Commonwealth of Australia

Gazette

Agricultural and veterinary chemicals

APVMA Special Gazette, Monday 11 October 2021

Published by the Australian Pesticides and Veterinary Medicines Authority

Australian Government

Australian Pesticides and Veterinary Medicines Authority

The *Agricultural and Veterinary Chemical Code Act 1994* (the Act) commenced on 15 March 1995. The Agricultural and Veterinary Chemicals Code (the Agvet Code) scheduled to the Act requires notices to be published in the *Gazette* containing details of the registration of agricultural and veterinary chemical products and other approvals granted by the Australian Pesticides and Veterinary Medicines Authority. The Agvet Code and related legislation also requires certain other notices to be published in the *Gazette*. A reference to Agvet Codes in this publication is a reference to the Agvet Code in each state and territory jurisdiction.

ISSN 1837-7629

© Commonwealth of Australia 2021

This work is copyright. Apart from any use as permitted under the *Copyright Act 1968*, no part may be reproduced by any process without prior written permission from the Australian Pesticides and Veterinary Medicines Authority (APVMA). Requests and inquiries concerning reproduction and rights should be addressed to:

Assistant Director, Communications
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Email: communications@apvma.gov.au
Website: apvma.gov.au

General information

The APVMA Gazette is published fortnightly and contains details of the registration of agricultural and veterinary chemicals products and other approvals granted by the APVMA, notices as required by the Agricultural and Veterinary Chemicals Code (the Agvet Code) and related legislation and a range of regulatory material issued by the APVMA.

Pursuant to section 8J(1) of the Agvet Code, the APVMA has decided that it is unnecessary to publish details of applications made for the purpose of notifying minor variations to registration details. The APVMA will however report notifications activity in quarterly statistical reports.

Distribution and subscription

The APVMA Gazette is published in electronic format only and is available from the APVMA website.

If you would like to subscribe to receive email notification when a new edition is published, please complete a subscription form.

APVMA contacts

For enquiries regarding the publishing and distribution of the APVMA Gazette: Telephone: +61 2 6770 2300.

For enquiries on APVMA Gazette content, please refer to the individual APVMA contacts listed under each notice.

Privacy

For information on how the APVMA manages personal information when you contact us, see our Privacy Policy.

Contents

Notice under section 34AB of the Agricultural and Veterinary Chemicals Code: Molinate reconsideration – proposed decision on reconsideration 1

Attachment A: Active constituent approval(s), product registration(s) and approved label(s) placed under reconsideration 3

Attachment B: Draft statement of reasons 4

Attachment C: Sample label 25

List of tables

Table 1: Active constituent approval(s), product registration(s) and approved label(s) placed under reconsideration 3

Table 2: Legislative framework 5

Table 3: Buffer zones for fixed wing aircraft using Soluble Chemical Water Injection in Rice Technique (SCWIIRT) 16

Table 4: Buffer zones for helicopters using SCWIIRT 17

Notice under section 34AB of the Agricultural and Veterinary Chemicals Code: Molinate reconsideration – proposed decision on reconsideration

1) The Australian Pesticides and Veterinary Medicines Authority (APVMA) is proposing to make a regulatory decision in relation to a reconsideration being conducted under part 2, division 4 of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code).

2) This notice relates to the reconsideration of the molinate active constituent approvals, product registrations, and label approvals. The molinate active constituent approvals, product registrations and label approvals are listed in Attachment A of this notice.

3) The APVMA proposes to:

    a. affirm under section 34(1) of the Agvet Code the molinate active constituent approvals listed in Attachment A

    b. vary the relevant particulars of the product registrations under section 34A(1) of the Agvet Code to allow affirmation (as varied in the manner set out in paragraphs 26 (b) to (d) of the Draft Statement of Reasons, Attachment B), and as reflected in the sample label, Attachment C under section 34(1) of the Agvet Code of the molinate chemical product registrations listed in Attachment A

    c. vary the relevant particulars of the label approvals under section 34A(1) of the Agvet Code to allow affirmation (as varied in the manner set out in the paragraphs 41(a) to (f) of the Draft Statement of Reasons, Attachment B and as reflected in the sample label, Attachment C), under section 34(1) of the Agvet Code of the molinate chemical product label approvals listed in Attachment A.

4) The APVMA proposes to determine under section 81(3)(b) that section 81(3) of the Agvet Code will apply to the earlier approved labels (that is, the labels in Attachment A before variation), allowing supply of products bearing those earlier approved labels for a period of two years from the date of the final regulatory decision.

Statement of reasons for the proposed regulatory decision

5) The Draft Statement of Reasons for the proposed course of action is provided at Attachment B of this notice.

Written submissions are invited

6) The APVMA invites written submissions on the proposed regulatory decision and the Draft Statement of Reasons attached to this notice (Attachment B). All submissions will be considered by the APVMA prior to finalisation of the reconsideration and publication of the final regulatory decision.

Preparing your submission

7) When making your submission:

- clearly identify the issue and clearly state your point of view
- give reasons for your comments, supporting them, if possible, with relevant scientific information and indicating the source of the information you have used.

8) Please structure your comments in a numbered form, referring each point to the relevant section in the Draft Statement of Reasons or Molinate Review Technical Report.

9) Electronic submissions to the APVMA are preferred.

10) When making a submission please include:

- contact name
- company or group name (if relevant)
- postal address
- email address
- the date you made the submission.

Please note: Submissions will be published on the APVMA website, unless you have asked for the submission to remain confidential (see public submission coversheet).

Please lodge your submission with a public submission coversheet, which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act 1982* and may be required to be released under that Act should a request for access be made.

Note that all submissions received are subject to legislative requirements, including the *Freedom of Information Act 1982*, the *Privacy Act 1988* and the Agvet Code. In providing your submission to the APVMA, you agree to the APVMA publicly disclosing your submission in whole or summary form. The APVMA confirms that if your submission includes confidential commercial information or protected information as defined in the Agvet Code, such information shall be subject to the relevant provisions of the Agvet Code including relevant limitations on use and disclosure by the APVMA.

11) The closing date for submissions is 11 January 2022.

12) Submissions or requests for further information can be sent to:

Chemical Review
Australian Pesticides and Veterinary Medicines Authority
GPO BOX 3262
Sydney NSW 2001

Telephone: +61 2 6770 2400
Email: chemicalreview@apvma.gov.au

Attachment A: Active constituent approval(s), product registration(s) and approved label(s) placed under reconsideration

Table 1: Active constituent approval(s), product registration(s) and approved label(s) placed under reconsideration

Type	Approval or registration number	Name	Holder	Prior label approval number(s)	New label approval number(s)
Active constituent	44008	Molinate manufacturing concentrate	Nufarm Australia Limited	N/A	N/A
Active constituent	44458	Molinate	Nufarm Australia Limited	N/A	N/A
Active constituent	52439	Molinate	Sipcam Pacific Australia Pty Ltd	N/A	N/A
Product	49597	Ordram Herbicide	Nufarm Australia Limited	1506	To be determined
Product	56744	Sirion Herbicide	Sipcam Pacific Australia Pty Ltd	1508	To be determined

Attachment B: Draft statement of reasons

1) The Australian Pesticides and Veterinary Medicines Authority (APVMA) has reconsidered the public health, work health and safety, and environmental aspects of the active constituent molinate, product registrations containing molinate and associated label approvals under Part 2, Division 4 of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code) to determine whether the approved active constituents and registered products meet the safety criteria (see section 5A of the Agvet Code) and labelling criteria (see section 5D of the Agvet Code).

