



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**



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Guidelines

For recalling Agricultural and
Veterinary Chemical Products

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1 INTRODUCTION AND DEFINITIONS

1.1 Introduction

These guidelines have been developed by the APVMA to outline the actions to be taken when agricultural and veterinary chemical products, for reasons relating to their legality, quality, safety or efficacy, are to be removed from supply.

Recall action may compulsorily be required when the possession and/or supply of an agricultural chemical product or veterinary chemical product would contravene the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code) or the *Agricultural and Veterinary Chemicals Code Regulations 1995* (Agvet Regulations).

Recall action includes stopping supply of a product (registered or unregistered), or taking active steps to locate, retrieve and correct or destroy an agricultural or veterinary chemical product within a distribution network. The objectives of taking recall action are to:

- identify the cause, and institute corrective measures to:
 - minimise potential hazards to humans, animals, plants or the environment, and
 - minimise the potential for recurrence of the problem that led to the recall action.
- effectively and efficiently locate and remove from the marketplace an unsafe, ineffective or non-compliant product or product that may be prejudicial to trade, including:
 - unsafe product – where the continued supply may pose an undue hazard to humans, animals, plants or the environment
 - ineffective product – where a product may fail to perform to the criteria determined for the product
 - where continued supply may unduly prejudice trade or commerce between Australia and other countries.
- subject the affected product to the appropriate corrective action, including rectification, modification or disposal
- minimise the cost and inconvenience to users and suppliers.

Most recalls are not compulsory but are sponsor initiated (i.e. voluntary recalls). The level, scope and urgency of recall action is dependent on a number of factors, including the potential risk posed to humans, animals, plants, the environment, Australia's export and commercial markets and the extent of the products distribution. Recall action may be from manufacturer/importer level only, or down to the end user (i.e. general public).

It is important to note that these guidelines are a guide only providing advice and information. A sponsor should not take these guidelines as a restriction or constraint on any recall action, and should be aware that they are responsible for determining the most appropriate action according to available information.

While the APVMA will liaise and assist with any recall wherever possible, this does not remove the responsibility for a recall from the sponsor.

Where a sponsor's voluntary recall is not carried out satisfactorily, the APVMA may consider if a compulsory recall is required.

Any written instruction provided by the APVMA in a recall notice issued under part 6 of the Agvet Code is compulsory and must be followed in all circumstances. Non-compliance with an APVMA recall notice may contravene the Agvet Code.

The content of these guidelines may assist companies when developing or updating their existing recall procedures.

1.2 Definitions

Agricultural chemical product

An agricultural chemical product is defined in section 4 of the Agvet Code together with Regulation 7 and Schedule 3 of the Agvet Regulations. An agricultural chemical product is a substance or mixture of substances that is represented, imported, manufactured, supplied or used as a means of directly or indirectly:

- destroying, stupefying, repelling, inhibiting the feeding of or preventing infestation by or attacks of any pest in relation to a plant, a place or a thing; or
- destroying a plant; or
- modifying the physiology of a plant or pest so as to alter its natural development, productivity, quality or reproductive capacity; or
- modifying an effect of another agricultural chemical product; or attracting a pest for the purpose of destroying it.

The Agricultural and Veterinary Chemicals Code

The Agvet Code is contained in the Schedule to the Commonwealth *Agricultural and Veterinary Chemicals Code Act 1994*. Each Australian State and Territory has adopted the Agvet Code as law. The laws concerning recall of agricultural and veterinary chemical products are principally contained in the Agvet Code.

APVMA

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the statutory body responsible for the regulation of agricultural and veterinary chemical products in Australia up to and including retail supply.

APVMA recall coordinator

The APVMA recall coordinator is the APVMA's representative responsible for liaising, advising and assisting (as appropriate) a notified person, a recall sponsor and / or the sponsor's recall coordinator.

Effective recall

An effective recall is one where the APVMA considers that a notified person or a sponsor has taken all appropriate steps to locate and either retrieve, modify or destroy stocks of the affected product.

Mutual Recognition Agreements

This refers to the Mutual Recognition Agreements (MRA) in relation to conformity assessment, certificates and markings. These are treaty level agreements between the Commonwealth of Australia and other parties with the objective of removing technical barriers to trade.

