



**Australian Government**  

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**Australian Pesticides and  
Veterinary Medicines Authority**

**ADVERSE EXPERIENCE REPORTING PROGRAM FOR AGRICULTURAL  
CHEMICALS**

**GUIDELINES FOR FARMERS, CHEMICAL USERS AND MEMBERS OF  
THE PUBLIC**

# ADVERSE EXPERIENCE REPORTING PROGRAM FOR AGRICULTURAL CHEMICALS

## GUIDELINES FOR FARMERS, OTHER CHEMICAL USERS AND MEMBERS OF THE PUBLIC

*The APVMA's Adverse Experience Reporting Program for agricultural chemicals (AERP Ag) is a quality assurance program established by the APVMA to facilitate responsible management of agricultural chemical products<sup>1</sup> 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.*

### Introduction

The Australian Pesticides and Veterinary Medicines Authority (APVMA) evaluates, registers and regulates pesticide products and veterinary medicines in Australia. Pesticide products include agricultural and household products such as insecticides, herbicides and fungicides. Veterinary medicines include all veterinary products such as vaccines, antibiotics, worming treatments, and flea and tick washes.

Before a pesticide or veterinary medicine can enter the Australian market, it must go through the APVMA's rigorous assessment process to ensure that it meets high standards of safety and effectiveness.

The APVMA is committed to ensuring that pesticides and veterinary medicines sold in Australia:

- are of a high quality,
- do not pose a threat to people, domestic or native animals, crops, plants, or the environment,
- will not pose any unacceptable risk to trade with other nations, and
- continue to work effectively.

To this end the APVMA therefore operates the AERP Ag to collect as much information as possible on any suspected adverse reactions (ie "adverse experiences") that might occur after the use of pesticides in Australia.

### Purpose and objectives of the Adverse Experience Reporting Program for agricultural chemicals

The *purpose* of the AERP Ag is to provide the APVMA with feedback about the performance of agricultural chemical products in the field to:

- ensure that registration decisions being made by the APVMA are appropriate and effective, and
- promote and maintain public confidence in the APVMA and the National Registration Scheme.

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<sup>1</sup> The terms 'agricultural', 'agricultural chemical' and 'pesticide' products have the same meaning when used throughout this document.

The *objectives* of the AERP Ag are to:

- record and describe the range of common problems reported in relation to use of registered pesticides,
- identify the numbers, types and source of adverse experience reports received each year,
- process all adverse experience reports received each year in a timely manner,
- identify and take appropriate corrective actions when required for pesticide products in response to adverse experience information received each year,
- identify problems with and recommend modifications to internal APVMA procedures as necessary,
- identify and recommend relevant corrective action to application practices that are causing problems,
- identify trends and recommend further investigation,
- identify and recommend appropriate action for correcting problems with situations (eg crops, locations and areas treated), application systems and climate issues,
- report on actions taken by the APVMA in response to adverse experience information, and
- provide and maintain a database of reported effects for further study when appropriate and authorised.

### Scope of the AERP Ag

The Scope of the AERP Ag is broad and allows for the receipt of adverse experience reports involving registered agricultural chemical products (as defined in the *Agvet Codes*), when used according to label or APVMA Permit directions, for:

- human health issues, where people are exposed to these products either by using them, consuming treated produce, or as bystanders,
- animal health issues, including both domestic and native birds and animals,
- crop and plant damage,
- residue issues,
- problems that lead to unacceptable exposure to users,
- environmental damage, and
- lack of efficacy.

The scope of the program does **not** include:

- registered veterinary medicines (these are dealt with as part of the AERP *Vet*),
- trade issues, (as these are dealt with under other programs within the APVMA),
- household or home garden product issues (such as damaged packaging of home-use pesticides not caused by the product itself, minor efficacy issues), which are dealt with under other protection laws such as consumer affairs, trade practices act etc,
- packaging design faults,
- illegal off-label uses (ie contrary to label or APVMA Permit directions), or
- products not registered by the APVMA.

