Adverse Event Reporting Programme for Agricultural Chemicals

ACVM guideline (October 2019)

1. Introduction

The adverse event reporting programme is a quality assurance programme developed by New Zealand Food Safety, which is part of the Ministry for Primary Industries (MPI). It aims to ensure that all agricultural chemicals in the marketplace are efficacious, of acceptable quality, used appropriately, and that product labels provide sufficient consumer information for correct use.

Agricultural compounds that are applied to plants or to land, places or water in which plants or animals are managed are agricultural chemicals. The 'agricultural' reference is not intended to limit outcomes. However, the purpose for applying the product must be included in those listed in the definition* of an agricultural compound in the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 and must be intended to have an effect on animals or plants.

2. Definition of an *'adverse event'*

We define an agricultural chemical 'adverse event' as any observation in target crop, species, claim or disease or non-target plants that is unintended, and that occurs after the use of an agricultural chemical. This may include unintended effects, unacceptable residues, lack of efficacy, Good Agricultural Practice (GAP) issues, and/or application issues (such as application issues from sprayers as a result of poor quality product, sedimentation occurring after stirring/shaking, and compatibility issues).

All unfavourable or unintended events that are recognised outcomes of product use and that may or may not be identified on the product label are classified as adverse events.

3. Risks posed by agricultural chemicals

The ACVM Act legislates the importation, manufacture, sale and use of agricultural chemicals.

The purpose of the ACVM Act is to prevent or manage the following risks associated with the use of agricultural chemicals:

- risks in trade in primary products
- risks to public health
- risks to animal welfare
- risks to agricultural security.

In addition, the Act is to ensure that there are no breaches in domestic food residue standards and that there is provision of sufficient consumer information about the agricultural chemical.

During the registration process we review and appraise agricultural chemicals and they undergo a technical appraisal and risk assessment of their quality, residue profile and efficacy, as applicable. However, this process will not always detect unexpected events following the use of agricultural chemicals because of:

- the relatively small size of plots used in registration trials compared to the large land areas treated (especially due to low application rates, weather conditions, range of crops, resistance issues and so on)
- the wide range of environmental conditions, and
- the fact that it is impossible to include in registration trials all cultivars, pest/disease/weed pressures etc. that may be exposed to the product.

Therefore, even after a thorough review and appraisal prior to registration, it is possible that unforeseen problems that may affect the target crops, species, claims, diseases or trade can arise. It is critical that adverse events (see definition above) are brought to the attention of the person responsible for the product (that is, the registrant or distributor) and to our attention so that unusual, rare or individual conditions that were not evident in trials conducted before registration are detected and, if necessary, action can be taken.

4. The Adverse Event Reporting Programme

Objectives of the programme are to:

- ensure risks under the ACVM Act are appropriately managed
- maintain public confidence in the registration process.

SCOPE

The programme covers adverse event reports involving:

- target crops, species, claims, diseases
- non-target events (if a number of concerning non-target events are occurring, we may review how the product is used and revise label instructions/conditions of registration etc. if the product is not working as intended)
- inefficacy, if applicable, and
- potential residue issues.

Off-label use (that is, contrary to label directions) is also included in the programme.

SOURCE OF REPORTS

There are two complementary components of the Adverse Event Reporting Programme: registrants and others.

Registrants

The registrant component is mandatory. Registrants of agricultural chemicals must report the full details of any adverse events that they become aware of for their products.

Others

The voluntary component encourages users and the general public (including landowners, farmers, orchardists and other users) to report any adverse events to us and the product registrant.

Some adverse events are expected outcomes and are managed by registration or by label information (for example, the desired effect of agricultural chemicals such as herbicides is to control unwanted weed species). However, these adverse events should be reported when they are observed at an increased frequency or risks in relation to residues in primary produce or efficacy issues if a product is being applied at an increased rate (for example) are considerations. If there is a limited body of knowledge surrounding a recently registered agricultural chemical, reporting of adverse events is an essential tool in ensuring residue management, crop safety and efficacy of the product.

5. What to do if an adverse event occurs

If you consider an adverse reaction to have been associated with the use of a registered agricultural chemical (and is not the desired effect), you should report the matter to the product registrant (refer to the contact details on the product label). When doing so, inform them that you wish to report an adverse event. As mentioned above, the registrant must report the matter to us.

You may also provide a report directly to us using this AER form:

Adverse event report: agricultural chemicals

INFORMATION REQUIRED

Please take the time to complete the form as thoroughly as possible because this allows a more robust investigation.

CONFIDENTIALITY, RIGHTS AND RESPONSIBILITIES

All information provided on suspected adverse events is treated as confidential. However, all information we hold is subject to the provisions in the Official Information Act 1982 and the Privacy Act 1993. Any request for information will be considered on case by case basis under the Official Information Act 1982 and the Privacy Act 1993. The consideration will take into account whether the request for information relates to information that could be considered to be commercially sensitive under section 12 or Part 6 of the ACVM Act.

The Adverse Event Reporting Programme is not intended to replace a person's right or responsibility to complain to the registrant or distributor about an adverse event with an agricultural chemical.

6. What happens once an adverse event report is received

Reports made directly to us are copied to the product registrant or distributor for immediate investigation. The registrant may then contact either you or your contractor and discuss the matter to determine if any follow up laboratory, phytotoxicity, residue analysis or any other work is required.

The product registrant will subsequently provide us with an investigation report into the incident. We will assess this information and determine if the product was used according to label directions and whether any

further investigative work is required. We also consider scientific information publicly available either on the Internet or from other international regulatory agencies (such as in Australia, UK, Canada or USA).

The person making the report of an adverse event will be advised of the outcome of the investigations. This will include an explanation of whether the observed adverse effects were considered likely to be related to the use of or exposure to the product. Note that if a causal link is not established between the adverse event and the use of or exposure to the product, or if there is insufficient information to make a definite conclusion, then no action may be taken.

If an adverse event is reported directly to the product registrant, they will investigate the matter and provide a report to us. We will then assess this information and determine whether any further investigative or regulatory work is required, and if any corrective actions should be taken.

7. Possible regulatory outcomes

Based on evaluation of the investigation information, and whether there have been any other similar reports for the product, we will determine if any regulatory action is required. This may take the form of:

- additional label warning statements
- product recalls
- formulation or manufacturing process changes
- education of product users through the media or other appropriate forums, or
- tighter conditions of registration (such as restrictions on off-label use).

FURTHER INFORMATION

For further information about the Adverse Event Reporting Programme contact us:
ACVM-AdverseEvents@mpi.govt.nz

** ACVM Act definition of agricultural compound*

(a) any substance, mixture of substances, or biological compound, used or intended for use in the direct management of plants and animals, or to be applied to the land, place, or water on or in which the plants and animals are managed, for the purposes of—

- managing or eradicating pests, including vertebrate pests; or
- maintaining, promoting, or regulating plant or animal productivity and performance or reproduction; or
- fulfilling nutritional requirements; or
- the manipulation, capture, or immobilisation of animals; or
- diagnosing the condition of animals; or
- preventing or treating conditions of animals; or
- enhancing the effectiveness of an agricultural compound used for the treatment of plants and animals; or
- marking animals; and

(b) includes—

- any veterinary medicine, substance, mixture of substances, or biological compound used for post-harvest treatment of raw primary produce; and
- anything used or intended to be used as feed for animals; and
- any substance, mixture of substances, or biological compound declared to be an agricultural compound for the purposes of this Act by Order in Council made under subsection (2).