2) The APVMA proposes to:

    a. affirm under section 34(1) of the Agvet Code the molinate active constituent approvals listed in Attachment A

    b. vary the relevant particulars of the product registrations under section 34A(1) of the Agvet Code to allow affirmation (as varied in the manner set out in paragraphs 26 (b) to (d) of this Draft Statement of Reasons and as reflected in the sample label, Attachment C), under section 34(1) of the Agvet Code of the molinate chemical product registrations listed in Attachment A

    c. vary the relevant particulars of the label approvals under section 34A(1) of the Agvet Code to allow affirmation (as varied in the manner set out in the paragraphs 41(a) to (f) of this Draft Statement of Reasons and as reflected in the sample label, Attachment C) under section 34(1) of the Agvet Code of the molinate chemical product label approvals listed in Attachment A.

3) The APVMA proposes under section 81(3)(b) that section 81(3) of the Agvet Code apply to the earlier approved labels, allowing supply of products bearing the earlier approved labels for 2 years from the date the final regulatory decision is made.

4) The reasons for the proposed decisions are set out below as outlined in the table of contents.

Table of contents

Legislative framework 5

Information on which the decision is based 5

Material findings of fact and reasons for the proposed decisions 6

Scope of the reconsideration of molinate 6

Active constituent approval 6

Consideration of whether the active constituents meet the safety criteria 7

Conclusion on whether the active constituents meet the safety criteria 8

Consideration of whether the active constituents meet the prescribed regulations 10

Conclusion of consideration of active constituents 10

Registered chemical products 10

Consideration of whether the registered chemical products meet the safety criteria 10

Consideration of whether the registered chemical products can be varied in such a way as to meet the safety criteria 16

Consideration of whether the registered chemical products meet the efficacy criteria 18

Consideration of whether the registered chemical products meet the trade criteria 18

Consideration of whether the registered chemical products complies with any requirement prescribed by the regulations 18

Conclusion of considerations of chemical products 19

Label approvals 19

Consideration of whether the approved labels meet the labelling criteria 20

Conclusion of whether the labels meet the labelling criteria 22

Consideration of whether the labels can be varied to meet the labelling criteria 22

Conclusion of considerations of labels 23

Attachment C: Sample label 25

Directions for use 26

Restraints 26

Spray drift restraints 26

Legislative framework

5) The following sections of the Agvet Code, and clause 4 of Part 2 of the Agricultural and Veterinary Chemicals Code (Efficacy Criteria) Determination 2014 were relevant to the reconsideration of molinate.

Table 2: Legislative framework

Section	Provision
5A	Definition of meets the safety criteria
5B	Definition of meets the efficacy criteria
5C	Definition of meets the trade criteria
5D	Definition of meets the labelling criteria
19	How approval of active constituent takes place
20	How registration of chemical product takes place
21	How approval of label takes place
31	The APVMA may reconsider an approval or registration
33	The APVMA may require information, reports, results or samples
34	Reconsideration by APVMA
34A	Varying relevant particulars or conditions to allow affirmation
34AA	Suspension or cancellation
34AB	Notice of proposed decision

Information on which the decision is based

6) The APVMA considered the following information in making its proposed decision:

a. The relevant provisions of the Agvet Code, in particular those set out above.

b. Information provided in response to notices issued under section 32(1) of the Agvet Code from:

    i. SIPCAM Australia Pacific as identified in the Molinate Review Technical Report.

c. Information provided in response to notices issued under section 33 of the Agvet Code from:

    i. Ricegrowers Australia Inc. as identified in the Molinate Review Technical Report

    ii. Cropcare Australia as identified in the Molinate Review Technical Report.

d. Other information as detailed in the Molinate Review Technical Report.

e. APVMA records for approval of relevant active constituents and registration records of the relevant products.

Material findings of fact and reasons for the proposed decisions

Scope of the reconsideration of molinate

7) The reconsideration of molinate was initiated on the basis that information available showed that the APVMA might not be able to maintain its satisfaction that the continued approvals of the active constituent molinate and registration of products containing molinate based on the current use pattern would not be:

    a. an undue hazard to the safety of people exposed to it during its handling

    b. likely to have an effect that is harmful to human beings

    c. likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

8) The following aspects of the active constituent approvals, product registrations and label approvals were specifically included in the reconsideration of molinate:

    a. Toxicology, including the potential for:

        i. impaired fertility and neuropathy in humans which might pose an undue hazard to human health

        ii. adverse effects to humans resulting from exposure via the oral, dermal and inhalation routes.

    b. Environmental, including the potential:

        i. for contamination of waterways indicated by varying levels of molinate recorded in drainage water from rice fields

        ii. hazard to non-target fauna and flora.

    c. Work health and safety, including:

        i. possible risks to workers health associated with short and intermediate term occupational exposure

        ii. the potential for hazards to worker safety.

    d. The adequacy of instructions and warnings on product labels.

Active constituent approval

9) Section 34(1) of the Agvet Code provides that the APVMA must affirm the approval of an active constituent if and only if it is satisfied that the constituent:

a. meets the safety criteria

b. complies with any requirement prescribed by the regulations.

Consideration of whether the active constituents meet the safety criteria

10) Section 5A(1) of the Agvet Code provides that an active constituent meets the safety criteria if use of the active constituent, in accordance with any instructions approved or to be approved by the APVMA for the constituent is not, or would not be:

a. an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues (section 5A(1)(a))

b. likely to have an effect that is harmful to human beings (section 5A(1)(b)).

c. likely to have an unintended effect that is harmful to animals, plants or things or to the environment (section 5A(1)(c)).

11) In determining that the active constituents meet the safety criteria, the APVMA has had regard to the criteria set out in section 5A(2)(a) as follows:

a. Section 5A(2)(a)(i) – the toxicity of the constituent and its residues, including metabolites and degradation products in relation to relevant organisms and ecosystems, including human beings, in accordance with section 5A(2)(a)(i).

i. In considering the toxicity of the constituent and its residues, the APVMA has had regard to acute, short term, chronic, reproduction, developmental, genotoxicity and neurotoxicity studies which are detailed in the Molinate Review Technical Report.

ii. The use of the active in agricultural chemical products.

iii. The fate of the active in the environment, its toxicity to off target species and data on the discharge of irrigation water containing molinate to the environment.

iv. The acute dietary exposure estimated by the National Estimated Short Term Intake (NESTI) calculation for molinate.

b. Section 5A(2)(a)(ii) – the method by which the constituent is manufactured.

i. In considering the method of manufacture, the APVMA has had regard to the existing approval records. Additionally, there have been no concerns raised as part of this reconsideration regarding the method of manufacture.

c. Section 5A(2)(a)(iii) – the extent to which the constituent will contain impurities.

i. In considering the extent to which the constituent will contain impurities, the APVMA has had regard to the existing approval records. Additionally, there have been no concerns raised as part of this reconsideration regarding impurities.

d. Section 5A(2)(a)(iv) – whether an analysis of the chemical composition of the constituent has been carried out and, if so, the results of the analysis.

i. Batch analyses and a "Declaration of Composition" of the active constituent were assessed by the APVMA as part of the approval application.

ii. There have been no concerns raised during this reconsideration regarding the chemical composition of the active constituent.

e. Section 5A(2)(a)(v) – any conditions to which its approval is subject, in accordance with section 5A(2)(v).

    i. The conditions to which the approval of an active constituent is subject are set out in the table in regulation 17C of the Agricultural and Veterinary Chemicals Code Regulations 1995 (the Agvet Regulations). These are appropriate and apply to each source of active constituent.

    ii. The active constituent must be manufactured in accordance with the composition and purity entered for that source of active constituent in the Record.

    iii. The active constituent must be manufactured by the manufacturer whose name is entered in the Record.

    iv. The active constituent must be manufactured at the site of manufacture entered in the Record.

    v. The identifying information for the holder of the approval and the nominated agent (if any), must be the identifying information entered in the Record.