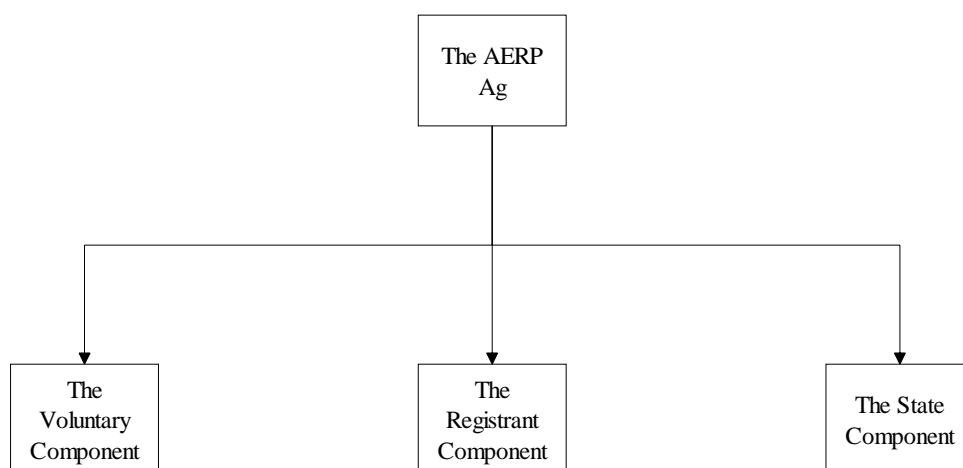
The AERP Ag may decide not to investigate a report because it falls outside the scope of the program as outlined above.

## Source of reports

The three complementary components of the AERP Ag:

1. The ‘*voluntary*’ component that encourages the general public (including farmers and other chemical users, agronomists and bystanders), and health workers (including doctors, nurses, alternative medicine specialists etc) to report any adverse experiences to both the APVMA and the product registrant.
2. The ‘*state*’ component through which state agencies are encouraged to report to the APVMA any adverse experience reports that they receive that are within APVMA jurisdiction. It also provides a mechanism for the APVMA to inform the relevant state authority of any information that it becomes aware of that falls within state jurisdiction (such as state control of use issues etc).
3. The ‘*registrant*’ component that provides a mechanism for registrants of pesticides to report to the APVMA any adverse experiences that they become aware of for their products.

**Figure 1: The AERP Ag Source of Reports**



## Definitions

### Definition of an adverse experience (including serious and minor):

*“An adverse experience is an unintended or unexpected effect (deleterious) on plants, plant products, animals, human beings or the environment, including injury, sensitivity reactions or lack of efficacy associated with the use of an agricultural chemical product<sup>2</sup> when used according to label directions<sup>3</sup>.”*

<sup>2</sup> The term ‘agricultural chemical product’ includes all pesticides and household insecticides and pesticides.

<sup>3</sup> Or “when a product is believed to have been used in accordance with the label”, this also includes APVMA Permit directions.

The following definitions outline what constitutes “serious”, “minor” and “urgent” adverse experiences.

**Definition of a serious adverse experience:**

*“A serious adverse experience is one that involves:*

- *widespread and significant crop and plant damage (eg crop death, severe stunting or significant yield loss),*
- *life-threatening or other significant effects in a human, including death,*
- *farm, domestic and native animal deaths,*
- *significant environmental damage, including fish kills and water quality issues.*

**Definition of a minor adverse experience:**

*“A minor adverse experience is one that involves:*

- *crop and plant damage that is not widespread or significant (eg minor wilting or yellowing of crops, minor yield loss),*
- *human health effects that require medical attention, but are not life-threatening,*
- *injury to domestic and native animals that require veterinary attention,*
- *minor environmental damage.”*

**Definition of urgent matters:**

*“Urgent matters include serious adverse experiences that involve acute effects.”*

**Legislation and legal issues**

It should be noted that although there is no legislative obligation for the APVMA to conduct a formal AERP (either for pesticides or veterinary medicines), the APVMA has a duty to act in relation to any adverse experience reports it receives.

