Australian Government

Australian Pesticides and Veterinary Medicines Authority

Methiocarb Proposed Regulatory Decisions

The reconsideration of the active constituent methiocarb, registration of products containing methiocarb and approvals of their associated labels

August 2018

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FOREWORD

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority with responsibility for the regulation of agricultural and veterinary chemicals in Australia. Its statutory powers are provided in the Agvet Codes scheduled to the Agricultural and Veterinary Chemicals Code Act 1994.

The APVMA has legislated powers to reconsider the approval of an active constituent, registration of a chemical product or approval of a label at any time after it has been registered. The reconsideration process is outlined in sections 29 to 34 of Part 2, Division 4 of the Agvet Codes.

A reconsideration may be initiated when new research or evidence has raised concerns about the use or safety of a particular chemical, a product containing that chemical, or its label. The scope of each reconsideration can cover a range of areas including human health (toxicology, public health, work health and safety), the environment (environmental fate and ecotoxicology), residues and trade, chemistry, efficacy or target crop or animal safety. However, the scope of each reconsideration is determined on a case-by-case basis reflecting the specific issues raised by the new research or evidence.

The reconsideration process includes a call for data from a variety of sources, a scientific evaluation of that data and, following public consultation, a regulatory decision about the ongoing use of the chemical or product. The data required by the APVMA must be generated according to scientific principles. The APVMA conducts scientific and evidence-based risk analysis with respect to the matters of concern by analysing all the relevant information and data available.

In undertaking reconsiderations, the APVMA works in close cooperation with other regulators the Department of the Environment and Energy, the Department of Health, Food Standards Australia New Zealand (FSANZ), state departments of agriculture, as well as other expert advisers as appropriate.

This document sets out the proposed regulatory decisions (PRD) relating to the active constituent methiocarb and products containing methiocarb when used in accordance with current approved label instructions.

This PRD and supporting technical reports on methiocarb are available from the APVMA website. The technical reports cover:

- toxicology
- occupational health and safety
- residues
- environment.

SUBMISSIONS FROM THE PUBLIC ARE INVITED

This proposed regulatory decisions report:

- outlines the APVMA reconsideration process
- summarises the technical assessments
- outlines the proposed regulatory action to be taken in relation to the continued approval and registration of methiocarb in Australia.

The APVMA invites written comments on this report. All comments on this report will be assessed by the APVMA prior to finalisation of the reconsideration and publication of the final regulatory decision report.

Preparing your comments for submission

When making your comments:

- 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
- suggest to the APVMA any alternative risk management solutions you may have.

Please structure your comments in point form, referring each point to the relevant section in the report.

All submissions to the APVMA will be acknowledged in writing via email or by post.

When making a submission please include:

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

Note that all submissions received are subject to the Freedom of Information Act 1982, the Privacy Act 1988 and the Agvet Code. All personal and confidential commercial information (CCI) material contained in submissions will be treated confidentially. (A full definition of 'confidential commercial information' is contained in the Agvet Code).

The closing date for submissions is 30 November 2018

Submissions can be sent to:

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EXECUTIVE SUMMARY

Introduction

Methiocarb is a carbamate, non-systemic pesticide that has been registered for use in Australia for over 30 years. It kills insects, slugs and snails by interfering with the activity of acetylcholinesterase, an enzyme in the nervous system.

In Australia, methiocarb is currently registered for use in the control of snails, slugs, false wireworm beetles, millipedes and slaters in a range of agricultural and home garden situations. At present methiocarb is available only as granular bait (20 g/kg methiocarb) formulation.

The APVMA began its reconsideration of methiocarb in 1995 because of concerns over public health, occupational health and safety, residues in food, and possible risks to Australian trade and the environment. There were also some adverse experience reports relating to domestic animals inadvertently consuming pellets of methiocarb products.

The scope of the reconsideration includes the following aspects of active constituent approvals, product registrations and label approvals for methiocarb:

- toxicology
- occupational health and safety (OHS)
- residues including dietary exposure and trade
- environment.

Reconsideration findings

As part of the methiocarb reconsideration, the APVMA published the toxicology, OHS, environment, and residues and trade assessment reports along with the Preliminary Review Findings (PRF) in 2005. These assessment reports were since updated to take into account the public comments on the PRF and the additional data received after the publication of the PRF report.

Based on the toxicology and OHS assessments of methiocarb, no change is recommended to the current Acceptable Daily Intake (ADI) for methiocarb of 0.002 mg/kg bw/d. The acute reference dose (ARfD) for methiocarb has been amended from 0.03 mg/kg bw to 0.005 mg/kg bw. There have been no changes recommended to the approval status of the active constituent or to the current poisons schedule of methiocarb. It was recommended that the label instructions be varied to amend the safety directions and first aid instructions.

The residue assessment concluded that, provided product labels be varied (as specified in Section 3.3 of this report), the use of methiocarb products meets the safety and trade criteria. Further, it was recommended that the maximum residue limits (MRLs) standard of methiocarb be amended, as specified in Table 4, to reflect the findings of the residue assessment.

The environmental assessment concluded that product labels be varied to minimise the risk to aquatic organisms resulting from runoff and harmful effects to birds and mammals. The proposed amendments are presented in Section 3.4 of this report.