Notified person

A notified person is the person (and / or business) to whom the APVMA has issued a recall notice under part 6 of the Agvet Code. The APVMA would normally issue this notice to the person (and / or business) who has the primary responsibility for the marketing and distribution of the product. However, a recall notice may be issued to any person who has or has had possession or custody of non-compliant agricultural or veterinary chemical product. Part 6 applies to compulsory recalls only.

Product

For the purposes of these guidelines, product includes an agricultural or veterinary chemical product or an active constituent contained in an agricultural or veterinary chemical product. The product concerned may be APVMA registered or unregistered depending on the particular recall situation.

Recall

A recall refers to the action stated in a notice given to the notified person **or** the action taken voluntarily by a sponsor to prevent or reduce any harmful effects of an agricultural or veterinary chemical product (or batch).

Two distinct types of recall action are discussed in these guidelines:

Voluntary recall

A voluntary recall is initiated and managed by the sponsor and / or the sponsor's recall coordinator. The APVMA encourages sponsors to act voluntarily whenever recall action is required. While the APVMA encourages voluntary recalls, where the APVMA is not satisfied that a voluntary recall is effective (or will be effective) it may institute a compulsory recall by issuing a recall notice under part 6 of the Agvet Code.

Compulsory recall

A compulsory recall is one that the APVMA initiates through issuing a recall notice. A recall notice is issued to the notified person, providing specific instructions on what actions must be undertaken. Individuals and / or businesses who do not comply with a recall notice may contravene the Agvet Code.

Recall Notice

A recall notice is a notice issued under part 6 of the Agvet Code requiring persons who have, or have had, stocks of chemical products in their possession to stop supplying the products and to take action in relation to the products as detailed in the notice.

Holder

The holder is the person holding the registration of an agricultural or veterinary chemical product and is listed as the registrant on the APVMA register of chemical products.

Sponsor

The sponsor is a person, business or company having the primary responsibility for the possession or supply of a product. A sponsor will generally be the holder of the product (as defined above), however may also be a consultant or contractor or a manufacturer, importer, wholesaler, distributor, reseller or retailer of the agricultural or veterinary chemical product concerned.

Sponsor's recall coordinator

As the case may be, the sponsor's recall coordinator is the person designated by the sponsor as their representative for a particular recall event.

Veterinary chemical product

A veterinary chemical product is defined in section 5 of the Agvet Code together with Regulation 8. Vitamins, minerals and additives are included as veterinary chemical products if used for any of the purposes set out in section 5 of the Agvet Code. Certain exclusions are contained in the Regulations. A veterinary chemical product is a substance or mixture of substances that is represented, as being suitable for, or is manufactured, supplied or used for, administration to an animal by any means or consumption as a means of directly or indirectly:

- preventing, diagnosing, curing, or alleviating a disease or condition in the animal or an infestation of the animal by a pest; or
- curing or alleviating an injury suffered by the animal; or
- modifying the physiology of the animal:
 - so as to alter its natural development, productivity, quality or reproductive capacity; or

- so as to make it more manageable; or
- modifying the effect of another veterinary chemical product.

2 TYPES OF RECALLS AND STAGES

Table 1: Types of recalls and stages

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3 ISSUE OF A COMPULSORY RECALL NOTICE

3.1 Compulsory recall notices

A compulsory recall notice is issued whenever the APVMA requires a notified person to do certain things in relation to a chemical product. The APVMA issues a recall notice under the provisions of part 6 of the Agvet Code.