## **The Voluntary Component**

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 for example 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 should you initially do if an adverse experience occurs? (see Figure 2)**

#### **Human health issues**

In situations where human health is suspected of having been affected by exposure to agricultural chemical products, the first priority is to seek medical advice either from your local doctor or medical centre or from the National Poisons Information Centre (phone 131126 from anywhere in Australia). It is important to discuss the matter with a doctor and obtain any medical treatment needed. You should also discuss with your doctor the possibility that your clinical symptoms may be related to pesticide exposure. Further advice can be sought from environmental and clinical toxicologists (who are often associated with hospitals) if human health issues continue to be of concern.

#### **Crop damage or lack of effect**

In cases where crop or plant damage is observed it is advisable to seek advice from the relevant state authority (usually the state department of agriculture) to confirm that the damage is chemical-related and whether anything can be done to minimise the damage.

#### **Animal health issues**

Veterinary advice should be sought for any adverse effect on animals. Again it is important to discuss the possibility that the clinical signs observed may be related to pesticide exposure.

#### **Environmental issues**

In cases where environmental damage (including effects on native wildlife) has been observed, it is advisable to first seek advice from the relevant state environmental authority to confirm that the damage is chemical-related and whether anything can be done to minimise the effect of the chemical.

#### **Use that is contrary to label or APVMA Permit directions**

If an adverse experience has occurred when a product was known to have been used contrary to label or APVMA Permit directions, then the matter should also be reported to the appropriate state authority responsible for the administration of the state control of use legislation, once any immediate issues have been addressed (eg if human health concerns – seek medical advice etc). It is important to note that the APVMA will only investigate matters involving products registered by the APVMA used in accordance with the label or APVMA Permit directions.

## Reporting the matter to the product registrant

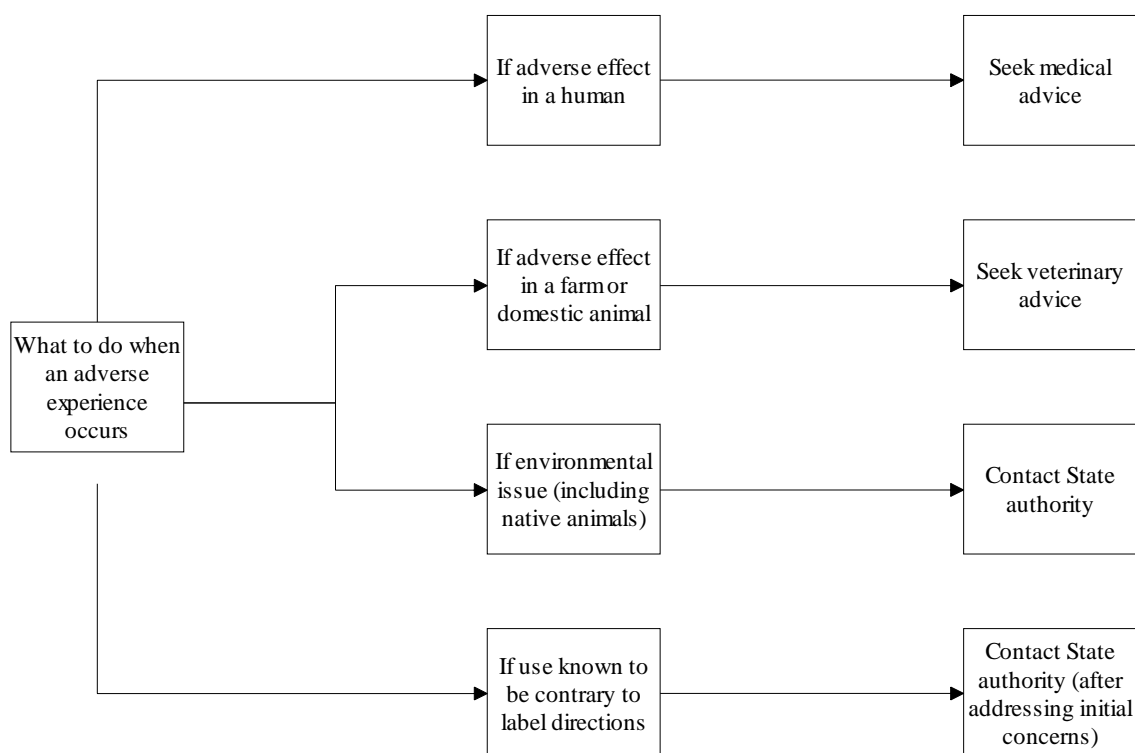
All adverse experiences should also be reported to the chemical company responsible for the product used (ie the product registrant). Contact information is available on the product label.

