

## **RECONSIDERATION OF REGISTRATIONS OR APPROVALS (CHEMICAL REVIEW)**

### **When the APVMA gives notice of proposed reconsideration (review)**

Before reconsidering the approval of an active constituent, the registration of a chemical product or the approval of a label the APVMA may, if it thinks it appropriate, publish a notice stating that it proposes to reconsider (review) the approvals or registrations relating to a specific chemical or a group of chemicals. In this notice the APVMA will invite the public to make a written submission to the APVMA in relation to the review. In most cases this is in the form of a gazette notice.

New legislation now requires the APVMA to set out the matters to be dealt with in the review and the issues of concern (in relation to the legislative criteria for safety, efficacy and trade) that form the basis of the review when seeking public submissions.

This new requirement has in fact already been implemented for some time in the form of our review scope documents, which now accompany the announcement of the reconsideration/review. In line with the new legislation the review scope document sets out the reasons for review, issues of concern and therefore the scope of the review and lists the actives, products and labels to be affected by the review.

### **When the APVMA decides on the outcome of a review**

A review can result in one of three broad outcomes:

- The APVMA is satisfied that active constituents, products and/or labels continue to meet the conditions to which registration or approval are currently subject and confirms the registration and approvals; or
- The APVMA is satisfied that the conditions to which the registration or approval are currently subject can be varied in such a way that the requirements for continued registration or approval will be complied with, and varies the conditions of approval or registration; or
- The APVMA is not satisfied that the conditions continue to be met and suspends or cancels the registrations or approvals.

New legislation requires that we change the process whereby the APVMA varies the relevant particulars and/or conditions of approval or registration. In particular, if the recommendation from the review is that a label is to be varied then the label variations can only be approved, that is the outcome of the review decided, after a new label has been provided to the APVMA. Further, if the variation affects any instructions for use the APVMA must finalise the variation until it has consulted State co-ordinators and taken into account any recommendation made by the co-ordinators.

Before proceeding to make a decision to vary a label the APVMA will write to registrants requiring them to provide a new label that includes the variations. The

type of label we will require will be the same type that we require under the normal label approval process. The registrant will be given a certain time to provide this label. This timeframe will be closely aligned with particular Board meetings where the final review report and recommendations are to be presented to the Board for decision. The timeframe will factor in the need to consult State co-ordinators before the Board makes the decision.

If a label is not provided in the timeframe specified the Board will be unable to make a decision on that label and/or associated product. In these circumstances it will be most likely that the label approval will be suspended or cancelled until such a time that a new label is provided and the Board is able to make a decision. .

### **When the decision is to suspend or cancel**

The registrant or the appointed approved person will be notified by the APVMA when a decision to suspend or cancel an active, product or label has been made. The notice will give the reasons for the suspension or cancellation, instructions for possessing, supplying or using the active or the product and a warning of the consequences if instructions are not complied with. The new legislation permits continued possession, supply and use in accordance with the instructions for a two-year period unless the APVMA decides otherwise (eg where continued possession, supply and/or use of the active or product is harmful, ineffective or may prejudice trade).

When a decision to suspend or cancel is made the APVMA will also publish a notice to this effect. This notice will be similar to the notice issued to the registrant and will contain the relevant instructions for possessing, supplying or using the active or the product and a warning of the consequences if instructions are not complied with. The notice will also provide details on whether the 'deemed' permit for continued possession, supply and use will apply.

### **Data protection**

The right of the data owner to compensation for the use of the data in relation to other application does not apply if the APVMA has received the information 'voluntarily' eg with an application for registration or approval or in response to a call for general public comment.

The APVMA will be requiring registrants or the appointed approved person to declare that any data/information that they have provided in response to a specific data request has not previously been submitted to the APVMA.

