



## **Dichlorvos Review – Backgrounder**

### **What is dichlorvos?**

Dichlorvos is a volatile organophosphorus insecticide with fumigant and penetrant action.

### **What is it used for?**

It is commonly used for the control of a large variety of insects in storage areas in domestic, commercial and industrial premises. Its main food use is for stored grain and potatoes, while it is also applied to animal housings, greenhouses, glasshouses, and mushroom houses. Outdoor uses include the treatment of garbage bins, picnic areas and rockeries. Home garden products are available for use in rooms or non-food storage areas such as wardrobes and drawers, or outside.

### **Why is the APVMA reviewing dichlorvos?**

Dichlorvos was nominated for review as part of the APVMA's Chemical Review Program because of its high acute toxicity and concerns over its carcinogenic potential. In December 1996, the APVMA [then the National Registration Authority (NRA)] announced that dichlorvos was one of the seven chemicals selected for reconsideration in the second cycle of the NRA's Existing Chemical Review Program. The chemical was placed under review because of toxicological concerns and human poisoning; concerns about adverse health effects in workers resulting from sprayed workplaces; regulatory actions in the USA arising from environmental concerns; and residue violations in cereals and their products.

### **What aspects of dichlorvos is the AVMA reviewing?**

The APVMA review covers all aspects of the use of dichlorvos products, including toxicology and public health, occupational health and safety, residues in food, the safety of the environment, and the adequacy of label instructions and warnings. It is considering the approval of active constituents, the registrations of all products using dichlorvos as an active constituent, and also the approvals of product labels.

### **What kind of information did the APVMA assess?**

The information assessed in the review included a large number of published and unpublished scientific studies. In conducting the review of dichlorvos, the APVMA obtained specialist advice from the Office of Chemical Safety within the Department of Health and Ageing, and from the Department of the Environment, Water, Heritage and the Arts (DEWHA).

### **What are APVMA review's key findings so far?**

Based on the available data, the APVMA considers that the information available to its review enables it to make the following conclusions:

- The active constituent dichlorvos meets the requirements for continued approval.
- The home garden product 'Sureguard Pest Strip Household Insecticide' (product number 45596) poses an unacceptable chronic inhalational risk to human health.
- There is insufficient information to predict the extent of operator exposure in relation to application of dichlorvos by the following methods - surface sprays, space sprays, crack and crevice treatments, pressurised gas in enclosed spaces where the operator must enter the space under fumigation, outdoor and indoor applications by fogging or misting, mechanical applications to

grain, foliar application to avocados, application by paintbrush, and application by watering can in household situations. Modelling studies showed that operator exposure could occur at unacceptable levels.

- Insufficient data were available to allow the establishment of appropriate MRLs for potatoes, mushrooms and food crops grown in glasshouses and greenhouses. Without information relating to residues in crops and commodities in these situations, the resulting dietary exposure to dichlorvos residues from such uses cannot be estimated.
- Detectable dichlorvos residues are not expected to occur in animal commodities as a result of the post-harvest use of dichlorvos on cereal grains or from other approved uses. Therefore, continued use of registered dichlorvos products would not unduly prejudice trade between Australia and places outside Australia.
- The safety directions on the existing product labels are inadequate as they do not reflect current specifications contained in the First Aid Instructions and Safety Directions Handbook. Similarly, the product labels do not contain adequate instruction to protect the environment.
- The existing product labels do not carry adequate instructions for Re-entry Intervals to prevent post-application exposure of people to levels of dichlorvos that may be harmful. It is recommended that labels of relevant products be varied to impose appropriate re-entry intervals.

#### **What does the APVMA propose to address the above findings?**

To address the key proposed findings outlined above, the APVMA is proposing the following regulatory path.

#### **Active constituent**

The active constituent approvals can be affirmed. However, the approval holders will be required to provide justification, on toxicological grounds, for inclusion of a recommended impurity limit for chloral at 5 g/kg in the standard for the dichlorvos active constituent.

#### **Product labels**

For continued registration, the labels of products will need to be amended ('varied') as follows:

Include:

- Appropriate restraints, first aid and safety directions and personal protective equipment
- Instructions and restraints for environmental protection
- Appropriate REIs
- Appropriate with-holding periods and out-turn periods
- Restrictions to limit the use on stored grains to stored cereal grains only
- Restrictions to limit the use in empty silos to empty grain silos

Delete:

- Post-harvest use of dichlorvos on pulses, and use on avocados, mushrooms, potatoes, greenhouse/glasshouse crops (excepting ornamentals).
- Use patterns involving surface spraying; space spraying; crack and crevice treatment; outdoor and indoor application by fogging or misting; mechanical application to grain; pressurised gas in enclosed spaces where the operator must enter the space under fumigation; portable fogging or misting equipment in enclosed spaces where the operator must enter the space under

fumigation; application by watering can; application by paintbrush; and broadacre application to avocados.

### **Product registrations**

Continued use of or any other dealing with the product Sureguard Pest Strip Household Insecticide (APVMA product code 45596) is likely to have a harmful effect on human beings. Therefore, as a consequence of the proposed finding of the review, the supply and use of this product will be stopped.

The registration of other dichlorvos products will be continued if the product labels are amended as discussed above.

### **Is the APVMA proposing to take regulatory action now?**

At this stage, the publication of the Preliminary Review Findings document does not indicate the final actions being taken by the APVMA, it simply flags its proposed regulatory action for comment from the public, the agricultural chemical industry and users, before a final decision on review outcomes is made.

Accordingly, the findings and the regulatory actions outlined in the PRF are referred to as 'proposed findings' and 'proposed regulatory actions'.

### **How can interested parties provide comment?**

The APVMA invites persons and organisations to submit their comments and suggestions on this Preliminary Review Findings document directly to the APVMA. Your comments will assist the APVMA in preparing the Final Review Report and Regulatory Decision. Submissions specifically addressing the areas of concern noted in the Preliminary Review Findings report must be in writing and reach the APVMA by 29 August 2008.

Submissions can be sent either by email to [chemrev@apvma.gov.au](mailto:chemrev@apvma.gov.au) or by mail to:

Manager, Dichlorvos Review  
Australian Pesticides & Veterinary Medicines Authority  
PO Box 6182  
KINGSTON ACT 2604

### **What are the next steps in the review?**

After the public consultation period, the APVMA will revise the technical assessments and the PRF if necessary. If warranted, it will also amend the review findings and the regulatory framework. It will then publish the Review Findings and Regulatory Decisions document. It will also exercise the regulatory actions outlined in that document.

### **What is the impact of the proposed regulatory actions on stakeholders?**

APVMA's remit is to protect human health, the environment and Australia's international trade. The proposed regulatory actions will protect the public, workers and the environment from unacceptable exposure to dichlorvos.

Since the time dichlorvos was placed on the ECRP list of chemical to be reviewed, several use patterns appear to have changed. It is possible that users might opt to achieve necessary pest control with other currently available chemicals.

However, the stored-grain industry may consider the use of dichlorvos to be critical in certain situations. The APVMA's proposed regulatory action to delete the specific use(s) by stored-grain industry is necessitated because of lack of worker exposure

data. If the industry decides that it wants to retain the use on stored-grain, they will need to conduct studies to generate worker exposure data to show acceptable levels of exposure.

As the PRF indicates that the estimated worker-exposure exceeds acceptable levels, the APVMA will allow interim use for a period necessary to generate exposure data, but only if the stored-grains industry can implement necessary measures to mitigate the risks.