## Reporting the matter to the APVMA

Reports of adverse experiences can be made to the APVMA by phone or in writing. Written reports can be either a simple letter or by filling out the form available from the APVMA, state authorities and product registrants.

It is always difficult to assess matters and to relate cause and effect when incidents are reported to the APVMA or other authorities long after the incident has occurred because usually evidence has been lost. It is also important to note that when reporting the matter to the APVMA you should provide as much information as possible to assist us in the investigation and assessment of the matter. This may include providing medical reports for human health incidents and field investigation reports for crop, plant or environmental issues.

**Figure 2: What should you do if an adverse experience occurs?**



## **What will the APVMA do when we receive an adverse experience report? (see Figure 3)**

When the APVMA receives an adverse experience report we will look into the matter in an effort to determine whether the adverse effect may have been related to the legal use of the product or not, and whether any regulatory action is required. It is important to note that the APVMA will only investigate matters involving products registered by the APVMA used in accordance with the label or APVMA Permit directions.

The APVMA will acknowledge the report and follow up with the reporting person if any further information is required and indicate if the report fits within the definition of an 'adverse experience'. The APVMA will evaluate the information in the report and also consider any other relevant information that might be available in the scientific literature or in our database. It is therefore important that the reporting person provides the APVMA with as much information as possible on the matter to assist us in our assessment of the incident. The APVMA will determine what, if any, corrective action is required and will inform the reporting person of our conclusions.

Figure 3 is a schematic representation of how an adverse experience report will be handled when received by the APVMA. The following text explains in more detail what each step in the process entails.

### **Report receipt and acknowledgement (A)**

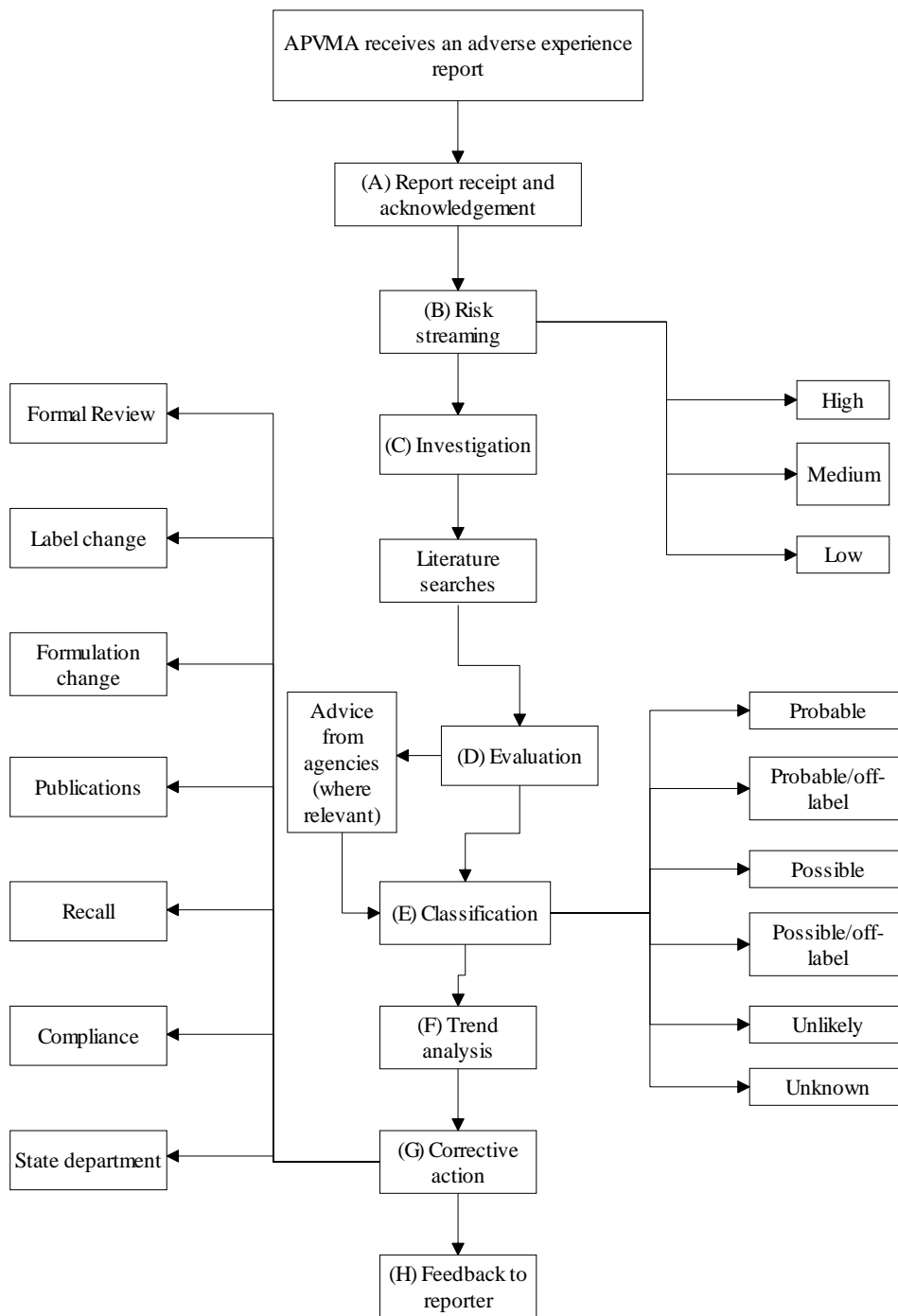
All reports that the APVMA receives will normally be acknowledged within ten working days. The reporting person will also be given an indication of how the APVMA will investigate the matter and be asked for further information, if required, to assist in the investigation. The APVMA will require information about:

- the product used (or at least the active constituent),
- the person reporting the matter and the person (or people) involved in the adverse experience (so we can follow up on the details of the incident),
- the adverse experience itself, including details of when and where the incident occurred, what happened, the type and extent of damage/injury, the crop or area treated with the chemical, the application rate,
- what precautions were taken at the time of using the product (eg protective clothing worn etc),
- in cases where human health has been affected, whether medical advice was sought, the nature of that advice and whether a medical report is available, and
- in cases of environmental or crop damage, details of any other authorities to whom the incident was reports, any investigations carried out and whether a report of those investigations is available.

These requirements are clearly explained in the reporting forms.

Some of this information may be unknown to the reporter and the APVMA may need to find it out as part of the investigation process. For example if a spray application had drifted from the field where it was being applied the APVMA may need to find out what chemical had been used. As long as the reporting person can let the APVMA know when and where the incident occurred, we are likely to be in a position to follow it up or at least indicate the minimum information that will be required to proceed with an investigation.

**Figure 3: What will the APVMA do when we receive an adverse experience report?**



## **Risk streaming (B)**

The APVMA will conduct risk-streaming of all adverse experience reports that are received for the purposes of prioritisation (high, medium and low risk). These priorities are based on the seriousness of the report, the risk to public health, public sensitivities of the issue and whether any other similar adverse experience reports have been received for the product involved.

Essentially the definitions of each risk-streaming category are:

- High** Reports that involve reactions in humans requiring medical attention; serious widespread crop or plant damage or lack of efficacy; residues in or deaths of farm, domestic or native animals; environmental damage (eg measurement of pesticide levels above ANZECC 95% water quality guidelines, evidence of significant harm at ecologically relevant levels to non-target plants or animals and evidence of synergism with other pesticides); risk to public health or high level of public sensitivity. For example where a medical professional has provided evidence of direct injury or illness, or where there have been multiple reports in a specific locality (eg less than 10km apart or the local government area).
- Medium** Reports that involve reactions in humans that do not require any medical attention; medium crop, plant or animal reactions or minor environmental issues.
- Low** Reports that are not known to have occurred previously or involve only minor crop or plant damage.