Proposed regulatory decisions

After consideration of all data and assessments, and all submissions to the preliminary review findings report, the APVMA proposes the following regulatory actions:

- **Affirm** active constituent approvals for methiocarb (as listed in Appendix A, Table A1).
- **Vary** relevant particulars of registrations and label approvals of methiocarb products (as listed in Appendix A, Table A2) to delete, add or amend certain use patterns; amend safety directions and first aid instructions; add restraint statements; and amend withholding periods.
- **Affirm** these product registrations and label approvals once the necessary particulars and conditions have been varied.
- **Cancel** all previous product label approvals that are not consistent with the review outcomes.
- **Allow** a one-year phase-out period for the continued supply and use of registered products bearing the earlier approved labels.

Appendix B contains product specific label variations for all methiocarb products to be affirmed.

1 INTRODUCTION

Methiocarb is a carbamate pesticide of high acute toxicity that has been used in both agricultural and home garden situations. Products are registered to control snails and slugs in berry crops, cereals, gardens, nurseries, oilseed crops, orchards, pastures and vegetable crops, and as a control measure for false wireworm beetle in sunflowers. It is also used to control snails, slugs, slaters and millipedes in home gardens.

Methiocarb has been registered for use in Australia since the early 1980s. Its mode of action is through inhibition of the enzyme acetylcholinesterase, an enzyme in the nervous system. This inhibition results in the over-stimulation of those parts of the nervous system that use acetylcholine to transmit nerve impulses.

1.1 Current regulatory status of methiocarb in Australia

As of August 2018 there are two active constituent approvals for methiocarb and two registered products containing methiocarb (Appendix A). Of the two products, one is for home garden use and one for agricultural use (Table 1). All registrations and approvals are held by Bayer CropScience Pty Ltd. Products containing methiocarb are applied by hand and equipment such as fertiliser spinners, combines or sod seeders.

Table 1: Formulation types for methiocarb products

Formulation type	Level of Active Constituent	Product Type
Bait	20 g/kg methiocarb	Home garden
Bait	20 g/kg methiocarb	Commercial

1.2 APVMA reconsideration of methiocarb

Methiocarb was selected for review from the Priority Candidate Review List as part of the APVMA's Existing Chemicals Review Program. This program was established to systematically review a number of Agvet chemicals that have been on the Australian market for some time.

The APVMA began its review of the active constituent methiocarb, all products containing methiocarb and their associated labels in 1995. Methiocarb was nominated because of concerns over public health, occupational health and safety, exposure to methiocarb residues in food, and possible risks to Australian trade and the environment. These concerns included:

- lack of appropriate maximum residue limits (MRLs) for some agricultural uses (including cereal grains and oilseeds)
- residue detections in produce above MRLs (detected through the National Residue Survey)
- MRL inconsistencies with major trading partners (US, Canada, Codex), and
- potential risk to workers from exposure.

State agricultural departments also submitted reports of adverse effects for products containing methiocarb, in particular in respect of its high toxicity to dogs.

The scope of the reconsideration included the following aspects of active constituent approvals, product registrations and label approvals for methiocarb:

- toxicology
- occupational health and safety
- residues, and
- environment.

The basis for the reconsideration of the registration and approvals for methiocarb is whether the APVMA is satisfied that the safety and trade criteria listed in sections 5A and 5C of the Agvet Codes for continued registration and approval are being met. These requirements are that the use of the product, in accordance with instructions approved, or to be approved, by the APVMA for the product or contained in an established standard:

- would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues
- would not be likely to have an effect that is harmful to human beings
- would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment, and
- would not unduly prejudice trade or commerce between Australia and places outside Australia.

The APVMA also considered whether labels for containers for chemical products containing methiocarb meet the labelling criteria as defined in section 5D of the Agvet Code, which requires that labels have adequate instructions relating to:

- the circumstances in which the product should be used
- how the product should be used
- the times when the product should be used
- the frequency of the use of the product
- the re-entry period after use of the product
- the withholding period after the use of the product
- disposal of the product and its container
- safe handling of the product and first aid in the event of an accident
- any matters prescribed by the regulations.

1.3 Submissions received since the publication of the Preliminary Review Findings report

Since the publication of toxicology, occupational health and safety, environment and residue component reports in 2005, along with the Preliminary Review Findings Report (PRF), the APVMA received several submissions from a government authority (the former NSW Department of Environment and Conservation), industry groups and the registration holder Bayer CropScience Pty Ltd. New toxicology, residues and environment studies were received from the registration holder. These submission were considered and assessed by the APVMA.

1.4 Regulatory options

There are three possible outcomes to the reconsideration of the active constituent methiocarb, registration of products containing methiocarb and all associated label approvals. Based on the information reviewed the APVMA may be:

- satisfied that the products and their labels continue to meet the prescribed requirements for registration and approval and therefore affirms the registrations and approvals
- satisfied that the conditions to which the registration or approval is currently subject can be varied in such a way that the requirements for continued registration and approval will be complied with and therefore varies the conditions of registration or approval
- not satisfied that the requirements for continued registration and approval continue to be met and thus suspends or cancels the registration and/or approval.

1.5 Next steps for this reconsideration

In this PRD report certain regulatory actions are proposed based on the assessments conducted by the APVMA and its partner agencies.

Persons and organisations are invited to submit their comments and related information relevant to these proposed decisions directly to the APVMA. This consultation period continues for three months ending on Friday 30 November 2018.

After the consultation period the APVMA will assess the submissions and make the final regulatory decisions for this review.

2 INTERNATIONAL REGULATORY STATUS

This information is collated from various sources for the information of stakeholders and community groups.

Methiocarb is approved for use in the United States (US), Europe, United Kingdom (UK) and New Zealand.