f. Section 5A(2)(a)(vi) – any relevant particulars that are entered into the Record for molinate. These include the distinguishing number and the particulars prescribed by the Regulations (see section 19 of the Agvet Code). The particulars prescribed by the Regulations for the purposes of section 19(c) of the Agvet Code are set out in regulation 15 of the Agvet Code Regulations. The APVMA does not consider any changes are required to the particulars of any of the sources of active constituent currently approved. The particulars on the record for each approved source of the active molinate have been reviewed including: the IUPAC name, the composition and purity of the active, the name of the manufacturer, the address of each site at which the active constituent is manufactured, the holder of the approval and the date of entry of these particulars. The entries are considered appropriate and no concerns have been raised.

g. Section 5A(2)(a)(via) – whether the constituent conforms, or would conform, to any standard made for the constituent under section 6E to the extent that the standard relates to matters covered by subsection 5A(1).

    i. The APVMA proposes to establish a standard for Molinate under section 6E as outlined in the Molinate Review Technical Report.

    ii. The Molinate Review Technical Report concludes that the sources of molinate listed in Attachment A would conform to the proposed standard.

h. Section 5A(2)(a)(vii) – any matters prescribed by the regulations

    i. Regulation 8AA prescribes the method of analysis (if any) of the chemical composition of the active constituent concerned for the purposes of section 5A(2)(a)(vii) of the Agvet Code. Details of the method of analysis used to determine the chemical composition of the active constituent were submitted and assessed as part of the application to approve the constituent. There have been no concerns raised as part of this reconsideration regarding the method of analysis of the chemical composition of the active constituent.

Conclusion on whether the active constituents meet the safety criteria

12) Having regard to the matters in section 5A(2)(a), the APVMA is satisfied that use of molinate as an active constituent in agricultural chemical products is not, or would not be:

    a. an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues: see section 5A(1)(a))

b. likely to have an effect that is harmful to human beings: section 5A(1)(b))

c. likely to have an unintended effect that is harmful to animals, plants or things or to the environment: see section 5A(1)(c).

13) Reasons for satisfaction:

a. Section 5A(1)(a) – the APVMA is satisfied that the use of the active constituent is not an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues because:

i. the toxicology assessment detailed in the Molinate Review Technical Report found no objections on toxicological grounds to the ongoing approval of the active constituent molinate

ii. an acceptable daily intake (ADI) has been determined for molinate of 0.0003 mg/kg bw/d as a safe level of exposure for long term dietary exposure. The ADI is the level of intake of a chemical that can be ingested daily over an entire lifetime without appreciable risk to health. The ADI incorporates a 1000 fold uncertainty factor to account for inter- and intra-species variation in sensitivity, as well as for the use of a low observed adverse effect level rather than a no observed adverse effect level

iii. an acute reference dose (ARfD) has been established for molinate of 0.002 mg/kg bw for safe levels of exposure for short term dietary exposure. The ARfD is the estimate of the amount of a substance in food or drinking water, expressed on a milligram per kilogram body weight basis, that can be ingested over a short period of time, usually one meal or one day, without appreciable health risk to the consumer on the basis of all known facts at the time of the evaluation

iv. the worker exposure assessment detailed in the Molinate Review Technical Report has identified safe levels of exposure for occupational exposure to molinate

v. molinate will remain in Schedule 7 and Appendix J of the Standard for the Uniform Scheduling of Medicines and Poisons.

b. Section 5A(1)(b) – the APVMA is satisfied that the use of the active constituents is not, or would not be, likely to have an effect that is harmful to human beings because:

i. as noted above, the toxicology and worker exposure assessments detailed in the Molinate Review Technical Report have established safe levels of exposure for both long and short term exposure to molinate respectively and also for occupational exposure

ii. the worker exposure assessment has identified safe levels of exposure for occupational exposure to molinate which includes a restriction on the amount handled per day

iii. acceptable ADI and ARfD are able to be established indicating there is a level of dietary exposure to molinate through consumption of foods containing residues of molinate which is not likely to have an effect that is harmful to human beings.

c. Section 5A(1)(c) – the APVMA is satisfied that the use of the active constituent is not, or would not be, likely to have an unintended effect that is harmful to animals, plants or things or to the environment because:

i. the assessment of water monitoring data demonstrated adequate management of discharge to the environment from the current use pattern.

14) The APVMA is satisfied, for the purposes of section 34(1)(a), that the molinate active constituent approvals in Attachment A meet the safety criteria set out in section 5A(1) of the Agvet Code.

Consideration of whether the active constituents meet the prescribed regulations

15) The particulars to be recorded for an active constituent are listed under regulation 15. Based on the information submitted with the application for approval of each source of active, the APVMA is satisfied that the current entries are correct and that no concerns have been raised as part of this reconsideration.

16) The conditions of approval for active constituents are detailed in regulation 17C(1). The APVMA is satisfied that these conditions are appropriate for all current sources of this active constituent.

Conclusion of consideration of active constituents

17) As the APVMA is satisfied that the active constituent meets the safety criteria, including compliance with requirements prescribed by the regulations, section 34(1) of the Agvet Code provides that the APVMA must affirm the approval of the active constituent.

18) As the APVMA is able to establish both an ADI and ARfD for safe levels of consumption for long term and short term dietary intake, respectively, the APVMA is satisfied that the use of the active constituent in products can be assessed as to whether it presents an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues. Both ADI and ARfD are health based guidance values which underpin the assessment of product use patterns. Although they indicate safe levels of exposure they are not relevant particulars that are entered into the Record for the active constituent. Therefore a change to these values does not change any relevant particulars in the Record for the active constituent.

Registered chemical products

19) Section 34(1) of the Agvet Code provides that the APVMA must affirm the registration for a chemical product if, and only if it is satisfied that the product:

    a. meets the safety criteria (section 5A)

    b. meets the efficacy criteria (section 5B)

    c. meets the trade criteria (section 5C)

    d. complies with any requirement prescribed by the regulations.

Consideration of whether the registered chemical products meet the safety criteria

20) As both registered products are 960 g/L molinate, emulsifiable concentrate formulations with the same use pattern, the following considerations have been made for each product and apply equally to each product.

21) Section 5A(1) of the Agvet Code provides that a chemical product 'meets the safety criteria' if use of the product, in accordance with any instructions approved, or to be approved, by the APVMA for the product or contained in an established standard is not, or would not be:

    a. an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues (section 5A(1)(a))

    b. likely to have an effect that is harmful to human beings (section 5A(1)(b))

    c. likely to have an unintended effect that is harmful to animals, plants or things or to the environment (section 5A(1)(c)).

