



INFORMATION SHEET

Australian Pesticides & Veterinary Medicines Authority

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 existing agricultural and veterinary chemicals. A review may be initiated when new research or evidence raises concerns about the safety of a particular chemical or product.

Reviews may be based on one or more areas of concern including environmental safety, worker safety, public health, residues, or trade. Less commonly, a review may consider the issue of product efficacy. Depending on the degree of urgency, the APVMA may initiate a review immediately (within 28 days) or it may give notice for up to three years in advance.

History

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

Considerable new data has been generated, both here and overseas, for chemicals which have been on the market for a number of years. Sometimes information becomes available indicating that certain older chemicals need to be reassessed using the current regulatory standards.

Legislative Basis

The APVMA has powers under the *Agricultural and Veterinary Chemicals Code Act 1994* to review currently approved active constituents and registered products.

These powers allow the APVMA to reconsider the registration of chemical products, the approvals of active ingredients and labels, and to require the relevant information to be provided by sponsor companies. Relevant trial work can be requested by the APVMA to generate results needed for the review, and additional information can be requested for delivery within specific timeframes.

Outcomes of a review can include the suspension or cancellation of a 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 other Australian Government advisory agencies to review agricultural and veterinary chemicals. It may also seek advice from state and territory primary industry departments on matters relating to product efficacy. 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 of the Australian Government Department of the Environment and Heritage (DEH) who review the environmental aspects of the selected chemical
- evaluators in the Office of Chemical Safety (OCS) of the Therapeutic Goods Administration who conduct human health risk assessments (public health and occupational health and safety).

The APVMA may also call on other expert agencies for advice if required.

Steps in Review Process

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

The process for reviewing chemicals can be summarised as:

1. APVMA becomes aware of concerns about a chemical, product or label and determines if a review is warranted
2. the review is prioritised, scoped, and scheduled based on the urgency and nature of the concern
3. chemical companies that have registered products and Active Constituent approvals for the review chemical are notified and are required to submit specific data relevant to the review

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- the APVMA calls for public submissions that address the benefits of, or problems with, the continued registration of the chemical under review
- all submissions and scientific data are evaluated by the APVMA and external advisory agencies (OCS and DEH) as appropriate
- based on these evaluations, a draft regulatory approach is developed. The Preliminary Review Findings Report is generally released for public comment (for a period of 6–12 weeks), prior to any final regulatory decisions
- a regulatory approach is recommended to the APVMA Board which makes the final decision on the future use of the chemical. Evaluation of additional data may be required for chemicals for which an interim regulatory approach has been approved
- participants in the review are notified of the Board's decision and the regulatory actions are implemented
- outcomes of the reviews are published in the APVMA's Agricultural and Veterinary Chemicals Gazette and on its website

Public Consultation

The review process 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 its use is important in the development of realistic regulatory recommendations. Any feedback on the draft review should be made during the advertised public comment period and before the APVMA Board makes its final decision about future use of the chemical.

Individuals who make submissions to the review are asked 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
- be effective when used according to the label directions

Outcomes of Reviews

The APVMA must be satisfied that continued registration and approval of the 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 to the environment
- would not unduly prejudice trade or commerce between Australia and other countries

The APVMA must be satisfied that Agvet products, if used according to instructions for use, are effective for their intended use.

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
- suspended, cancelled or withdrawn from the market

Results of Reviews

Reviews are available on the APVMA's website <http://www.apvma.gov.au>. Agency contact details are listed below.

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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