United States

Methiocarb was first registered in the US in 1972. The United States Environmental Protection Agency (US EPA) issued a Registration Standard for methiocarb in March 1987, requiring additional product chemistry, residue chemistry, ecological effects, environmental fate, toxicology and occupational and residential exposure data. The methiocarb producers deleted all food uses from their product labels between 1989 and 1992.

Currently, 22 registered pesticide products contain the active ingredient methiocarb. All methiocarb products for outdoor use, except products with homeowner uses, are classified as Restricted Use Pesticides, and may be applied only by or under the direct supervision of certified applicators.

Canada

Currently, Canada has no registered pesticide products containing methiocarb. In 2003 the Pest Management Regulatory Agency (PMRA) announced that “since the initiation of the re-evaluation program, the registrations of methiocarb and their associated end-use products have been discontinued by registrants”. The use of methiocarb in food producing plants was already discontinued at this time.

Europe and the United Kingdom

Methiocarb is authorised for use in the European Union (EU) under Directive 91/414/EEC. Methiocarb was added to Annex I of the directive (for approved substances) in September 2006 following a review by the rapporteur Member State the United Kingdom.

FAO/WHO Joint Meeting on Pesticide Residues (JMPR)

Methiocarb has been reviewed by the Joint FAO/WHO Meeting of Pesticide Residues (JMPR) in 1981, 1983, 1984, 1985, 1987 and 1998. In the most recent review in 1998, the JMPR amended the acceptable daily intake (ADI) to 0.02 mg/kg bw/day, based on a revised NOEL of 1.5 mg/kg bw/day from the same 2-year dog study and a safety factor of 100.

3 SUMMARY OF ASSESSMENTS AND PROPOSED FINDINGS

The 2005 PRF report considered four registered products containing methiocarb that were approved at the time. Two products were formulated as baits, one was a suspension concentrate (SC) and one was a wettable powder (WP). Both the SC and WP products are no longer registered in Australia, leaving only the two bait formulations as registered products containing methiocarb.

As a result, the following assessments for the reconsideration of methiocarb only considerd data for bait formulations which are currently approved. Data for bait formulations considered in the 2005 preliminary review and data that have been submitted since the preliminary review has been evaluated.

All of the reports mentioned below are available from the methiocarb chemical review webpage (in the Publication Archive).

3.1 Toxicology

In April 2005, the APVMA published the toxicology report of methiocarb. This report was updated by the then Office of Chemical Safety (OCS—within the Department of Health) and was published in May 2013. The OCS assessed toxicology data submitted to the review, together with information from its toxicological database and relevant published data. After the publication of the 2013 toxicology update, the APVMA received 24 additional toxicological studies. Following this, the APVMA Health Assessment Team updated the toxicology assessment and this report has been published concurrently with this PRD.

Toxicology assessment

Methiocarb has high acute oral toxicity and low dermal toxicity. The Median Lethal Dose (LD_{50}) for methiocarb is 9–135 mg/kg bw in rats and the dermal LD_{50} was determined to be in excess of 2000 mg/kg in rat studies. It is not an eye irritant, not a skin irritant and not a skin sensitiser. In repeat dose studies in rats, dogs and rabbits, dose–related inhibition of plasma, erythrocyte and brain cholinesterase (ChE) activities was generally the most sensitive manifestation of methiocarb toxicity.

Methiocarb is not genotoxic or carcinogenic.

Approval status

The toxicology assessment concluded that there are no objections on toxicological grounds to the ongoing approval of the active constituent methiocarb.

Acceptable Daily Intake (ADI)

The Acceptable Daily Intake (ADI) for humans is the level of intake of a chemical that can be ingested daily over an entire lifetime without appreciable risk to health. It is established by dividing the overall NOAEL (No Observed Adverse Effect Level) for the most sensitive, relevant adverse effect from a suitable study by an appropriate safety factor—the magnitude of the safety factor is selected to account for uncertainties in extrapolation of animal data to humans and intraspecies variation.

The current ADI for methiocarb is 0.002 mg/kg bw/d which was derived by applying a 100-fold safety factor to a NOAEL of 0.2 mg/kg bw/d (5 ppm), based on plasma ChE depression and reduced food consumption observed in a 2-year dietary dog study at the next highest dose tested (60 ppm).

No change to the current Australian ADI is proposed, as this review has not identified any other study that is more suitable for setting the pivotal NOAEL, and it is considered that the decreased plasma cholinesterase and reduced feed intake are appropriate toxicological endpoints on which to base the NOEL. The 100-fold safety factor is considered appropriate and does not require revision.

Acute Reference Dose (ARfD)

The Acute Reference Dose (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.

The APVMA has revised the Australian ARfD for methiocarb from 0.03 mg/kg bw/d to 0.005 mg/kg bw/d (4 December 2017), based on a NOEL of 0.5 mg/kg bw/d for clinical signs (muscle fasciculations) in dams in a rat developmental study, with a 100-fold safety factor.

Poisons Schedule

The toxicology assessment concluded that methiocarb (for pelleted preparations containing 2 percent or less of methiocarb) remain in Schedule 5 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

First aid instructions

The toxicology assessment concluded that the first aid instructions for methiocarb products be amended as specified in Table 2. On the basis of the estimated acute toxicity, the current first aid instruction ‘m’ is not appropriate for the bait products. These pelleted preparations containing 2% or less of methiocarb are in Schedule 5 of the SUSMP due to their low acute toxicity profile. Therefore, the following first aid instruction for methiocarb products is recommended:

Table 2: Recommended first aid instructions for methiocarb products

Methiocarb	Codes	Text
≤20%	a	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131 126, New Zealand 0800 764 766.