## **Investigation (C)**

In most instances, adverse experience reports received by the APVMA will be followed up and investigated by the APVMA. However, we will need to rely on advice from other sources during the course of investigation, and in some cases certain follow up work and investigation may be carried out by other parties (see below). For example when investigating a crop damage incident the matter will be referred to the product registrant for direct follow up with the reporting person. This is outlined in the privacy statement on the reporting form.

### APVMA investigation

Initially, when the adverse experience report is received the APVMA will determine whether the matter should be investigated solely by the APVMA or whether advice from other agencies or organisations will be required during the investigation. The APVMA will consult widely, particularly with its official advisory agencies when determining this. Matters requiring investigation solely by the APVMA may include those categorised as high risk. An example of a report that will be investigated solely by the APVMA is a high risk report, possibly involving human health issues, where the APVMA needs to contact the reporting person and discuss their clinical symptoms to assist in determining the correct course of investigation. The APVMA will require the reporting person to provide as much information as possible on each incident to assist in the investigation, including medical reports, pathology results, sample analysis etc.

### Advice from other agencies or authorities

The APVMA currently relies on advice from a number of official governmental advisory authorities in relation to the environment, human health and efficacy. Therefore in some instances the APVMA may need to seek the advice of one of its official advisory agencies when investigating an adverse experience report. For example the APVMA may need to request advice from the staff at the Commonwealth Department of Health and Ageing when investigating a matter involving human health.

### State involvement

If there are any obvious indications that the product has been used contrary to the label or APVMA Permit directions then the APVMA may also notify the relevant state authority responsible for the administration of the state control of use legislation. The APVMA will rely on advice from state authorities when determining this.

### Compliance involvement

Similarly, issues involving non-compliant products or unregistered products may be followed up by the APVMA Compliance Program and State Compliance programs as appropriate.

### Registrant involvement

The APVMA may need to seek information on each adverse experience report from the product registrant. The product registrant will be able to provide the APVMA with information on any other similar adverse experience reports that they are aware of and whether they are aware of any other studies or international information that may be relevant.

### Other third party advice

In other cases the APVMA may also need to seek the involvement of third-party investigators such as agronomists, environmental medical specialists, clinical toxicologists, other health workers or veterinarians. These persons, authorities and businesses can only use the information for assisting the APVMA in its investigations.

## **Privacy of information supplied**

The APVMA is committed to ensuring that the personal details of each reporting person are protected. Each adverse experience reporting form includes a privacy statement which outlines that the information reported on the form will only be used by the APVMA for the purposes of investigating the adverse experience and determining corrective action based on trend analysis of similar reports.

### Human health issues

For reports involving human health issues, the APVMA will keep the personal details of the reporting person confidential and will not pass this type of information to anyone outside of the APVMA Quality Assurance Team or relevant official government advisory agencies bound by confidentiality, unless express permission has been provided by the reporting person or required to do so by a Court of Law. In conducting the investigation the APVMA may need to forward specific

case details (eg the reported adverse experience information) to Commonwealth, State and Territory government agencies, the person or business responsible for distribution of the pesticide in Australia (ie the product registrant) or other relevant experts such as medical practitioners or agronomists. These persons and businesses can only use the information for assisting the APVMA in its investigations. For this reason, each reporting form will request the reporting person to agree to this information being passed on to these people. The reporting person always has the right to decline that this information be passed on.

### Non-human health issues

For reports involving lack of efficacy, crop damage, environmental issues etc, the details of the report, including the personal details of the reporting person, will be forwarded to the people listed above in the normal course of investigation.

### **Evaluation (D)**

Once the APVMA has gathered all available information pertaining to each report of an adverse experience, we will conduct a search of the scientific literature for any information that may assist us in our assessment. This information may then be considered by a panel of experts to determine whether there was an association between the adverse experience reported and the use of or exposure to the product, and whether any regulatory action is required (please see more details on this under the heading “AERP Ag Advisory Committee”).

