



# Adverse Experience Reporting Program for Agricultural Chemicals

## Glossary

### KP82\_P02

#### 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>1</sup> when used according to label directions<sup>2</sup>.”*

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.”*

<sup>1</sup> The term ‘agricultural chemical product’ includes all pesticides and household insecticides and pesticides.

<sup>2</sup> Or “when a product is believed to have been used in accordance with the label”, this also includes APVMA Permit directions.

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## **Assessment**

Once the relationship between the use of the product and the reported effect has been assessed after investigation of the incident it 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**

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 rates etc).

### **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 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'.