22) In determining whether the chemical products meet the safety criteria the APVMA has had regard to the criteria set out in section 5A(3)(a) as follows:

a. Section 5A(3)(a)(i) – the toxicity of the product and its residues, including metabolites and degradation products, in relation to relevant organisms and ecosystems, including human beings.

    i. The existing product registration records the existing approval records for the active constituents.

    ii. The findings in the Molinate Review Technical Report, that there are no objections on toxicological grounds to the ongoing approval of molinate as an active constituent.

    iii. The results of acute, short term, chronic, reproduction, developmental, genotoxicity and neurotoxicity studies detailed in the Molinate Review Technical Report.

    iv. The recommendation of an ADI for molinate of 0.0003 mg/kg bw/d, based on degeneration or demyelination in the sciatic nerve in rats at 0.3 mg/kg bw/day following dosing for 2 years.

    v. The proposed establishment of an ARfD for molinate of 0.002 mg/kg bw based on a low observed adverse effect level of 1.8 mg/kg bw in a rat development neurotoxicity study, and the application of a 1000 fold safety factor to account for inter- and intra-species variation in sensitivity, as well as for the use of a low observed adverse effect level rather than a no observed adverse effect level.

    vi. The findings in the Molinate Review Technical Report and existing product registration records, that the current molinate residue definition in the Maximum Residue Limit (MRL) standard remains appropriate as parent only (molinate) and confirming the current MRL *0.05 mg/kg in rice which is set at the limit of quantification.

    vii. The assessment of worker exposure detailed in the Molinate Review Technical Report identified that the current use pattern may result in unsafe levels of occupational exposure to molinate and therefore the products would not meet the safety criteria. However, the report also detailed how the level of exposure could be reduced to be acceptable through the use of PPE, limiting the application rate and varying the use pattern to limit exposure.

    viii. The findings in the Molinate Review Technical Report and existing product registration records, of the fate of the active in the environment, its toxicity to off target species and data on the discharge of irrigation water containing molinate to the environment.

    ix. There are no restrictions on the current label to account for the impact of spray drift on relevant organisms and ecosystems, including human beings.

    x. The history of use of the product and that no reports of crop damage from the use of molinate products have been received by the Adverse Experience Reporting Program of the APVMA.

b. Section 5A(3)(a)(ii) – the relevant poison classification of the product under the law in force in this jurisdiction.

    i. Molinate was confirmed as a Schedule 7 Poison and is included in Appendix J of the Standard for the Uniform Scheduling of Medicines and Poisons.

c. Section 5A(3)(a)(iii) – how the product is formulated.

    i. In considering how the products are formulated, the APVMA has had regard to the existing approval records. The currently registered products containing molinate as an active constituent are both formulated as 960 g/L molinate emulsifiable concentrate products.

    ii. There have been no concerns raised as part of this reconsideration regarding the formulation of the products.

d. Section 5A(3)(a)(iv) – the composition and form of the constituents of the product.

i. In considering the composition and form of the constituents of the product, the APVMA has had regard to the existing approval records.

ii. There have been no concerns raised as part of this reconsideration regarding the composition and form of the constituents of the product.

e. Section 5A(3)(a)(v) – any conditions to which its registration is, or would be, subject.

i. The products are currently subject to the conditions of registration detailed under regulation 17(c)(2) items 1,2, 5, 6 and 7 (items 3 and 4 do not apply to agricultural chemical products as prescribed under regulation 59).

ii. The products are currently subject to the additional conditions originally applied under the Ag QA Scheme.

i. Manufacture of Active Constituent – the registrant must not supply the chemical product, or cause it to be supplied, unless the active constituent contained in the chemical product:

a. complies with the APVMA Standard for that active constituent

b. was manufactured at a site of manufacture listed in the Record of approved active constituents.

ii. Analysis results – the registrant must not supply the chemical product or cause it to be supplied unless the registrant has in its possession prior to the supply of each batch of the chemical product, batch analysis results that show:

a. the active constituent contained in the chemical product complied with the APVMA Standard for that active constituent

b. if there is an APVMA standard for a constituent in the chemical product that is not an active constituent, the constituent complied with the APVMA standard for that constituent

c. the batch number of the active constituent contained in the chemical product.

iii. Records – the registrant must, at or prior to the supply of a batch of the chemical product by the registrant or by another person on behalf of the registrant, make or have in its possession, a record that contains the following information:

a. The name of the chemical product.

b. The APVMA product number of the chemical product.

c. If the chemical product was imported into Australia by another person on behalf of, or pursuant to an arrangement with the registrant, the name and address of that person.

d. If the chemical product was manufactured in Australia by another person on behalf of, or pursuant to an arrangement with the registrant, the name and address of that person.

e. The date of importation into, or manufacture in, Australia as the case may be.

f. The batch number of the chemical product from which the supply was made.

g. The quantity of the chemical product that constitutes the batch.

h. The batch number, and name and address of the manufacturer of the active constituent contained in the chemical product.

iv. The registrant must produce, or cause to be produced, to the APVMA any batch analysis results or record within 10 working days of the request having been made by the APVMA, or other such period as determined by the APVMA.

v. The registrant must keep, or cause to be kept, any batch analysis results or record for 2 years after any batch analysis results or record is made.

vi. Possession of batch analysis results and records – for the purposes of these conditions, batch analysis results or records are in the possession of the registrant if batch analysis results or records are in the possession of:

a. the registrant

b. another person pursuant to an arrangement with the registrant.

vii. Compliance with the standard – For the purposes of these conditions, a constituent complies with the APVMA standard if the constituent, when measured using a validated analytical method does not contain:

a. less than the minimum purity and/or content of the constituent as set out in the APVMA standard for the constituent

b. more than the maximum level of any impurity as set out in the APVMA standard.

viii. Definitions and interpretation – In these conditions the following words have the following meanings:

'APVMA standard' means the standard determined by the APVMA to which a constituent contained in chemical products must comply and which is published on the APVMA website.

'Batch' means a defined quantity of material produced in a single series of operations.

'Batch number' means that a distinctive combination of numbers and/or letters that specifically identifies a batch and from which the production history can be determined.

'Batch analysis results' means the results of analysis from each batch of the constituent that include:

a. the name of the manufacturer and the manufacturing site address

b. the date of the analysis

c. the batch number and date of manufacture of the batch

d. the analysis result(s) for the constituent purity and/or content and/or isomer ratio and/or the specified impurities as per the APVMA standard for the constituent

e. full details and validation data for the analytical method(s) used for the determination of the constituent purity (linearity and precision) and/or the content and/or the isomer ratio and/or the specified impurities (linearity, precision, accuracy and limit of quantitation if relevant).

If analytical methods and validation data have been previously provided to the APVMA, a reference to that submission will suffice.

'Record' means a document in written or electronic form that contains the particulars set out in paragraph 3 and which is readily accessible for the purposes of part 9 of the Agvet Codes (enforcement).

'Supply' has the same meaning as given to it in section 3 of the Agvet Codes and includes the doing of those things through, or pursuant to an arrangement with, another person.

f. Section 5A(3)(a)(vi) – any relevant particulars that are, or would be, entered in the register for the product.

   i. The distinguishing number remains appropriate.

   ii. The instructions for use considered during the reconsideration were those previously applied to the product and detailed on the product labels. These instructions could not be supported due to unacceptable levels of exposure to workers under the current instructions for use, but it was determined that the instructions for use could be varied such that the product will meet the safety criteria. These are detailed in the Molinate Review Technical Report.

   iii. Other particulars prescribed by the regulations (see regulation 16) were confirmed by existing product registration records.

g. Section 5A(3)(a)(via) – whether the product conforms, or would conform, to any standard made for the product under section 6E to the extent that the standard relates to matters covered by subsection (1).

   i. There is no standard for these products made under s6E.

h. Section 5A(3)(a)(vii) – any matters prescribed by the regulations.

   i. Regulation 8AB(1)(a) of the agvet regulations prescribes the method of analysis (if any) of the chemical composition and form of the constituents of the chemical product. In considering method of analysis of the chemical composition and form of the constituents in the chemical products, the APVMA has had regard to the existing product records. Additionally, there have been no concerns raised as part of this reconsideration regarding analysis of the composition and form of the constituents in these chemical products.

   ii. Regulations 8AB(1)(b) and (c) do not apply as the product is an agricultural product and is prescribed under regulation 59(1) for the purposes of section 120A of the Agvet Code.

   iii. Regulations 8AB(1)(d), (e) and (f) do not apply based on the use pattern of the product.