The APVMA may issue a recall notice in cases where:

- a chemical product is not registered under the Agvet Code (s.101)
- the APVMA is reconsidering registration of a chemical product (s.101)
- it appears to the APVMA that a product, even though it may be a registered chemical product, may
 - not meet the safety criteria, the trade criteria or the efficacy criteria (s.102); or
 - the constituents of stocks of a registered chemical product (or a batch) differ by more than the prescribed extent from the constituents stated in relation to the product in the APVMA register of agricultural and veterinary chemical products (s.102); or
 - the concentration of the constituents of stocks of a registered chemical product (or a batch) differs by more than the prescribed extent from the concentration of the constituents stated in relation to the product in the APVMA register of agricultural and veterinary chemical products (s.102); or
 - the composition or purity of any constituent of stocks of a registered chemical product (or a batch) differs by more than the prescribed extent from the composition or purity of that constituent stated in relation to the product in the APVMA register of agricultural and veterinary chemical products (s.102)
- a registered chemical product is supplied in a container where there is no label attached to the container, or the label attached to the container differs from the approved label (s.103).

A recall notice may require a notified person to:

- immediately not supply the product or specified batches of the product
- recover stocks of the product or specified batches of the product from other persons who the product has been supplied to by the notified person
- destroy stocks of the product or specified batches of the product
- take action to prevent or reduce any harmful effects that may have resulted from the use of the product
- attach labels to the containers that are the same as the approved label for the product, or the label required by the established standard for the product, and
- report to the APVMA within a stated period on the action taken by the notified person under the notice.

3.2 Appeals

Under section 166 of the Agvet Code a person may, by writing, request the APVMA to reconsider the decision to issue a recall notice. Under section 167 of the Agvet Code, and subject to the *Administrative Appeals Tribunal Act 1975*, a decision of the APVMA to issue a recall notice may be reviewed by the Administrative Appeals Tribunal (AAT).

3.3 Other obligations

The Australian Competition & Consumer Commission (ACCC) also provides information on recalls. See Appendix B for ACCC contact information.

3.4 APVMA publication of compulsory recall notices

Commencing 29 June 2017, in addition to our responsibility to publish details of a compulsory recall notice in the Gazette, we will also be publishing details of new compulsory recall notices on our website, see: apvma.gov.au/node/27171.

4 RECOGNISING A POTENTIAL VOLUNTARY RECALL

The potential for a product to be recalled (i.e. unsafe, ineffective or non-compliant) may be identified from one or a combination of information sources accessed directly by the sponsor or provided by the APVMA. The possible information sources include but are not limited to:

- complaints received from Australian or international manufacturers, suppliers or users
- reports from manufacturers on their quality assurance program or product test results
- information from industry groups
- reports in scientific literature
- advice received by the APVMA from international authorities
- inspections of premises by the APVMA
- results of product tests conducted by the APVMA
- reports of non-compliance received by the APVMA or outcomes from APVMA programs (such as the Chemical Review Program or the Adverse Experience Reporting Program).

5 NOTIFICATION OF A POTENTIAL OR ACTUAL VOLUNTARY RECALL OF A REGISTERED CHEMICAL PRODUCT

5.1 Notifying the APVMA

Holders have legal obligations under section 161 of the Agvet Code to advise the APVMA in writing if they become aware of any relevant information in relation to a registered product or any of its constituents. Information is relevant information if it:

- contradicts any information entered in the APVMA Record, Register or Record of Permits for the constituent or product; or
- shows that the constituent or product may not meet the safety criteria, the trade criteria or the efficacy criteria.

Notwithstanding this legal obligation, the APVMA encourages sponsors to notify the APVMA recall coordinator as soon as they become aware of any information relating to the potential / actual recall status of a registered product. In the first instance, the notification should be submitted to the APVMA via email recalls@apvma.gov.au.

Notifications should be supported by using the APVMA form titled '*Notification of a Potential or Actual Recall of an Agricultural or Veterinary Chemical Product*' apvma.gov.au/node/1081. A copy of this form is also provided at Appendix A.

Alternative approaches such as an email or phone call to the APVMA recall coordinator may also be used for first notification, however we will ask for the notification form to be completed and submitted. Irrespective of the approach used, the notification should, as a minimum, include all information as requested by the form. This information is important and will give the APVMA a clear indication of the issue, the recall parameters and the urgency of the recall.

Upon APVMA receipt of the notification the APVMA recall coordinator will liaise with the sponsor or the sponsor's recall coordinator.

Further notifications may be submitted if necessary. For example if additional batches of affected product are later identified.

