Australian Government
Australian Pesticides and Veterinary Medicines Authority

Notification of a potential or actual recall

This form may be used to notify the Australian Pesticides and Veterinary Medicines Authority (APVMA) of any relevant information in accordance with section 161 of the Agricultural and Veterinary Chemicals code as scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code).

A notification must be lodged by a person who is authorised to act on behalf of the company they represent.

Please ensure you **download and save the form** from the APVMA website before completing it.

Responsibility to notify the APVMA

Under section 161 of the Agvet Code, if the holder of:

- the approval of an active constituent for a proposed or existing chemical product or the registration of a chemical product; or
- a permit in relation to an active constituent for a proposed or existing chemical product or in relation to a chemical product

becomes aware of any relevant information in relation to the constituent or in relation to the product or of any of its constituents, the holder must, as soon as the holder becomes aware of the information, give that information to the APVMA. It is an offence not to do so.

Product recalls

Compulsory recalls

Part 6, section 102 to 103 of the Agvet Code, identify that the APVMA may initiate the recall of an agricultural or veterinary chemical (Agvet) product. The recall of an agvet product may be necessary for a variety of reasons, including that it is not registered, there are safety oncerns, a lack of efficacy and mislabelling.

Compulsory recall actions are not limited to the physical recall of affected product. Recall actions may include relabelling of product, notification of retailers and/or consumers advising of the issue, rectifications made to the product whilst in the supply chain and limiting or stopping further supply.

Voluntary recalls

Part 6, section 106 of the Agvet Code provides that the APVMA may allow the Holder of the registration or the manufacturer of an agvet product to commence and lead the voluntary recall of an agvet product. The APVMA's decision to allow this is based on evidence and the risk/s associated with the reason for the product recall.

A person may voluntarily take action to recall a chemical product if, the chemical product might not meet the safety, efficacy, trade or labelling criteria or product is not registered.

The person notifying must notify the APVMA in writing using this approved form **within 2 days** after taking the action to identify the need to voluntarily recall the chemical product. It is important to remember that the APVMA retains sole discretion for the conduct and resolution of recalls.

Publication of recalls

The APVMA is obliged to publish a short description of each product recall on the APVMA website. The APVMA will publish the description within 3 working days of receipt of the notification.

As part of responsible product stewardship, the APVMA encourages you to publish a notification of recall on your website and have an appropriate communication strategy in place.

Responsibility to notify the Australian Competition and Consumer Commission

Depending on the nature of the recall you may have an obligation to notify the Australian Competition and Consumer Commission (ACCC). Further information can be found on the Product Safety Australia website.

Additional information and resources

Additional information on the relevant legislation can be found at the APVMA website.

False or misleading information or documents

The provision of false or misleading information when completing this notification is an offence under section 146 of the Agvet Code and section 137.1 of the *Criminal Code Act 1995*.

I declare that:

- ☐ I have read and understood the information on this page
- ☐ I am authorised to submit this notification on behalf of the organisation listed below
- ☐ the information contained in, and accompanying this notification is complete and correct.

I understand that:

- ☐ giving false or misleading information is a serious offence.

Declaration/authorised person details

Signature

Date

Name:

Title/position:

ABN/ACN:

This form has been completed to advise the APVMA of:

☐ the recall of an agvet product

☐ relevant information (including an issue or potential issue) related to an agvet product or active constituent.

Organisation represented/holder:

Street address:

Contact phone number:

Contact email:

Do not send products, containers or chemicals to the APVMA

Please attach any labels, advertising material, photographs or photocopies relating to the product/s of concern but **do not send product containers, chemicals or product samples to the APVMA** as these may present a health and safety risk.

How to submit this notification

Please send this notification with any supporting information to either:

Email: recalls@apvma.gov.au

Post:

Att: Recalls Coordinator
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Part 1: Agvet chemical details

Product/active constituent name and registration number:

APVMA registration/approval/permit number:

Active constituent(s):

Poisons Schedule:

Batch details:

Please attach reports or documents which provide the information required. This may include certificates of analysis or evidence of the release for supply.

Part 2: Details of relevant information identified

Select all that apply:

- ☐ Constituents differ from the Record, Register or Record of permits
- ☐ Concentration differs from the Record, Register or Record of permits
- ☐ Composition or purity differs from the Record, Register or Record of permits
- ☐ Safety, trade or efficacy issue
- ☐ Quality, packaging or manufacturing issue
- ☐ Issue with label text or instructions
- ☐ New data or information indicates a change in risk
- ☐ Unregistered product
- ☐ Other

Description of relevant information:

Details of any associated adverse experiences:

Please identify any risks to humans, animals, the environment, international trade or other.

Please also complete an adverse experience report.

Description of risks and self assessed risk ranking (low, medium, high):

Distribution of affected product:

Please identify where the product has been distributed, including the Australian states and territories or international makets to which it has been sent.

Date relevant information was identified:

Details of how the relevant information was identified:

Part 3: Proposed resolution

☐ Recall initiated – complete **Part 4**

☐ Recall action not proposed – provide justification below:

Justification:

Part 4: Recall plans

Please complete this section if recall actions have been initiated or are proposed.

Proposed level of recall:

Will you initiate or have you initiated a recall at the level of manufacture, wholesale, retail, from the consumer?

Have you or do you intend to advise the Australian Competition and Consumer Commission, state and territory governments, international persons (including governments) or other? Please specify below:

Date recall initiated:

Estimated completion date:

Please list actions taken to date:

Communication/notification plans:

Published on company website?

☐ Yes – please provide URL below:

☐ No – please explain decision below:

Testing/investigation results attached?

☐ Yes – please provide details below:

☐ No

Plans for re-supply:

Personal information collection notice

Your personal information is protected by law, including the *Privacy Act 1988* and the Australian Privacy Principles (APPs).

Your personal information is collected for the purpose of providing reports to the APVMA about potential or actual recall events. Without this information, the APVMA may be unable to assess whether a recall is necessary. All reports are retained by the APVMA electronically and/or in hard copy.

The APVMA publishes information about product recalls. This may include publication of personal information if product recall notices are issued to an individual.

The APVMA may disclose your notification to Australian Commonwealth, state or territory government agencies, the registrant of the product(s), or any other relevant third party (for example medical practitioners or agronomists) contracted to provide advice or comments to the APVMA. These entities must not use this information for any other purpose. Personal information will only be disclosed to others where required by, or authorised under a law. The APVMA is unlikely to disclose personal information to overseas recipients.

The APVMA's Privacy Policy contains further information about how an individual may access or amend personal information held by the APVMA, or make a complaint about the APVMA's handling of personal information.