23) Under section 5A(3)(b) the APVMA may have regard to one or more of the following matters in determining whether a chemical product meets the safety criteria:

a. Section 5A(3)(b)(i) – the acceptable daily intake of each constituent contained in the product.

   i. An ADI has been determined for molinate of 0.0003 mg/kg bw/d as a safe level of exposure for long term dietary exposure.

b. Section 5A(3)(b)(ii) – any dietary exposure assessment prepared under subsection 82(4) of the *Food Standards Australia New Zealand Act 1991* as a result of any proposed variation notified under subsection 82(3) of that Act in relation to the product, and any comments on the assessment given to the APVMA under subsection 82(4) of that Act.

   i. The dietary exposure associated with the use of molinate on rice was considered and is detailed in the Molinate Review Technical Report.

c. Section 5A(3)(b)(ii) – whether any trials or laboratory experiments have been carried out to determine the residues of the product and, if so, the results of those trials or experiments and whether those results show that the residues of the product will not be greater than limits that the APVMA has approved or approves.

    i. In considering whether residues of the product will not be greater than limits that the APVMA has approved, the APVMA has had regard to the existing product records. Additionally, there have been no concerns raised as part of this reconsideration regarding the current MRL.

d. Section 5A(3)(b)(iv) – the stability of the product.

    i. In considering the stability of the chemical products, the APVMA has had regard to the existing product records. Additionally, there have been no concerns raised as part of this reconsideration regarding analysis of the composition and form of the constituents in these chemical products.

e. Section 5A(3)(b)(v) – the specifications for containers for the product

    i. In considering specifications for containers, the APVMA has had regard to the existing product records regarding the stability of the product in the proposed containers and the integrity of the container during storage of the product. Additionally, there have been no concerns raised with the current specifications for containers for these products.

    ii. The product is subject to the conditions of registration prescribed under regulation 18(2), which are satisfied.

f. Section 5A(3)(b)(vi) – there are no other matters that the APVMA thinks relevant.

24) The APVMA is not satisfied that the molinate chemical product registrations currently meet the safety criteria for the reasons set out below:

a. The toxicology assessment detailed in the Molinate Review Technical Report found that the current ADI and ARfD for molinate should be amended/established as follows:

    i. The ADI should be amended to be 0.0003 mg/kg bw/d as a safe level of exposure for long term dietary exposure.

    ii. The ARfD should be established at 0.002 mg/kg bw for safe levels of exposure for short term dietary exposure.

b. The assessment of work health and safety, detailed in the Molinate Review Technical Report found that:

    i. there is currently an unacceptable risk to operators involved in mixing and loading the products and for pilots during fixed wing and helicopter aerial application of the products when current instructions for use are followed.

c. The current use pattern does not ensure that Regulatory Acceptable Level (RALs), the level of exposure resulting from spray drift that must not be exceeded for protection of relevant organisms and ecosystems, including human beings, will not be exceeded. The basis for the establishment of each RAL is detailed in the Molinate Review Technical Report. They are:

    i. Bystander areas: 15 g ac/ha

    ii. Natural aquatic areas: 26 µg ac/L

    iii. Pollinator areas: not required

    iv. Vegetation areas: 123 g ac/ha

v. Livestock areas: a RAL was not determined as the method of application limits off target movement and there have been no known residue related trade incidents.

Consideration of whether the registered chemical products can be varied in such a way as to meet the safety criteria

25) Section 34A (1) provides that if the APVMA is not satisfied under section 34(1) but is satisfied that the relevant particulars or conditions of the registration can be varied in such a way as to allow the registration to be affirmed, the APVMA must vary the relevant particulars or conditions.

26) The APVMA has considered whether the ADI, ARfD, and instructions for use including spray drift restraints can be varied in such a way as to meet the safety criteria as follows:

a. The appropriate ADI and ARfD can be established.

b. The current instructions for use can be varied to limit the exposure to workers to an acceptable level by making all of the variations outlined below:

i. Maintaining the current PPE when mixing and loading and applying the product.

ii. Limiting the use pattern to be only when applied by Soluble Chemical Water Injection In Rice Technique (SCWIIRT) from aircraft.

iii. Restricting the quantity of product handled by applicators (pilots), to no more than 1066 L per day. At a label mixing rate of 3.75 L product in 10 L water, this is equivalent to 3866 L of diluted spray mix, sufficient to treat 281 ha.

iv. Restricting the quantity of product handled by workers undertaking mixing and loading, to no more than 1415 L per day. At a label mixing rate of 3.75 L product in 10 L water, this is equivalent to 5185 L of diluted spray mix, sufficient to treat 377 ha.

v. Ensuring that separate workers are undertaking the mixing/loading and applications (i.e. pilots/applicators must not mix and load and mixer/loaders must not apply).

c. Spraydrift restraints and buffer zones can be applied to fixed wing aircraft which will ensure that RALs are not exceeded as follows:

i. DO NOT apply unless the wind speed is between 3 and 20 kilometres per hour at the application site during the time of application.

ii. DO NOT apply if there are hazardous surface temperature inversion conditions present at the application site during the time of application. Surface temperature inversion conditions exist most evenings from one to 2 hours before sunset and persist until one to two hours after sunrise.

iii. DO NOT apply by fixed wing aircraft unless the following additional requirements are met:

- Apply only by SCWIIRT (Soluble Chemical Water Injection in Rice Technique).
- The release height is not greater than 3 m or 25% of wingspan above the ground whichever is the greatest.
- Minimum distances between the application site and downwind sensitive areas (see 'Mandatory buffer zones' section of the following table titled 'Buffer zones for fixed wing aircraft using SCWIIRT) are observed.

Table 3: Buffer zones for fixed wing aircraft using Soluble Chemical Water Injection in Rice Technique (SCWIIRT)

Buffer zones for fixed wing aircraft using SCWIIRT				
Application rate	**Mandatory downwind buffer zones**			
	Bystander areas	**Natural aquatic areas**	**Pollinator areas**	**Vegetation areas**
2.5 L in minimum 10 L/ha water	150 metres	85 metres	0 metres	30 metres
3.75 L in minimum 10 L/ha water	200 metres	110 metres	0 metres	45 metres

d. Spraydrift restraints can be applied to helicopters which will ensure that RALs are not exceeded as follows:

i. DO NOT apply unless the wind speed is between 3 and 20 kilometres per hour at the application site during the time of application.

ii. DO NOT apply if there are hazardous surface temperature inversion conditions present at the application site during the time of application. Surface temperature inversion conditions exist most evenings one to 2 hours before sunset and persist until one to 2 hours after sunrise.

iii. DO NOT apply by helicopter unless the following additional requirements are met:

- Apply only by SCWIIRT (Soluble Chemical Water Injection In Rice Technique).
- The release height is not greater than 2 metres above the ground.
- The flying speed is not greater than 50 knots (92 km/hr).
- Minimum distances between the application site and downwind sensitive areas that appear in the 'Mandatory downwind buffer zones' section of the following table titled 'Buffer zones for helicopter using SCWIIRT') are observed.

Table 4: Buffer zones for helicopters using SCWIIRT

Buffer zones for helicopters using SCWIIRT				
Application rate	**Mandatory downwind buffer zones**			
	Bystander areas	**Natural aquatic areas**	**Pollinator areas**	**Vegetation areas**
2.5 L in minimum 10 L/ha water	10 metres	10 metres	0 metres	0 metres
3.75 L in minimum 10 L/ha water	15 metres	10 metres	0 metres	5 metres

27) Section 34A (3) provides that if the variation would affect instructions for use of a chemical product, the APVMA must not make the variation until it has consulted each co-ordinator designated for a jurisdiction and taken into account any recommendations made by the coordinators.

a. The products are only registered for use in NSW. The NSW coordinator has been consulted and made no recommendations. Additional opportunity for comment will be afforded during the public consultation of this proposed decision.

