

## **An urgent industry response to the APVMA Chemical Review Program**

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### **Abstract**

As with other jurisdictions the APVMA is re-evaluating many pesticides to ensure that they meet current standards of safety and performance. As part of this process both dimethoate and fenthion are currently under review. Dimethoate has recently been reviewed internationally at Codex, the US and by the European Union, the outcome of which has been the loss of a number of uses.

A significant issue has been the lack of relevant data to support the continued use of the pesticides in crops. In the Australian reviews of dimethoate and fenthion, residue trial data relating to use patterns that will satisfy APVMA requirements will be needed. A preliminary assessment has indicated that the uses of dimethoate and fenthion in stonefruit will come under significant pressure. The most problematic are the **post-harvest treatments**; for these it is highly likely that the outcome of the review will be their **removal from the label**. For in-field use, it is expected that the provision of current residue data would result in a positive outcome and retention of the use. Therefore, to address the potential problem the industry needs to consider the possible funding of residue trials.

### **Introduction**

The APVMA (Australian Pesticide and Veterinary Medicine Authority) review of chemicals looks at the environmental, occupational health and safety, trade and human safety issues and attempts to assess the level of risk that might be posed by current uses. The aim is to ensure that uses for chemicals under review meet contemporary safety and performance standards. To undertake these risk assessments the APVMA needs to have access to current relevant data.

The outcome of these reviews can often be a proposal to remove a specific chemical use due to problems being identified as part of a risk assessment. This can occur either from specific concerns identified in the assessments, or the absence of suitable data, i.e., due to insufficient data the APVMA takes a worst case approach.

The pesticides dimethoate (Rogor, Saboteur etc) and fenthion (Lebaycid) are currently being reviewed by the APVMA. Both are used widely on a variety of fruit and vegetable crops including stone fruit. A combination of potential concerns arising from the risk assessments and the lack of suitable data means that many current uses for these two chemicals will probably come under significant regulatory pressure.

The review of fenthion commenced in 2002 but was delayed, in part to allow it to be done in parallel with the review of dimethoate. It is anticipated that both two reviews will be progressed during 2006 with Draft Reports becoming available towards the end of the year.

### **Risk assessments – Dietary intake**

One significant area of concern is short-term dietary intake, i.e., consumers' potential exposure to expected residues of a chemical. These risk assessments involve estimating pesticide residues in a commodity, and relating this to consumption data to calculate the potential level of pesticide exposure over a short time period, i.e., a single day. The derived value is then compared to an acute reference dose (ARfD)

calculated on the levels of pesticide known to cause acute toxicological effects. If the ARfD is exceeded, an MRL will not be promulgated. This area of risk assessment potentially raises concerns about both dimethoate and fenthion when they are used on commodities with edible peel, e.g., stone fruit.

The estimate of pesticide residues ingested is calculated by multiplying the expected residue in a commodity by the large portion size consumed and divided by average body weight of a consumer. Ideally residue trial data is needed, but if such data is lacking MRLs are often used. See the basic equation below.

$$\text{Dietary intake} = \frac{\sum \text{residue} \times \text{consumption}}{\text{bodyweight}}$$

As example preliminary calculations were done using the MRL for fenthion and dimethoate as the default value for residues and based on children (6 years and under). The reasons for this are:

- short-term intakes expressed as per kg of body weight are usually higher for children than for the total population,
- food consumption per kg body weight is usually higher for children,
- children are considered the most vulnerable segment of the population.

No acute reference dose (ARfD) has as yet been established for dimethoate in Australia. To undertake the preliminary assessments an ARfD, equivalent to the Australian ADI (0.02 mg/kg bw/day) was used. An Australian ARfD of 0.007mg/kg bw/day has been established by the Therapeutic Goods Authority (TGA) for fenthion. Values highlighted in bold exceed the ARfD.

**Table 1.** Calculated acute intakes of dimethoate resulting from consumption of treated produce for children less than 6 years of age.

Commodity	MRL mg/kg	Intake, mg/kg bw/day	% acute RfD
Apricot	5	0.2065	<b>1032.6</b>
Cherries	5	0.0678	<b>339.0</b>
Nectarine	5	0.1453	<b>726.6</b>
Peach	3	0.0767	<b>383.7</b>
Plums	5	0.0761	<b>380.4</b>

**Table 2.** Calculated acute intakes of fenthion resulting from consumption of treated produce for children less than 6 years of age.

Commodity	MRL mg/kg	Intake , mg/kg bw/day	% acute RfD
Apricot	5	0.2065	<b>2950.3</b>
Cherries	5	0.0678	<b>968.6</b>
Nectarine	5	0.1453	<b>2076.1</b>
Peach	5	0.1279	<b>1827.1</b>
Plums	5	0.0761	<b>1086.8</b>

Based upon these preliminary calculations, it can be seen that the estimated short-term intake of dimethoate and fenthion residues would exceed the acute reference dose (ARfD) for currently approved uses in stone fruit.

Some Australian dimethoate residue data is available from the pre and post-harvest treatment of peaches and nectarines (Projects SF97016<sup>1</sup> & SF90021<sup>2</sup>). Based on the residue levels found following post-harvest treatment, the ARfD would be exceeded by approximately 180%. For pre-harvest use the data indicates that the ARfD would not be exceeded where a withholding period of approximately 7 days was observed. Unfortunately, there is no current interstate quarantine protocol available for pre-harvest use of dimethoate.

### Data availability

The availability of relevant data, i.e., recently generated, to support the continued use of the pesticides in the various crops is likely to be a significant issue in the reviews of dimethoate and fenthion. Residue trial data that both relate to current use patterns and that satisfies APVMA requirements will be needed. As indicated above the preliminary assessment suggests that the uses of dimethoate and fenthion in stonefruit will come under significant pressure due to dietary intake concerns.

### Conclusion

The most problematic uses are the dimethoate post-harvest treatments. It is highly likely that the outcome of the review will be their removal from the label. For in-field use (both for fenthion and dimethoate), it is believed that the provision of relevant residue data would result in a positive outcome and retention of the use, through refinement of the risk assessment. For these uses the assessments need further refinement with additional data to more accurately determine the extent of the actual risk once the TGA calculated ARfD is notified. To address any potential data short-fall consideration needs to be given by industry to funding residue trials. Also, to preserve market access, industry will have to give consideration to either funding the generation of new data to maintain existing uses, or support the development of alternate procedures or technologies that will satisfy interstate and international quarantine requirements.

<sup>1</sup> Adriaansen, C. 1999. Dimethoate residue management in peaches. HAL Final Report SF97016.

<sup>2</sup> Jessup, A. and Walsh, C. 2001. Evaluation of pre-harvest dimethoate against Qld Fruit Fly for interstate certification assurance of peaches. Final Report SF98021.