3.2 Occupational Health and Safety (OHS)

In April 2005, the APVMA published the OHS report of methiocarb, undertaken by the OCS. This was based on the information obtained from industry submissions, responses to an APVMA user questionnaire, state agriculture departments, published literature and overseas reviews. This report was updated by the APVMA to revise the first

aid instructions and safety directions for methiocarb products. The updated report: *Update to Occupational Health and Safety Assessment* was published in May 2017.

Findings of the OHS assessments

The occupational risk assessment takes into consideration the hazard of the chemical as determined by toxicology, its use pattern in Australia and worker exposure for each exposure situation.

The occupational risk during loading, application and post-application is evaluated using a Margin of Exposure (MOE) approach, where estimated occupational exposures are compared to a toxicological threshold (the No-Observed-Adverse-Effect-Level (NOAEL) for the most sensitive adverse effect relevant to humans. The larger the MOE the lower the risk—typically a MOE of 100 is considered an adequate margin of safety based on non-cancer effects in laboratory animals whereas a MOE of 10 is considered appropriate based on human data.

Based on the risk assessment, risk management measures are then recommended to reduce human exposures to an acceptable level. Those measures may include engineering controls, safety directions (including for personal protective equipment (PPE)), use restraints, re-entry intervals and scheduling recommendations.

Methiocarb exposure is usually associated with the inhibition of cholinesterase activity. As the extent of cholinesterase inhibition increases, clinical effects that are characteristic of carbamates may be observed. To estimate methiocarb risk, short-term studies were considered the most appropriate, as most exposures are expected to be infrequent (one to two applications per year) with applications made on a small number of consecutive days.

A number of repeat dose animal studies were considered suitable to establish NOAELs relevant for an OHS risk assessment. Based on a consideration of the likely duration and routes of worker exposure (ie. dermal and inhalation), the OHS risk assessment used NOAELs derived from a 3-week dermal study and a 3-week inhalational study in rabbits and rats respectively. The methiocarb risk assessment relies on animal data only, therefore a MOE of 100 or more is considered acceptable.

The NOAEL, based on cholinesterase inhibition and decreased food consumption and weight gain, was 60 mg/kg bw/d for dermal exposure whereas for inhalational exposure, with the same toxicological endpoint, the NOAEL was 6 mg/m^3 [converted to a systemic exposure of 1.6 mg/kg bw/d].

Safety directions

The following changes to safety directions are recommended.

Safety directions to be deleted

Given that methiocarb SC 500 g/kg or less and WP 750 g/kg or less formulations are no longer registered, the safety direction entries for these formulations should be deleted from the FAISD Handbook – *Handbook of First Aid Instructions, Safety Directions, Warning Statements and General Safety Precautions for Agricultural and Veterinary Chemicals*.

Safety directions to be amended

Table 3: Recommended Safety directions for methiocarb products

Codes	Text
Product type: BA 20g/kg or less (>1 kg pack size)	
129 133 160 162 210 211 250 252 310 290 306 (dust) 289 290 294c 350 360 361	Harmful if swallowed. May irritate the eyes. Avoid contact with eyes and skin. Do not touch bait. If on skin and after each baiting, wash thoroughly with soap and water. If dust is present, wear disposable dust face mask covering mouth and nose. If applying by hand, wear elbow length chemical resistant gloves. 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.
Product type: BA HG 20g/kg or less (1kg pack or less)	
129 133 160 162 210 211 250 277 279 290 321 310 290 306 (dust) 252 351	Harmful if swallowed. May irritate the eyes. Avoid contact with eyes and skin. Do not touch bait except when wearing disposable gloves. If dust is present, wear disposable dust face mask covering mouth and nose. If on skin and after each baiting, wash thoroughly with soap and water. Wash hands after use.

3.3 Residues, Dietary Risk Assessment and Trade

The residues assessment for the reconsideration of methiocarb was undertaken by the APVMA and published in 2005. This report and its findings were updated by the APVMA to consider new information received after the publication. This considered the available metabolism, residue trial data, analytical methodology, fate in storage and processing data, and residues in trade information, including that submitted by the applicant. The report: *Update to Residues Assessment* has been published concurrently with this PRD.

Dietary risk assessment

Chronic dietary exposure

The chronic dietary exposure to methiocarb is estimated by the National Estimated Daily Intake (NEDI) calculation encompassing all registered and temporary uses of the chemical and the mean daily dietary consumption data derived primarily from the 2011–2012 National Health and Physical Activity Survey. The NEDI calculation is made in accordance with WHO Guidelines[1] and is a conservative estimate of dietary exposure to chemical residues in food. The NEDI for methiocarb is equivalent to <40 % of the ADI.

It is concluded that the chronic dietary exposure of methiocarb is acceptable. It is noted that the exposure estimates were conservative as values at the Limit of Quantitation (LOQ) were included in the calculation, and residues are not expected in commodities in which LOQ MRLs have been recommended.

[1] WHO (2008). Consultations and workshops: Dietary Exposure Assessment of Chemicals in Food: Report of a joint FAO/WHO Consultation, Annapolis, Maryland, USA, 2–6 May 2005.

Acute dietary exposure assessment

The acute dietary exposure is estimated by the National Estimated Short Term Intake (NESTI) calculation. The NESTI calculations are made in accordance with the deterministic method used by the JMPR with 97.5th percentile food consumption data derived primarily from the 2011–2012 National Health Survey. NESTI calculations are conservative estimates of short-term exposure to chemical residues in food.

