



## REVIEW OF AGRICULTURAL AND VETERINARY CHEMICALS

**The Australian Pesticides and Veterinary Medicines Authority (APVMA) has a Chemical Review Program which can reconsider the registration of agricultural and veterinary chemicals in the marketplace if potential risks to safety and performance have been identified. A review may be initiated when new research or evidence has raised concerns about the use or safety of a particular chemical or product.**

**Reviews may focus on one or more areas of concern including environmental safety, worker safety, public health, residues or trade, or less commonly, may consider product efficacy. The scope of a review is determined by the specific concerns about the chemical.**

### History

When the National Registration Scheme was introduced in March 1995, the APVMA assumed responsibility for over 5000 chemical registrations granted under earlier arrangements in Australia's States and Territories. Some of these were issued as far back as the 1950s.

Considerable new data have been generated, both here and overseas, for chemicals which have been on the market for a number of years. Sometimes this data may indicate that certain older chemicals need to be reassessed.

### Legislative Basis

The APVMA has powers under the Agricultural and Veterinary Chemicals Code Act 1994 to conduct reviews of registered chemicals.

In broad terms, these powers include the authority to reconsider the registration of products and approvals of active ingredients and labels, and to require registrants to provide information. Relevant trial work can be requested to generate results needed for consideration, and additional

information can be requested for delivery within specific timeframes. Outcomes of a review can include the suspension or cancellation of the product's registration and the approval of active ingredients and labels.

### People Involved in Reviewing Chemicals

The APVMA draws on the specialist expertise of its own staff and that of other Australian government agencies in the review of agricultural and veterinary chemicals. Work teams conducting reviews comprise:

- APVMA review managers, responsible for project management of individual chemical reviews;
- specialist staff in the APVMA who review details of product efficacy, chemistry, residues and implications for trade;
- evaluators in the Chemical Assessment Section, Environment Protection Branch of the Department of the Environment, Water, Heritage and the Arts (DEWHA), who review the environmental aspects of the selected chemicals;
- evaluators in the Office of Chemical Safety of the Department of Health and Ageing who conduct human health risk assessments (public health and occupational health and safety).

### Steps in the Review Process

The time taken to conduct reviews is influenced by the number of stakeholders who need to be consulted, the amount of data that is submitted, the number of products and uses currently registered, the complexity of issues and the extent of review outcomes that require implementation.

The process for reviewing chemicals can be briefly summarised as:

1. The APVMA is made aware of concerns about a chemical, product or label, and decides whether a review is warranted;
2. The review is prioritised, scoped and scheduled based on the urgency and nature of the concerns;
3. The APVMA notifies chemical companies with active constituent approvals and registered products containing the review chemical and writes to them to submit data relevant to the scope of the review;

4. The APVMA calls for public submissions which address the benefits of, or problems with, the continued registration of the chemical under review;
5. All submissions and scientific data are evaluated by the APVMA and external advisory Australian government agencies as appropriate;
6. Based on these evaluations, a draft regulatory approach is developed. The draft report and regulatory approach are released for public comment for a period of 6-8 weeks, prior to any final regulatory decisions;
7. The APVMA CEO makes the final decision on the future use of the chemical. Generation and then evaluation of additional data may be required for chemicals where an interim regulatory approach has been approved;
8. Participants in the review are notified of the APVMA's decision and the regulatory actions are implemented;
9. Outcomes of the reviews are published in the APVMA's Agricultural and Veterinary Chemicals Gazette and the APVMA's website.

## Public Consultation

The review process generally involves extensive consultation with the public and industry.

Submissions from farmers, householders, local government authorities, pest controllers and other chemical users help the APVMA to construct a picture of chemical use, identify problems or concerns and determine implications for agriculture if a chemical is to be withdrawn or its use continued.

Accurate information about a chemical and how it is used is important in the development of realistic regulatory recommendations. Opportunity to provide feedback on the draft review recommendations is provided through the public comment period before the APVMA makes its final decision about future use of the chemical.

Individuals who make submissions to the review are invited to provide evidence (where appropriate) of whether a chemical would or would not:

- adversely affect human beings;
- be harmful to workers;
- be hazardous to the environment;
- pose a threat to trade; or
- be effective when used according to the label directions.

## Outcomes of Reviews

The APVMA must be satisfied that continued registration and approval of a chemical:

- would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues;
- would not be likely to have an effect that is harmful to human beings;
- would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; and
- would not unduly prejudice trade or commerce between Australia and other countries.

The APVMA's Chemical Review Program makes objective, scientifically based recommendations about the future registration of chemicals under review. Depending on a review's findings, chemicals (and the products containing them) might be:

- confirmed as safe and appropriate for registered use;
- restricted in use;
- required to be reformulated;
- required to have a change in labelling to limit the situations in which product/s may be used; or
- suspended, cancelled or withdrawn from the market.

## Results of Reviews

Reviews are available on the APVMA's website:

[www.apvma.gov.au](http://www.apvma.gov.au).

## CONTACTING THE APVMA

### Want more information?

If you would like to know more about the APVMA or any of its services please contact us.

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