5.2 Notifying other relevant bodies

The APVMA, on behalf of the Commonwealth of Australia, has specific reporting obligations in respect of veterinary chemical product recalls under the Mutual Recognition Agreements (MRAs). Those obligations include the implementation of a *Rapid Response Alert* system for timely notification of veterinary product recalls relating to:

- product defects that pose a serious, potentially life threatening risk to animals, consumers, operators or the environment

- the APVMA must notify all MRA member countries irrespective of whether the affected product batch was exported to that country, at the same time as notification is effected in Australia
- product defects that could cause illness or mistreatment to animals or illness to consumers or operators
 - must be notified only to those MRA member countries to which it is likely or known that the affected batch has been distributed, within 24 hours of notification being effected in Australia.

5.3 APVMA publication of voluntary recall details

Commencing 29 June 2017, the APVMA is publishing details about new voluntary recall notifications on our website, see: apvma.gov.au/node/27166.

6 ASSESSMENT OF A VOLUNTARY RECALL

Each voluntary recall is a unique exercise. In assessing a recall and determining an appropriate recall strategy there are a number of factors that need to be considered. These include: the nature of the deficiency in the product, the incidence of complaints, consumer safety, distribution networks, recovery procedures, resources for corrective action, and the availability of alternative products.

6.1 Voluntary recall parameters

Urgency

The urgency with which recall action needs to occur is dependent on the nature of the risk posed by the particular product deficiency. In determining the risk, consideration should be given by the sponsor to who or what could be affected by the handling, storage, transport or use of the affected product. An estimation of the possible severity of harm and likelihood of harm occurring should be considered, and expert advice may be necessary. For the purposes of these guidelines, two levels of urgency are applied:

- Urgent: Which relates to those recalls assessed as presenting a high risk (i.e. product defects/non-compliances that are serious or life threatening to animals, consumers, operators or the environment).
- Routine: Relates to all other recalls.

Level

The sponsor should consider the level of a voluntary recall. The levels of a sponsor's distribution network include:

- manufacturer/importer
- wholesaler
- retailer
- end-user.

7 VOLUNTARY RECALL ACTIONS

7.1 Strategy

Because each recall situation is different, a recall strategy specific to the situation is required. The sponsor's recall strategy should be consistent with the company's recall procedure and should define the recall parameters and responsibilities for the particular recall.

Where a voluntary recall strategy appears ineffective the APVMA may issue a recall notice under part 6 of the Agvet Code thereby requiring a compulsory recall.

7.2 Notifying stakeholders

The overall effectiveness of a recall is dependent on the extent to which affected product is able to be retrieved. The sponsor will need to circulate information about the recall to relevant stakeholders (i.e. manufacturers, wholesalers, distributors, retailers, end-users), as determined by the level of the recall action.

7.3 Communication to stakeholders

The sponsor's communication to stakeholders should describe the issue/s and provide clear instructions on what is required from them. The sponsor's correspondence should include but not be limited to the following:

- clearly describe the subject and purpose of the correspondence
- provide information to allow stakeholders to clearly identify affected product
- advise (if known) how much affected product was originally supplied to their business
- describe the product recall
- identify the problem and reason for the recall
- provide instructions for minimising and preventing hazards (i.e. quarantine stocks of the product from further supply), and any first aid instructions or safety directions, if applicable
- detail all actions to be taken by the stakeholder
- the stakeholder may be requested to advise exactly how much affected product they have on hand, and
- a contact person within the sponsor's organisation.

Sample correspondence to stakeholders is provided in Appendix C.

7.4 Advertisements

If the level of recall action is to the end-user level and the individual end-users cannot be readily identified, advertisements paid by the sponsor should be published in the print media of each state/territory in which distribution of the product has taken place. Where no one media outlet is likely to reach the majority of the affected end-users, consideration should be given to using an appropriate combination of media outlets.

Sponsors may also consider any appropriate:

- industry related magazines
- electronic media (i.e. sponsors website)
- ethnic publications.

A list of major and rural newspapers can be found in Appendix D.

7.5 Advising of product recall advertisements

Sponsors should advise the APVMA recall coordinator of the content and format of recall advertisements, including their choice of publication.