With the exclusion of the leafy vegetable crop group (except head lettuce), the acute exposures for the uses of methiocarb supported by residues data are acceptable. The continued use on leafy vegetable crop group (except head lettuce) will not be supported.

Residue related aspects of trade

Citrus fruit, grapes (including dried grapes and wine) and animal commodities are considered to be major trade commodities. Finite residues of methiocarb are not expected in citrus, grapes or animal commodities, and MRLs at the LOQ are recommended. The use of methiocarb as per the proposed label instructions is therefore unlikely to pose an undue risk to trade.

Supported uses of methiocarb

In support of this reconsideration, Bayer CropScience Pty Ltd has provided a number of trials for a variety of commodities conducted in Australia and Europe, which have been used for the residues assessment. Data considered in the 2005 PRF and data that have been submitted since the PRF were considered. The following use patterns are acceptable from a residues perspective:

Crop	Pest	Rate
Citrus, Grapes, Strawberries, Ornamentals	Common garden snail, slugs	5.5 kg/ha (110 g ai/ha)
	White Italian snail, white snail (not Qld)	or 11-22 kg/ha (220-440 g ai/ha)
Cereals and Oilseeds (Pre-emergent uses only), Pastures, Artichoke, Brassica vegetables, Head lettuce and Potato	Common garden snail, slugs	5.5 kg/ha (110 g ai/ha)
	White Italian snail, white snail (not Qld)	
Sunflowers (Qld, SA only)	False wireworm beetle	2.5 kg/ha (50 g ai/ha) (10 pellets/m^2)

Crop	Pest	Rate
Gardens	Snails, Slugs, Slaters, Millipedes	100 pellets/m^2 (500 g ai/ha equivalence)

Summary of the assessment recommendations

No amendments are required to the home garden product *Baysol Snail and Slug Bait* based on the residues assessment, as this product is not approved for use on food-producing crops. However, the following amendments and recommendations are proposed to *Mesurol Snail and Slug Bait* product label to meet the safety criteria as defined by section 5A of the Agvet Code:

- Delete the critical comment “When applying in vegetable crops, ensure pellets do not become lodged in plant foliage”.
- Delete the precaution “Avoid application of pellets to foliage of edible crops”.
- Add the restraint “DO NOT apply directly onto edible plants or to crops where baits may be collected with harvested commodities”.
- Add the restraint “DO NOT apply to cereal or oilseed crops after crop emergence”.
- Add the words “treated areas” to the grazing WHP.
- Move the statement “DO NOT treat areas on which poultry graze” from protection of livestock to the withholding period section of the label.
- Change the grazing WHP for cereals, oilseeds and pastures from 7 days to 28 days. The submitted trials do not address the 7 day WHP for cereals and oilseeds. Additionally, considering that pellets should degrade within 28 days, it is prudent to consider the grazing WHP of 28 days after application, to prevent inadvertent ingestion of the pellets by livestock during grazing.
- Change the WHP headings from “Edible crops” and “Treated areas” to “Harvest” and “Grazing” respectively.
- The uses on berry crops (including grapevines), gardens, nurseries, orchards and vegetable crops cannot be supported due to the insufficient residue data.
- The uses on citrus, grapes, strawberries, ornamentals, cereals, oilseeds, pastures, artichoke, brassica vegetables, head lettuce and potato are supported at 5.5 kg/ha (110 g ai/ha). The 11–22 kg/ha (220–440 g ai/ha) rate cannot be supported due to the insufficient residue data for these uses.
- The 11–22 kg/ha (220–440 g ai/ha) rate is only supported for citrus, grapes, strawberries and ornamentals.
- Add the restraint “DO NOT graze treated orchards or vineyards”.

MRL recommendations

Based on the residues evaluation it is proposed that the following changes to the MRL Standard are recommended for implementation once any periods for the legal use of previous versions of varied or cancelled labels have ended:

Table 4: Proposed changes to maximum residue limits for methiocarb in food commodities as listed in Table 1, Table 4 and Table 5 of the MRL Standard

Table 1

COMPOUND		FOOD	MRL (mg/kg)
Methiocarb			
DELETE:			
FC	0001	Citrus Fruits	0.1
		Fruits (except citrus fruits; grapes)	T0.1
FB	0269	Grapes	0.5
		Vegetables	0.1
		Wine	0.1
ADD:			
VS	0620	Artichoke, globe	*0.06
VB	0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassica	0.1
GC	0080	Cereal grains	*0.06
FC	0001	Citrus fruits	*0.06
MO	0105	Edible offal (Mammalian)	*0.05
PE	0112	Eggs	*0.05
FC	0004	Grapes	*0.06
VL	0482	Lettuce, Head	0.2
MM	0095	Meat [mammalian]	*0.05
ML	0106	Milks	*0.005
SO	0088	Oilseeds	*0.06
VR	0589	Potato	*0.06
PO	0111	Poultry, Edible offal of	*0.05

COMPOUND		FOOD	MRL (mg/kg)
PM	0110	Poultry meat	*0.05
FB	0275	Strawberries	*0.06

Table 4

COMPOUND	Animal Feed Commodity	MRL (mg/kg)
Methiocarb		
ADD:		
	Primary feed commodities	1

Table 5

Substance	Use
DELETE	
Methiocarb	• In baits for the control of garden pests • {T} in baits for the control of gardens pests on herbs, lemon balm, lemon grass, kaffir lime leaves, lemon verbena and tumeric.

