. The processed commodities obtained from industrial processing are juice, marmalade, and wet and dry pomace from orange (one trial), and juice, oil, and pomace from lemon (one trial). For household processing (peeling and washing), data on residues in peel, pulp and washed fruit was available in most of the supervised residue trials.

For pulp, the calculated processing factor is very low (0.07) due to the fact that the fruit was peeled on the same day as the day of last application. Therefore, time for translocation of fludioxonil from the peel to the pulp was very limited, explaining the low processing factor for pulp. Only in 3 samples, another application was made 2 days before, as in all other samples, no other application was performed or it was performed at the same day as the last application. If the fruit is stored for longer periods before peeling, the processing factor for pulp will likely be higher. The other way around is the processing factor of 3.2 for peel derived from a worst-case scenario and this factor will likely be lower if fruit is stored for longer periods before peeling. For washed fruit, it can be concluded that the processing factor is not influenced by the period between last treatment and the washing of the fruit. Therefore, all trials are included in the calculation of the overall processing factor for washing (0.67).

Data on different kinds of citrus fruit (lemon, mandarin, orange and grapefruit) can be combined to derive one processing factor for each processed commodity of citrus fruit.

Processing factors and STMR-P values in citrus fruit

Commodity	Processed commodity	PF (mean)	STMR-P
Citrus fruit (STMR = 5.8)	pulp	0.07	0.41
	juice	0.11	0.64
	dry pomace	6.4	37

Residues in animal commodities

Waste pulp (pomace) from processed citrus fruits can contribute to animal diets and is listed on the OECD Dietary Burden Calculator. However, in commercial practice, post-harvest treatment is normally reserved for high value commodities and it is therefore unlikely that pomace from treated fruits would be fed to livestock. As a result of this, the Meeting considered that the proposed MRL and STMR for fludioxonil in citrus crops will not change the dietary burden calculation which was evaluated at the 2004 JMPR meeting.

Pomegranate and tropical root and tuber vegetables are not regarded as crops contributing significantly to animal diets and do not appear on the OECD Dietary Burden Calculator. Therefore the Meeting retained the recommendations for animal commodities as reported in 2004.

DIETARY RISK ASSESSMENT

Long-term intake

The IEDI of fludioxonil based on the STMRs for 48 commodities for the 13 GEMS/Food regional diets were 1–2% of the maximum ADI of 0.4 mg/kg bw (see Annex 3 of the Report). The Meeting

concluded that the long-term dietary intake of residues of fludioxonil is unlikely to present a public health concern.

Short--term intake

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