Consideration of whether the registered chemical products meet the efficacy criteria

28) Having regard to the matters in section 5B(1) and 5B(2)(a–d)[1] , and Clause 4 of the Agricultural and Veterinary Chemicals Code (Efficacy Criteria) Determination 2014, the APVMA is satisfied that use of the product is effective as a herbicide for post emergence control of barnyard grasses and silver top grass in rice in permanent water based on the following:

    a. It would, to a reasonable degree, achieve one of the effects listed in paragraphs 4(2)(a) to (e) of the Code, namely destroying a plant (section 4(2)(b)).

    b. There is a demonstrated history of sale and effective use in equivalent uses as outlined in the Molinate Review Technical Report.

Consideration of whether the registered chemical products meet the trade criteria

29) A chemical product meets the trade criteria under section 5C(1) if the use of the product in accordance with instructions approved or to be approved by the APVMA does not or would not unduly prejudice trade between Australia and places outside Australia.

30) As it is reasonably expected that rice (the only crop with an approved use pattern) might be provided to a place outside Australia, regulation 8AD(2) applies and APVMA must have full regard to all of the matters set out in section 5C(1) and (2) of the Code.

31) Having regard to all matters in section 5C (2):

    a. The conditions to which its registration is subject.

    b. The relevant particulars entered in the register for the product.

    c. That there is no relevant standard made for the product under section 6E for the product.

    d. There are no additional matters prescribed by the regulations.

The APVMA is satisfied that use of the product meets the trade criteria as described in section 5C(1) and does not or would not unduly prejudice trade or commerce between Australia and other places outside Australia. This is supported by the following:

    a. An MRL has been established at the limit of detection under the Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019.

    b. A history of use with no known residue related trade incidents.

Consideration of whether the registered chemical products complies with any requirement prescribed by the regulations

32) The particulars to be recorded for a chemical product are listed under regulation 16. Based on the information submitted with the application for registration of the product the current entries have been confirmed and no concerns have been raised as part of this reconsideration.

[1]The Agricultural and Veterinary Chemicals Code (Efficacy Criteria) Determination 2014 enacted under section 5B(1) contains efficacy criteria determined by the APVMA by legislative instrument. The APVMA considers this instrument to contain relevant matters for the purposes of section 5B(3).

33) The conditions of registration for chemical product are detailed in regulation 17C. Additional conditions apply to the current product registrations as outlined in paragraph 21 e above. The conditions that currently apply to these products remain appropriate.

Conclusion of considerations of chemical products

34) The APVMA is satisfied that the molinate chemical product registrations listed in Attachment A meet the efficacy and trade criteria. The APVMA is not satisfied that those same products meet the safety criteria, however the APVMA is satisfied that the product particulars can be varied to allow affirmation (as varied) under section 34(1) of the Agvet Code.

Label approvals

35) Section 34(1) of the Agvet Code provides that the APVMA must affirm the approval of a product label if, and only if it is satisfied that the label:

    a. meets the labelling criteria

    b. complies with any requirement prescribed by the regulations.

36) Section 5D(1) of the Agvet Code provides that a label for containers for a chemical product 'meets the labelling criteria' if the label contains adequate instructions relating to such of the following as are appropriate:

    a. The circumstances in which the product should be used

    b. How the product should be used

    c. The times when the product should be used

    d. The frequency of the use of the product

    e. The withholding period after the use of the product

    f. The re–entry period after the use of the product

    g. The disposal of the product when it is no longer required

    h. The disposal of containers of the product

    i. The safe handling of the product and first aid in the event of an accident caused by the handling of the product

    j. Any matters prescribed by the regulations. Regulation 8AE(1) of the Agvet Regulations relevantly prescribes the following:

        i. Regulation 8AE(1)(a) – for a chemical product that is a veterinary chemical product, the duration of the treatment

        ii. Regulation 8AE(1)(b) – the prevention of undue prejudice to trade or commerce between Australia and places outside of Australia

        iii. Regulation 8AE(1)(c) – the appropriate signal words (if any) required by the current Poisons Standard

        iv. Regulation 8AE(1)(d) – for a chemical product that is a date controlled product, the storage of containers for the product

        v. Regulation 8AE(1)(e) – any other matter determined by the APVMA CEO under regulation 8AE(2)

37) Section 5D(2) of the Agvet Code outlines the matters the APVMA must have regard to in determining whether a label meets the labelling criteria. These are:

a. any conditions to which its approval is, or would be, subject (section 5D(2)(a))

b. any relevant particulars and instructions that are, or would be, entered in the relevant APVMA file for the label (section 5D(2)(b))

c. whether the label conforms, or would conform, to any standard made for the label under section 6E to the extent that the standard relates to matters covered by subsection (1) (section 5D(2)(c)).

Consideration of whether the approved labels meet the labelling criteria

38) The APVMA has considered the current label instructions (as voluntarily varied by the registrant following the publication of the Preliminary Review Findings) to determine whether the current label contains adequate instructions as follows:

a. Section 5D(1)(a) – the circumstances in which the product should be used.

i. The product is to be used as a herbicide for the control of barnyard grasses and silver top grass in rice crops in permanent water. This is acceptable.

b. Section 5D(1)(b) – how the product should be used.

i. The product is applied by aerial application using Soluble Chemical Water Injection Rice Technique (SCWIRT) at rates of 2.5 L and 3.75 L in 10 L of water and 5.2 L in a minimum of 20 L of water per hectare by aerial application. As detailed in the Molinate Review Technical Report, the rates of application of 2.5 L and 3.75 L in 10 L of water are supported, however the rate of 5.2 L in a minimum of 20 L of water per hectare is not supported as the higher rate result in unacceptable exposure to workers handling the product.

ii. The product is not subject to spray drift restraints and the APVMA is not satisfied that the current use pattern ensures an acceptable level of exposure resulting from spray drift exposure to bystanders, natural aquatic areas or off target vegetation areas.

c. Section 5D(1)(c) – the times when the product should be used have been considered and remain appropriate:

i. The product is only to be applied to rice crops under permanent water.

ii. The product should be applied when barnyard grass is in the 1 to 4 leaf stage and silver top grass is up to the 2 leaf stage

d. Section 5D(1)(d) – the frequency of the use of the product, is once per crop/season as the timing of the application is specific for the stage of the crop development. This assumption underpinned the safety assessment for the product and the label instructions are considered adequate to ensure that the product is only applied once per season.

e. Section 5D(1)(e) – the withholding period after the use of the product, is ″Not required when used as directed″, which remains appropriate given early application and the MRL set at the limit of quantification.

f. Section 5D(1)(f) – there is currently no re-entry period after the use of the product – this was not supported as detailed in the Molinate Review Technical Report.

g. Section 5D(1)(g) and (h) – the instructions for disposal of unused product and disposal of containers are appropriate for the type of containers used for the relevant products (i.e. plastic containers) and the instructions are consistent with the Agricultural Labelling Code:

i. For general containers:

Store in the closed, original container in a cool, well ventilated area. Do not store for prolonged periods in direct sunlight. Store in a locked room away from children, animals, food, feedstuffs, seed and fertilisers.

Triple rinse containers before disposal. Add rinsings to spray tank. Do not dispose of undiluted chemicals on site. If recycling, replace cap and return clean containers to recycler or designated collection point. If not recycling, break, crush, or puncture and deliver empty packaging to an approved waste management facility. If an approved waste management facility is not available, bury the empty packaging 500 mm below the surface in a disposal pit specifically marked and set up for this purpose, clear of waterways, desirable vegetation and tree roots, in compliance with relevant local, state or territory government regulations. Do not burn empty containers or product.

ii. For containers carrying the drumMUSTER logo:

Store in the closed, original container in a cool, well ventilated area. Do not store for prolonged periods in direct sunlight. Store in a locked room away from children, animals, food, feedstuffs, seed and fertilisers.