*: The MRL is set at or about the limit of analytical quantification. {T}: The MRL, residues definition or use is temporary.

3.4 Environment

The environmental assessment for the reconsideration of methiocarb was undertaken by the then Department of the Environment, Water, Heritage and the Arts (DEWHA), who considered all the environmental data and information submitted for the review. Findings of the environmental report were released in the 2005 PRF and then updated in 2006 to take into account public comments received on the original environmental assessment. This report was not published as additional environmental data were received after the report's finalisation and required extra assessment.

Since 2006, the APVMA has received 12 studies on the fate of methiocarb and its metabolites and 73 studies on the toxicity of methiocarb and its metabolites on non-target species. Therefore, the APVMA updated the environmental report to include the assessment of these studies. Additionally, this report updates the previous environmental risk assessment of methiocarb where the new data require a revision of the end-points previously applied. The *Supplementary Environmental Assessment* report has been published concurrently with this PRD.

Mesurol Snail and Slug Bait

New data showed residues in earthworms following field use of representative formulations. A revised assessment of secondary poisoning potential to Australian birds indicated a high risk from this exposure route. However, evidence provided in additional field tests in a wide range of cropping situations treated with methiocarb pellets indicated that, in reality, birds are unlikely to be impacted either lethally or sub-lethally.

Additional toxicity data for methiocarb and metabolites to soil organisms have necessitated an update to the soil organism risk assessment. It was demonstrated that the risk from methiocarb metabolites was no greater than that from the parent compound and the overall risk to soil organisms was considered acceptable.

The additional data provided has resulted in a lower aquatic end-point than previously applied and resulted in a re-assessment of runoff. Based on the maximum application rate (22 kg product/ha), risks from dryland cropping use were considered acceptable. Highest risks were associated with the use in vegetables.

In many cases, rate restrictions in summer months are proposed in the southern states of Victoria, South Australia and Tasmania. It appears counter intuitive that, as these are the driest months, the risks from runoff are expected to be lower. Given the lower probability of actual rainfall occurring in these southern states during the summer months, the APVMA proposes the following statement in lieu of the rate restrictions proposed for Victoria, Tasmania and South Australia:

> DO NOT apply in summer if rainfall of more than 10 mm per day is forecast for the next 48 hours.

The following table summarises the outcomes of the runoff assessment in terms of identified risks for different uses and the associated risk management options that would allow the risk to be considered acceptable.

Table 5: Risk management recommendations for runoff risk

Use situation	State/region	Risk management recommendations
Pasture	VIC, TAS	DO NOT apply more than 11 kg/ha in summer
Orchards	VIC, TAS, SA	DO NOT apply to orchards with bare soil inter-rows
	Northern Gulf	DO NOT apply more than 11 kg/ha in the Northern Gulf in November.
	Fitzroy	DO NOT apply more than 11 kg/ha in the Fitzroy catchment.
	SE Queensland	DO NOT apply more than 11 kg/ha in the South East QLD catchments.
Vegetables	VIC	DO NOT apply more than 11 kg/ha in summer
	TAS	DO NOT apply more than 11 kg/ha in spring DO NOT apply more than 5.5 kg/ha in autumn DO NOT apply in Tasmania in summer
	SA, WA	DO NOT apply more than 11 kg/ha in summer
	Cape York	DO NOT apply more than 11 kg/ha in November
	Northern Gulf	DO NOT apply more than 11 kg/ha in October DO NOT apply more than 5.5 kg/ha in November
	Mackay/Whitsunday	DO NOT apply more than 11 kg/ha in October and November
	SE Queensland	DO NOT apply more than 11 kg/ha in the South East QLD catchments.

Additionally, the label for Mesurol Snail and Slug Bait contains the following instruction aimed at minimising harmful effects to birds and mammals: “After filling the applicator, clean up spilled pellets so that they are not eaten by animals and birds”. It is recommended that this instruction be varied by insertion of “immediately” after “pellets” as the longer the spilled pellets remain available, the greater the risk of being eaten by non-target species, with concomitant poisoning. The revised statement would read:

> “After filling the applicator, clean up spilled pellets immediately so that they are not eaten by animals and birds.”

Baysol Snail and Slug Bait

The same instruction aimed at minimising harmful effects to birds and mammals appears on the label of the home garden product Baysol. Therefore, it is recommended that this instruction be varied by insertion of “immediately” after “pellets”. The revised statement would read:

“Clean up spilled pellets immediately so that they are not eaten by animals and birds.”

4 PROPOSED REGULATORY DECISIONS

On the basis of the risk assessments described in Section 3, the APVMA proposes to make the following decisions with regard to the continued approval of the active constituent methiocarb, product registrations containing methiocarb and associated label approvals in Australia.

4.1 Affirm approvals of the active constituent methiocarb

The APVMA proposes to decide, under s34(1)(a) of the Agvet Code, that it is SATISFIED that the active constituent methiocarb meets the safety criteria. That is, if the use of the constituent, in accordance with any instructions approved by the APVMA for the constituent or contained in an established standard, is not, or would not be:

- an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues, and
- likely to have an effect that is harmful to human beings, and
- likely to have an unintended effect that is harmful to animals, plants and things or to the environment.

Accordingly, the APVMA proposes to AFFIRM the approval of the active constituents listed in Table 6 below.