8 RESPONSIBILITIES OF SPONSORS

Sponsors have various responsibilities in relation to a voluntary recall action, these include:

- notifying the APVMA of a potential / actual recall of a product
- maintaining good records
- taking responsibility for implementing voluntary recall actions
- managing and monitoring the voluntary recall to its conclusion, and
- keeping the APVMA recall coordinator informed about the status of the voluntary recall.

8.1 Records

Sponsors are encouraged to implement recording systems that allow for batches of product/s to be quickly and easily identified, including who products have been distributed to.

8.2 Disposal of recalled product

The disposal instructions for the recalled product should be determined in consultation with the appropriate Commonwealth, state or local government or environmental authorities. Responsibility for appropriate disposal of recalled product rests with the sponsor.

8.3 Finalising a voluntary recall

The sponsor should notify the APVMA recall coordinator when it is of the opinion that the recall has, as far as practicable, achieved its purpose. The recall may be concluded when the entire affected product has been recalled and rectified, modified or disposed of, or when in the opinion of the APVMA (based on the information available from the sponsor), all reasonable efforts have been made to recall all the affected product.

The sponsor is encouraged to submit a written final report to the APVMA recall coordinator regarding finalisation of the voluntary recall. Information that may be included in the final report:

- a summary of the original problem including the root cause
- the total amount of product affected
- the total amount of affected product located
- the total amount of affected product subjected to corrective action (i.e. disposal) and the nature of the corrective action
- comments on the effectiveness of the voluntarily recall
- actions taken to prevent the problem re-occurring, and
- any other actions taken to improve the sponsor's processes as a result of the voluntary recall.

8.4 Documenting the voluntary recall

The sponsor should keep comprehensive records of the recall. The APVMA may wish to audit the recall, or using its monitoring powers may examine relevant records.



APPENDIXES

APPENDIX A—NOTIFICATION OF POTENTIAL OR ACTUAL RECALL OF AN AGRICULTURAL OR VETERINARY CHEMICAL PRODUCT



Australian Government
**Australian Pesticides and
 Veterinary Medicines Authority**

Notification of Potential or Actual Recall of an Agricultural or Veterinary Chemical Product*

Please use this form to report potential or actual recall events. Please provide as much detail as possible.

Date reported	
Your name	
Your title / position	
Organisation represented	
Street address	
Your contact details (Telephone; mobile; email)	
Product/s affected (Please detail full product name; active constituents, APVMA approval number, poisons scheduling (if any), pack sizes, batch numbers of affected product and dates available for sale)	
Describe the nature of the problem and any hazards (Provide any details of complaints or adverse experience reported)	
Quantity of affected product/s distributed (Please also provide details about the distribution network)	

APPENDIX B—LIST OF CONTACTS

APVMA

APVMA Recall Coordinator
Compliance and Monitoring
PO Box 6182
Kingston ACT 2604

Telephone: 1300 700 315 or +61 2 6210 4800

Facsimile: +61 2 6210 4813

E-mail: recalls@apvma.gov.au

Therapeutic Goods Administration

Australian Recall Coordinator
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Telephone: +61 2 6232 8935

Facsimile: +61 2 6232 8687

Email: recalls@tga.gov.au

Australian Competition and Consumer Commission (ACCC)

Telephone: 1300 302 502

Website: www.productsafety.gov.au/recalls

Administrative Appeals Tribunal

Deputy Registrar
Administrative Appeals Tribunal
GPO Box 9955 in any capital city in Australia, except for Darwin (direct enquiries to Brisbane office).

Telephone: 1800 228 333 (Anywhere in Australia)

APPENDIX C—SAMPLE LETTER TO BE SENT BY SPONSORS TO STAKEHOLDERS ADVISING OF A VOLUNTARY RECALL

Product Recall

The Manager
Acme Rural Produce

Subject: Recall of Acme 200 Selective Herbicide (APVMA Approval # XXXX).

<Company Name>, following consultation with the Australian Pesticides & Veterinary Medicines Authority, is recalling Acme 200 Selective Herbicide supplied to your company between the dates 10 February 20XX and 10 April 20XX.

The recall has been initiated due to a labelling error in the Directions for Use table.

