



INFORMATION SHEET

Australian Pesticides & Veterinary Medicines Authority

The Adverse Experience Reporting Program for Agricultural Products

In Australia, all agricultural pesticide products that are used to prevent pests, weeds, etc infesting plants or crops, must be registered by the Australian Pesticides and Veterinary Medicines Authority (APVMA). This registration process ensures that these products on the market have been rigorously assessed and meet high standards for safety, quality and efficacy.

To ensure that high standards are maintained, the APVMA has introduced the Adverse Experience Reporting Program for agricultural products (AERP Ag) to collect information on any suspected adverse reactions (ie "adverse experiences") that might occur after the use of agricultural chemical products. The APVMA has a similar program in place for veterinary medicines (the AERP Vet).

What is the AERP Ag?

The AERP Ag is a quality assurance program established by the APVMA to facilitate responsible management of agricultural chemical products throughout their lifecycle. The aim of the AERP Ag is to ensure that products on the market remain safe, effective, are of acceptable quality and are used in the best possible way, and that instructions and warnings on labels are appropriate.

Why have the AERP Ag?

Recording and investigating reports of adverse experiences from people who use or are exposed to agricultural pesticide products is important in detecting unusual and rare conditions that were not evident in clinical or field trials prior to registration.

The purpose of the program is to provide the APVMA with feedback about the performance of pesticide products in real use situations to ensure that registration decisions being made by the

APVMA are appropriate and effective, and to promote and maintain public confidence in the APVMA and the National Registration Scheme.

Who can report on an adverse experience?

Anyone. Members of the public, farmers, agronomists, "bystanders" (ie people who have been exposed to pesticides either directly or indirectly by aerial spraying or ground rig spraying or consuming treated produce) and health workers (including doctors, nurses, alternative medicine specialists etc) are encouraged to report any adverse experiences that have occurred after the use of or exposure to pesticides that have been used according to label or APVMA Permit directions to both the APVMA and the product registrant. Such reporting is voluntary.

What does the APVMA do when it receives a report?

Reports received by the APVMA are assessed to determine whether the adverse experience is related to the use of or exposure to the product or not. The APVMA may rely on advice from other commonwealth government agencies (such as the Department of Health and Ageing), and relevant state or territory agencies (such as the relevant Department of Agriculture) when assessing adverse experience reports. The APVMA will also take into account any published material available from similar reports as well as any relevant scientific literature published worldwide.

APVMA Publications can be accessed via the world wide web.

www.apvma.gov.au

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Based on the assessment of adverse experience reports certain risk mitigation strategies or corrective actions may be required. These may include, but are not restricted to, the following:

- registration amendments, such as label changes, changes to the method of manufacture or product's physical or chemical design, changes to container design, changes to production line processes, or suspension and/or cancellation of registration and approval
- referral for action, such as compliance action, including product and batch recalls, referral to state authorities for action, or nomination of products or active constituents for formal chemical review by the APVMA, (note that once the recommendation for review has been made by the AERP the review program will conduct consultation and scoping prior to determining whether a review is necessary or not); and
- education and publicity, such as providing scientific papers or articles on issues identified for relevant journals, magazines or newspapers.

The conclusions drawn by the APVMA during investigation and evaluation of each adverse experience report will be provided to the reporting person. This will include an explanation of whether the APVMA considers that the observed adverse effects (including health symptoms) were related to the use of or exposure to the product. The APVMA will explain what these conclusions are and what corrective action, if any, will be taken in response to the information.

Reporting

Based on the assessment and evaluation of the adverse experience reports received each year, the APVMA will publish "Annual Reports of Adverse Experiences". The information in these reports will

be arranged according to the active constituent of the products, so that individual products are not identified. Only reports classified as 'probable' or 'possible' (ie where there is an association between the use of the product and the adverse experience). A summary of regulatory actions taken by the APVMA will also be included in these reports.

How Do I Make a Report

Reports should preferably be submitted using the reporting form found on the APVMA Website at:

www.apvma.gov.au/qa/subpage_qa.shtml

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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