This container can be recycled if it is clean, dry, free of visible residues and has the drumMUSTER logo visible. Triple rinse container for disposal. Dispose of rinsate by adding it to the spray tank. Do not dispose of undiluted chemical on site. Wash outside of the container and the cap. Store cleaned container in a sheltered place with cap removed. It will then be acceptable for recycling at any drumMUSTER collection or similar container management program site. The cap should not be replaced, but may be taken separately.

h. Section 5D(1)(i) – the safe handling of the product and first aid in the event of an accident caused by the handling of the product were considered and detailed in the Molinate Review Technical Report.

i. The current exposure to users mixing and loading the product, and those applying the product was not supported based on current use instructions.

ii. The current safety directions, ″May irritate the eyes and skin. Avoid contact with eyes and skin. DO NOT inhale spray mist. When preparing the spray wear elbow length PVC gloves. If product on skin, immediately wash area with soap and water. After use and before eating drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use wash gloves and contaminated clothing.″ were not supported on the basis of providing inadequate instruction″ as detailed in the Molinate Review Technical Report.

iii. The current first aid instructions ″If poisoning occurs contact a doctor or Poisons Information Centre. Phone Australia 13 11 26″ were not supported on the basis of providing inadequate instruction as detailed in the Molinate Review Technical Report.

i. Section 5D(1)(j) – any matters prescribed by the regulations (Regulation 8AE(1)).

i. Regulation 8AE(1)(a) – is not relevant as the products are agricultural chemical products.

ii. Regulation 8AE(1)(b) – the prevention of undue prejudice to trade or commerce between Australia and places outside of Australia. The current label does not include any specific instructions to prevent undue prejudice to trade or commerce between Australia and places outside of Australia. Given the history of use with no known residue related trade incidents, this is acceptable.

iii. Regulation 8AE(1)(c) the appropriate signal words (if any) required by the current Poisons standard. The product is designated as a Schedule 7 poison under the current Poisons

standard. As a Schedule 7 poison, the appropriate signal heading is ″DANGEROUS POISON″ and the label also requires the cautionary phrase ″KEEP OUT OF REACH OF CHILDREN″. As safety directions are required, the signal heading must also include the statement ″READ SAFETY DIRECTIONS BEFORE OPENING OR USING″. The current label meets these requirements.

iv. Regulation 8AE(1)(d) – The product is not a date controlled product, therefore specific storage requirements are not required.

v. Regulation 8AE(1)(e) – the APVMA CEO has not determined any other matter under regulation 8AE(2)(e).

j. Section 5D(2)(a) – the prescribed conditions for label approval (regulations 18B – 18J) currently apply to the label and will apply to the varied labels. These conditions are appropriate.

k. Section 5D(2)(b) – the relevant particulars and instructions to be entered into the relevant file for the label are appropriate.

l. Section 5D(2)(c) – this section does not apply as there is no standard made for this product under section 6E.

Conclusion of whether the labels meet the labelling criteria

39) The APVMA has identified that the current labels do not meet the labelling criteria in regards to the following:

a. How the product should be used, specifically:

i. rate of application

ii. level of exposure resulting from spray drift exposure to bystanders, natural aquatic areas or off target vegetation areas.

b. The re-entry period after the use of the product.

c. The safe handling of the product, specifically:

i. exposure to users mixing and loading the product, and those applying the product

ii. safety directions

iii. first aid instructions

Consideration of whether the labels can be varied to meet the labelling criteria

40) If the APVMA is not satisfied under subsection 34(1), but is satisfied that the relevant particulars or conditions of the label approval can be varied in such a way as to allow approval to be affirmed, the APVMA must vary the relevant particulars or conditions.

41) The APVMA has determined that the labels particulars can be varied as follows to allow the labels to be affirmed:

a. The label can be varied to limit the use of the product to application by fixed wing aircraft or helicopters using Soluble Chemical Water Injection Rice Technique (SCWIRT) at rates of 2.5 L and 3.75 L in 10 L of water per hectare.

b. The label can be varied to include spray drift restraints, including buffer zones, to decrease the risk of an unacceptable level of exposure resulting from spray drift exposure to bystanders, natural aquatic

areas or off target vegetation areas. The restraints are outlined in paragraph 25(c) and 25(d) above and included on the sample label (Appendix C).

c. The label can be varied to include a re–entry period to treated areas of 24 hours.

d. The label can be varied to reduce the exposure to users who are mixing and loading the product and those applying the product. Label restraints can be included on the label to ensure that different workers undertake the mixing and loading to those who apply the product, and the amount of product handled per day can also be limited.

The following restraints have been assessed as limiting the exposure to an acceptable level:

i. DO NOT use open mixing and loading systems (use closed mixing and loading only).

ii. A single operator MUST NOT be involved in BOTH mixing/loading AND application in the same day.

iii. A single operator involved in mixing/loading of the product MUST NOT handle more than 1400 L neat product per day.

iv. A single operator (pilot) MUST NOT apply the product spray to an area exceeding 280 hectares per day.

e. The safety directions can be varied to be:

Harmful if inhaled or swallowed. May irritate the eyes and skin. Repeated exposure may cause allergic disorders. Repeated minor exposure may have a cumulative poisoning effect. Avoid contact with eyes and skin. DO NOT inhale vapour or spray mist. When mixing and loading for aerial spraying equipment wear cotton overalls buttoned to the neck and wrist and a washable hat, PVC or rubber apron, elbow length PVC gloves and water resistant footwear.

If applying by aerial spraying equipment, wear cotton overalls, buttoned to the neck and wrist (or equivalent clothing), and water resistant footwear.

After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use wash gloves and contaminated clothing.

f. The First Aid instructions can be varied to be:

If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (phone Australia 13 11 26; New Zealand 0800 764 766) or doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.

42) Section 34A (3) provides that if the variation would affect instructions for use on a label, the APVMA must not make the variation until it has consulted each co–ordinator designated for a jurisdiction and taken into account any recommendations made by the co–ordinators.

a. The products are only registered for use in NSW. The NSW coordinator has been consulted on the proposed label variations and made no recommendations. Additional opportunity for comment will be afforded during the public consultation of this proposed decision.

Conclusion of considerations of labels

43) The label particulars for molinate chemical products can be varied to allow affirmation of the label approval under section 34(1) of the Agvet Code. The APVMA considers that if the label particulars are varied in accordance with Attachment C, then the label would contain adequate instructions relating to the matters in section 5D(1).

Conclusion

44) For the purposes of sections 34(1) and 34A(1) of the Agvet Code, and having regard to the matters set out above, the APVMA has determined that the APVMA is:

a. satisfied that the active constituent approvals listed in Attachment A meet the safety criteria.

b. not satisfied the molinate product registrations listed in Attachment A meet the safety criteria.

c. not satisfied the molinate label approvals listed in Attachment A meet the labelling criteria.

d. satisfied that the particulars of the product registrations and label approvals listed in Attachment A can be varied as detailed in the proposed label at Attachment C to allow the label approvals and the chemical product registrations to be affirmed.

45) Consequently, the APVMA proposes to:

a. affirm the active constituent approvals listed in Attachment A

b. vary the chemical product registrations and the label approvals listed in Attachment A, as set out in Attachment C

c. affirm the listed chemical product registrations and the label approvals (as varied) in Attachment A.