Table 6: Active constituent approvals to be affirmed

Approval number	Active Constituent	Approval Holder
44212	Methiocarb	Bayer CropScience Pty Ltd
55824	Methiocarb	Bayer CropScience Pty Ltd

4.2 Vary particulars of product registrations and label approvals, cancel previous labels and affirm product registrations with varied labels

The APVMA proposes to decide, under s34(1) of the Agvet Code, that it is NOT SATISFIED that the products listed in Table 7 below meet the safety criteria and/or the trade criteria and/or the efficacy criteria as defined in sections 5A, 5B, 5C and 5D of the Agvet Code.

However the APVMA also proposes to decide, under s34A of the Agvet Code, that the relevant particulars or conditions of the registration (or approval) can be varied in such a way (as listed in Appendix B) to allow the registration or approval to be affirmed.

Therefore the APVMA is proposing to VARY the registration and current label approval for these products, assigning new label approval numbers as listed in Column 6 of Table 7, and to CANCEL any previous label approvals so that there will be only one approved label for each of these products.

These variations to label instructions would satisfy the requirements for continued registration of products and the APVMA proposes that product registrations and label approvals listed be AFFIRMED once labels have been varied and previous labels cancelled.

Table 7: Product registrations and label approvals to be affirmed following variation of approved labels

Product Number (1)	Product name (2)	Holder (3)	Label approvals to be cancelled (4)	Label approval to be varied and no longer in force (5)	New label approval number (6)
33274	Mesurol Snail and Slug Bait	Bayer CropScience Pty Ltd	33274/1097 33274/0100 33274/0304	33274/1209	33274/RVmmyy
51851	Baysol Snail and Slug Bait	Bayer CropScience Pty Ltd	51851/0599 51851/55632	51851/100882	51851/RVmmyy

4.3 Phase-out periods

The APVMA proposes under s 81(3)(b) of the Agvet Code that a one-year phase-out period shall apply for the continued supply of registered products bearing the earlier approved labels (Column 5 of Table 7). During this time, products may continue to be used according to the earlier approved label instructions. After that period all product that is supplied should bear the varied approved label (Column 6 of Table 7).

The APVMA has determined under s 45A and s 45B of the Agvet Code that a one-year phase-out period shall apply for possessing, having custody of, or using products listed in Table 7 bearing cancelled labels shown in Column 4 of Table 7. During this time, product may continue to be used according to the earlier approved label instructions.

5 PROPOSED AMENDMENTS TO STANDARDS

5.1 Health-based guidance values

Acceptable daily intake (ADI)

The current ADI for methiocarb of 0.002 mg/kg bw/day is acceptable and no amendments are required.

Acute reference dose (ARfD)

The ARfD has been amended from 0.03 mg/kg bw/d to 0.005 mg/kg bw/d.

Poisons schedule

There are no changes required to the current Schedule 5 listing for methiocarb products.

First-aid instructions

The APVMA proposes that the following amended first-aid instructions be included in methiocarb product labels:

Methiocarb	Codes	Text
≤20%	a	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131 126, New Zealand 0800 764 766.

Safety directions including

The APVMA proposes that the following amended safety directions be included in methiocarb product labels:

Codes	Text
Product type: BA 20g/kg or less (>1 kg pack size)	
129 133 160 162 210 211 250 252 310 290 306 (dust) 289 290 294c 350 360 361	Harmful if swallowed. May irritate the eyes. Avoid contact with eyes and skin. Do not touch bait. If on skin and after each baiting, wash thoroughly with soap and water. If dust is present, wear disposable dust face mask covering mouth and nose. If applying by hand, wear elbow length chemical resistant gloves. 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.

Codes	Text
Product type: BA HG 20g/kg or less (1kg pack or less)	
129 133 160 162 210 211 250 277 279 290 321 310 290 306 (dust) 252 351	Harmful if swallowed. May irritate the eyes. Avoid contact with eyes and skin. Do not touch bait except when wearing disposable gloves. If dust is present, wear disposable dust face mask covering mouth and nose. If on skin and after each baiting, wash thoroughly with soap and water. Wash hands after use.

Delete entries

The safety directions instructions for methiocarb products containing SC 500 g/kg or less and WP 750 g/kg or less are to be deleted from FAISD Handbook as there are no registered products of this type.

5.2 MRL Standards

Arising from the assessment of data submitted during the reconsideration of methiocarb, changes to the MRL Standard presented in Section 3.3, Table 4 are recommended for implementation once any periods for the legal use of previous versions of varied or cancelled labels have ended.

Appendix

APPENDIX A: LIST OF ACTIVE CONSTITUENTS APPROVALS, PRODUCT REGISTRATIONS AND LABEL APPROVALS

Table A-1: Active constituent approvals included in the reconsideration

Approval number	Active Constituent	Approval Holder
44212	Methiocarb	Bayer CropScience Pty Ltd
55824	Methiocarb	Bayer CropScience Pty Ltd

Table A-2: Product registrations and label approvals included in the reconsideration

Product Number	Product name	Holder	Label approval number
33274	Mesurol Snail and Slug Bait	Bayer CropScience Pty Ltd	33274/1209 33274/1097 33274/0100 33274/0304
51851	Baysol Snail and Slug Bait	Bayer CropScience Pty Ltd	51851/100882 51851/0599 51851/55632

APPENDIX B: PROPOSED LABEL CHANGES

Product 1: Mesurol Snail and Slug Bait (APVMA Registration No: 33274)

Current and proposed label instructions:

Note that current label instructions are in black font, proposed additions to label instructions are in green font and proposed deletions to label instructions are in ~~strikethrough~~.

Restraints

DO NOT heap pellets.