The affected product can be identified as follows:

<i>Batch Number</i>	<i>Expiry Date</i>	<i>Quantity Supplied</i>	<i>Pack sizes</i>	<i>Total Supplied</i>	<i>Total Quarantined</i>	<i>On-supplied to:</i>
B0001	5/12/20XX	10	2 Litres	20 Litres		
B0002	5/12/20XX	25	10 Litres	250 Litres		
B0003	5/12/20XX	2 x 5 boxes of product. Each box contains 5 individual containers.	2.5 Litres	125 Litres		
Totals				395 Litres	Litres	

To assist <company name> with the recall please complete the 'Total Quarantined' column of the above table, advising the amount of affected product you currently have on hand. All affected product should be immediately quarantined. As this is a labelling error, there are no immediate first aid or safety issues with handling the affected product.

If any affected product has been on-supplied, please complete the 'On-supplied to:' column of the above table.

This form should be returned by facsimile (or email) to 1800 ### ## within 48 hours of receipt.

A sales representative from <company name> will contact you by Friday 20 April 20XX. Our representative will visit all premises identified as possessing affected product for re-labelling by Friday 8 July 20XX. Please keep this letter in a prominent position for one month in case stock is in transit.

<Company name> sincerely regrets any inconvenience this product recall may cause your company. All queries should be directed to our recalls number on 1800 ### ##.

APPENDIX D—EXAMPLE END USER LEVEL PRINT MEDIA ADVERTISEMENT



URGENT RECALL

ACME 200 SC INSECTICIDE (12345)

Batch Numbers: B0001, B0002, B0003

Product Sponsor: Acme Chemical Company Pty Ltd

Reason for Recall: It has been discovered that Acme 200 SC Insecticide may contain a toxic impurity.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has determined that the product may pose an undue hazard to the safety of people exposed to it during its use and handling; and may be likely to have an unintended effect that is harmful to plants.

Remedial Action: Product with the above batch numbers should not be used and returned to the point of supply.

Safety Directions: The product is poisonous if swallowed. Avoid contact with eyes and skin.

Consumer Information: For further information, please contact Edward Smith, Administration Manager, Acme Chemical Company Pty Ltd, on **1800 ### ##**.

Appendix E—Newspapers

Major Australian newspapers

State/Territory	Newspaper	Phone	Fax
National	The Australian	+61 2 9288 3000	+61 2 9288 2250
Canberra (ACT)	The Canberra Times	+61 2 6280 2122	+61 2 6280 4884
Sydney (NSW)	The Sydney Morning Herald	+61 2 9282 2833	+61 2 9282 2986
	The Daily Telegraph	+61 2 9288 3507	+61 2 9288 2608
	The Sun-Herald	+61 2 9282 2833	+61 2 9282 3332
	The Sunday Telegraph	+61 2 9288 3507	+61 2 9288 2608
Melbourne (Victoria)	The Age	+61 3 9601 2014	+61 3 9670 1329
	Herald Sun	+61 39292 2739	+61 39292 2141
	Sunday Herald Sun	+61 39292 2000	+61 3 9292 2100
Perth (WA)	The West Australian	+61 8 9482 3111	+61 8 9482 9091
	The Sunday Times	+61 8 9326 9000	+61 8 9326 8383
Brisbane (Qld)	The Courier Mail	1300 304 020	+61 7 3666 6687
	The Sunday Mail	13 22 02	+61 7 3666 6689
Adelaide (SA)	The Advertiser	1300 130 370	+61 8 8206 3622
Hobart (Tas)	The Mercury	+61 3 6230 0665	+61 3 6230 0765
Launceston (Tas)	Launceston Examiner	+61 3 6336 7111	+61 3 6331 4858
Darwin (NT)	Northern Territory News	+61 8 8944 9801	+61 8 8944 9965

Rural newspapers

State/Territory	Newspaper	Phone	Fax
NSW	The Land	+61 2 4570 4444	+61 2 4570 4630
Victoria	The Weekly Times	1800 809 033	+61 3 9292 2320
	Stock and Land	+61 3 8667 1102	+61 3 8667 1141
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