### **Classification (E)**

The relationship between the use of the product and the reported adverse experience is expressed in terms of:

#### Probable

For inclusion in the category ‘probable’ all of the following minimum criteria should be met:

- there should be a reasonable association between the use of the product and onset and duration of the reported adverse experience,
- the description of the effect should be consistent with, or at least plausible given the known mode of action, toxicology and metabolism of the product, and
- there should be no other equally plausible explanation (or contributing factors) for the clinical signs.

When any of the above criteria cannot be satisfied (due to lack of sufficient information or conflicting data) then the association cannot be assessed as ‘probable’.

#### Probable/Off-label<sup>4</sup>

As per the classification of ‘probable’ and where there is obvious evidence of off-label use (including use in crops/plants/situations not listed on the product label, excessive application rates etc).

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<sup>4</sup> Use contrary to label or APVMA Permit directions generally falls outside the scope of the AERP Ag but some instances (eg human health issues where a pesticide product was used to control an off-label pest, but safety directions were followed), may be followed up.

### **Possible**

For inclusion in the category ‘possible’ association of the adverse experience with use of the product is one of other possible and equally plausible explanations (or contributing factors) for the described adverse experience.

### **Possible/Off-label**

As per the classification ‘possible’ and where there is obvious evidence of off-label use (including use in crops/plants/situations not listed on the product label, excessive application rates etc).

### **Unlikely**

Where sufficient information exists to establish that the described adverse experience was not likely to have been associated with use of the product(s), or other more plausible explanations exist, the assessment should be categorised as ‘unlikely’.

### **Unknown**

All adverse experiences where reliable data is either unavailable or is insufficient to make an assessment should be categorised as ‘unknown’.

## **Trend analysis (F)**

The APVMA will assess the adverse experience information relating to each product and for other similar products (eg different brands of similar formulations) to determine whether there are any trends or emerging issues that require regulatory action. The APVMA will also calculate the relationship between the number of adverse experience reports classified as ‘probable’ or ‘possible’ against the total amount of product sold for the relevant timeframe. Similar types of reports received in specific locations will also be considered (even if these reports were previously classified as ‘unknown’) to determine if there are any emerging issues in localities that require further investigation. For example, a cluster of similar clinical signs may be identified in a specific location, which may indicate that there is an issue in the area that requires follow up investigation.

## **Corrective action recommendations (G)**

Depending on the findings and conclusions drawn from conducting trend analysis certain risk mitigation strategies or corrective actions may be required. The AERP can only make corrective actions recommendations and actual corrective actions many not be possible without a formal review being undertaken. Some corrective action recommendations 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 reporting person will be informed of any corrective action(s) that the APVMA intends to take in response to the information provided (H). Details of any corrective action taken will also be reported in Annual Reports for the AERP Ag and more often as required.

### **Feedback to reporting person (H)**

The conclusions drawn by the APVMA during investigation and evaluation of each adverse experience report will be reported back 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 (see also Classification above). The APVMA will explain what these conclusions are and what corrective action recommendations, if any, will be taken in response to the information.

It should be noted that in some instances if a causal link is not established between the use of or exposure to the product, or if there is not enough information to make a definite conclusion then regulatory action may not be taken.

### **Complaints and grievances**

There will also be a formal channel for reporting people to have an opportunity to provide a grievance to the APVMA if they believe that the APVMA has not adequately protected their personal details, acted in any way that they believe is inappropriate or if they disagree with the outcome of the adverse experience report. In the first instance the complaint should be brought to the Program Manager Quality Assurance and Compliance. If the reporting person still does not believe that their grievance has been handled correctly then they can contact the APVMA Chief Executive Officer.

### **Reporting**

#### **Routine reports**

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) will be included. A summary of regulatory actions taken by the APVMA will also be included in these reports.

It is also proposed that information on “situations” may be included in these Annual Reports. For example, information on situations where annual spraying programs are causing health concerns for communities can be identified and located geographically using postcode information. It is also proposed to include information on health concerns for communities and any targeted regulatory action. This information may be presented in the Annual Reports in map form.

The APVMA will also publish interim reports as appropriate.