Attachment C: Sample label

Signal Heading:	DANGEROUS POISON KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING
Product Name:	[INSERT HERE]
Constituent Statement:	ACTIVE CONSTITUENT: 960 g/L MOLINATE
Mode of Action:	GROUP J HERBICIDE
Statement of Claims:	Post emergence control of grass weeds in rice in permanent water
Net Contents:	[INSERT HERE]
Directions For Use:	See directions for use section below. This can be uploaded as a separate section when submitting a label application
Withholding Period:	NOT REQUIRED WHEN USED AS DIRECTED
General Instructions:	For aerial application by SCWIIRT (Soluble Chemical Water Injection In Rice Technique) only
Resistance Warning:	[INSERT PRODUCT NAME] is a member of the thiocarbamates group of herbicides. [INSERT PRODUCT NAME] has the inhibitor of fat synthesis mode of action. For weed resistance management [INSERT PRODUCT NAME] is a Group J herbicide. Some naturally occurring weed biotypes resistant to [INSERT PRODUCT NAME] and other Group J herbicides may exist through normal genetic variability in any week population. The resistant individuals can eventually dominate the weed population if these herbicides are used repeatedly. These resistant weeds will not be controlled by [INSERT PRODUCT NAME] of other Group J herbicides. Since the occurrence of resistant weeds is difficult to detect prior to use, [INSERT COMPANY NAME] accepts no liability for any losses that may result from the failure of [INSERT PRODUCT NAME] to control resistant weeds.
Precautions:	DO NOT use if pregnant
Re-entry period:	DO NOT allow entry to treated area for 24 hours.
Protection Statements:	PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT DO NOT contaminate streams, rivers or watercourses with the chemical or used containers
Storage and Disposal:	STORAGE AND DISPOSAL: For general containers: Store in the closed, original container in a cool, well ventilated area. Do not store for prolonged periods in direct sunlight. Store in a locked room away from children, animals, food, feedstuffs, seed and fertilisers. Triple rinse containers before disposal. Add rinsings to spray tank. Do not dispose of undiluted chemicals on site. If recycling, replace cap and return clean containers to recycler or designated collection point. If not recycling, break, crush, or puncture and deliver empty packaging to an approved waste management facility. If an approved waste management facility is not available, bury the empty packaging 500 mm below the surface in a disposal pit specifically marked and set up for this purpose, clear of waterways, desirable vegetation and tree roots, in compliance with relevant local, state or territory government regulations. Do not burn empty containers or product. For containers carrying the drumMUSTER logo: Store in the closed, original container in a cool, well ventilated area. Do not store for prolonged periods in direct sunlight. Store in a locked room away from children, animals, food, feedstuffs, seed and fertilisers. This container can be recycled if it is clean, dry, free of visible residues and has the drumMUSTER logo visible. Triple rinse container for disposal. Dispose of rinsate by adding it to the spray tank. Do not dispose of undiluted chemical on site. Wash outside of the container and the cap. Store cleaned container in a sheltered place with cap removed. It will then be acceptable for recycling at any drumMUSTER collection or similar container management program site. The cap should not be replaced, but may be taken separately.
Safety Directions:	Harmful if inhaled or swallowed. May irritate the eyes and skin. Repeated exposure may cause allergic disorders. Repeated minor exposure may have a cumulative poisoning effect. Avoid contact with eyes and skin. DO NOT inhale vapour or spray mist. When mixing and loading for aerial spraying equipment wear cotton overalls buttoned to the neck and wrist and a washable hat, PVC or rubber apron, elbow length PVC gloves and water resistant footwear. If applying by aerial spraying equipment, wear cotton overalls, buttoned to the neck and wrist (or equivalent clothing), and water resistant footwear.

	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use wash gloves and contaminated clothing.
First Aid:	If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (phone Australia 13 11 26; New Zealand 0800 764 766) or doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.
Batch Number:	[INSERT HERE]
APVMA approval No:	[INSERT HERE]
Material Safety Data Sheet:	Additional information can be obtained from the material safety data sheet which can be obtained from the supplier.

Directions for use

Restraints

Under very cold conditions DO NOT apply to permanent water too early as crop may be drowned. A proportion of the first leaf must show above the water

DO NOT apply by ground based methods

DO NOT use open mixing and loading systems (use closed mixing and loading only)

A single operator MUST NOT be involved in BOTH mixing/loading AND application in the same day

A single operator involved in mixing/loading of the product MUST NOT handle more than 1400 L neat product per day

A single operator (pilot) MUST NOT apply the product spray to an area exceeding 280 hectares per day

Spray drift restraints

Specific definitions for terms used in this section of the label can be found at apvma.gov.au/spraydrift

DO NOT allow bystanders to come into contact with the spray cloud

DO NOT apply in a manner that may cause an unacceptable impact to native vegetation, agricultural crops, landscaped gardens and aquaculture production, or cause contamination of plant or livestock commodities, outside the application site from spray drift. The buffer zones in the relevant buffer zone table/s below provide guidance but may not be sufficient in all situations. Wherever possible, correctly use application equipment designed to reduce spray drift and apply when the wind direction is away from these sensitive areas

DO NOT apply unless the wind speed is between 3 and 20 kilometres per hour at the application site during the time of application

DO NOT apply if there are hazardous surface temperature inversion conditions present at the application site during the time of application. Surface temperature inversion conditions exist most evenings one to two hours before sunset and persist until one to two hours after sunrise

DO NOT apply by helicopter unless the following additional requirements are met:

- Apply only by SCWIIRT (Soluble Chemical Water Injection In Rice Technique)
- The release height is not greater than 2 metres above the ground

- The flying speed is not greater than 50 knots (92 km/hr)
- Minimum distances between the application site and downwind sensitive areas that appear in the 'Mandatory downwind buffer zones' section of the table below are observed

Buffer zones for helicopters using SCWIIRT				
Application Rate	**Mandatory downwind buffer zones**			
	Bystander areas	**Natural aquatic areas**	**Pollinator areas**	**Vegetation areas**
2.5L in minimum 10L/ha water	10 metres	10 metres	0 metres	0 metres
3.75L in minimum 10L/ha water	15 metres	10 metres	0 metres	5 metres

DO NOT apply by fixed wing aircraft unless the following additional requirements are met:

- Apply only by SCWIIRT (Soluble Chemical Water Injection In Rice Technique)
- The release height is not greater than 3m or 25% of wingspan above the ground whichever is the greatest
- Minimum distances between the application site and downwind sensitive areas (see mandatory buffer zones section of the following table titled Buffer zones for fixed wing aircraft using SCWIIRT) are observed

Buffer zones for fixed wing aircraft using SCWIIRT				
Application Rate	**Mandatory downwind buffer zones**			
	Bystander areas	**Natural aquatic areas**	**Pollinator areas**	**Vegetation areas**
2.5L in minimum 10L/ha water	150 metres	85 metres	0 metres	30 metres
3.75L in minimum 10L/ha water	200 metres	110 metres	0 metres	45 metres

Directions for use				
CROP/SITUATION	**WEEDS CONTROLLED**	**STATE**	**RATE**	**CRITICAL COMMENTS**
Rice – Permanent water Combine sown, sod sown and aerial sown rice	Barnyard Grasses (*Echinochloa* spp.) Silver top grass (*Diplachne fusca*)	NSW only	3.75L in minimum 10L/ha water	Apply when Barnyard grass in in the 1–4 leaf stage and Silver top is up to the two leaf stage. Weeds are usually 5–10cm high. NO MORE than one third plant bulk should be above water at spraying, nor should more than one third of the bay be covered by these plants. DO NOT allow movement of water through bays for 2 hours before spraying. ALLOW ONLY MINIMUM water movement through bays for 3 days after application. After this time normal water coverage should be maintained. DO NOT use if excess rice and weed vegetation will impede re–distribution of [the product] in water resulting in inadequate control.
	Barnyard Grasses (*Echinochloa* spp.) 0–2 leaf stage	NSW only	2.5L in minimum 10L/ha water	Coverage of the rice field with permanent water must be maintained after spraying. Water movement to and through bays should cease 2 hours before application. Minimum water movement should be maintained for 3 days after application. After this time normal water coverage should be maintained.

NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.