DO NOT apply directly onto edible plants or to crops where baits may be collected with harvested commodities.

DO NOT apply in Victoria, Tasmania and South Australia in summer if rainfall forecast is more than 10 mm per day for the next 48 hours.

Direction for use and critical comments

Crop	Pest	Rate	Critical Comments
~~Berry crops (including grapevines), gardens, nurseries, orchards~~, ~~vegetable crops~~ Citrus, Grapes, Strawberries, Ornamentals	Common garden snail, slugs White Italian snail, white snail (not Qld)	5.5 kg/ha (110 g ai/ha) or 11-22 kg/ha (220-440 g ai/ha)	For most infestations apply low rate. For heavy infestations ~~or where pasture is tall or dense~~ apply higher rate. Scatter bait evenly onto ground where snails or slugs occur. ~~DO NOT HEAP PELLETS.~~ ~~When applying in vegetable crops, ensure pellets do not become lodged in plant foliage~~. Equipment such as fertiliser spinners, combines or sod seeders are satisfactory for spreading the pellets and can easily be calibrated to apply 5.5 kg/ha. Gloves should be worn when pellets are spread by hand. Citrus: DO NOT apply with bare soil inter-rows. Also DO NOT apply more than 11 kg/ha in the following regions of Qld - Northern Gulf, Fitzroy and SE Qld.
Cereals, Oilseeds ~~crops~~, Pastures, Artichoke, Brassica vegetables, Head lettuce, and Potato	Common garden snail, slugs White Italian snail, white snail (not Qld)	5.5 kg/ha (110 g ai/ha) ~~or~~ ~~11-22 kg/ha~~ ~~(220-440 g ai/ha)~~	~~For most infestations apply low rate.~~ ~~For heavy infestations or where pasture is tall or dense apply higher rate.~~ Scatter bait evenly onto ground where snails or slugs occur. ~~DO NOT HEAP PELLETS.~~ ~~When applying in vegetable crops, ensure pellets do not become lodged in plant foliage~~. Equipment such as fertiliser spinners, combines or sod seeders are satisfactory for spreading the pellets and can easily be calibrated to apply 5.5 kg/ha. Gloves should be worn when pellets are spread by hand. Cereals and Oilseeds: DO NOT apply after crop emergence. Artichoke, Brassica vegetables, Head lettuce, and Potato: DO NOT apply in Tasmania in summer.
Sunflowers (Qld, SA only)	False wireworm beetle	2.5 kg/ha (50 g ai/ha) (10 pellets/m^2)	Apply Mesurol 1-3 days after sowing. Scatter bait evenly onto ground where false wireworm beetles occur. ~~DO NOT HEAP PELLETS.~~

Precaution

~~Avoid application of pellets to foliage of edible crops~~. Store in original container. Lock in a safe place preventing access of children, animals, poultry or ducks. Keep away from domestic pets. Keep away from dogs. Dogs find this bait attractive and it may kill them. If pets are poisoned, contact a veterinary surgeon.

Protection of Livestock

After filling applicator, clean up spilled pellets immediately so they are not eaten by animals and birds. Dogs find this bait attractive and if ingested it may kill them. Do not heap as heaping is unnecessary and such heaps could be eaten by dogs. If a dog eats pellets take it to a veterinarian immediately. Do not give dogs Ipecac Syrup. ~~DO NOT treat areas on which poultry graze~~.

Withholding periods

~~**Edible crops:** DO NOT harvest for 7 DAYS after application~~.

~~**Treated areas:** DO NOT graze or cut for stock food for 7 DAYS after application~~.

Harvest:
Cereals and Oilseeds: Not required when used as directed.

Artichoke, Brassica vegetables, Citrus, Grapes, Head lettuce, Strawberries, Potato: DO NOT harvest for 7 DAYS after application.

Grazing:
Cereals, Oilseeds and Pastures: DO NOT graze or cut treated areas for stock food for 28 DAYS after application.

DO NOT treat areas on which poultry graze.

DO NOT graze treated orchards or vineyards.

Safety directions

Product is ~~poisonous~~ harmful if swallowed. May irritate the eyes. Avoid contact with eyes and skin. Do not touch bait. ~~When using the product, wear cotton overalls buttoned to the neck and wrist and a washable hat. If applying by hand, wear elbow- length PVC gloves. If product on skin, immediately wash area with soap and water~~. If on skin and after each baiting, wash thoroughly with soap and water. If dust is present, wear disposable dust face mask covering mouth and nose. If applying by hand, wear elbow length chemical resistant gloves. 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 instructions

~~If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (phone Australia 131 126) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated~~

~~charcoal may be advised. Give atropine if instructed.~~ If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131 126, New Zealand 0800 764 766.

Product 2: Baysol Snail and Slug Bait (APVMA Registration No: 51851)

Current and proposed label instructions:

Restraints

DO NOT apply to food-producing crops.

DO NOT heap pellets.

Direction for use

Situation	Pest	Rate	How to Apply
Gardens	Snails, Slugs, Slaters, Millipedes	100 pellets/m^2 (500 g ai/ha equivalence)	Sprinkle evenly onto ground. Heaping is unnecessary and wasteful, and may pose a risk to dogs and cats.

Precaution

CAUTION – PET PROTECTION

BAYSOL contains a pet taste deterrent, but some pets may still find the bait attractive and eat the pellets.

DOGS FIND THIS BAIT ATTRACTIVE AND IT MAY KILL THEM IF EATEN.

KEEP AWAY FROM DOMESTIC PETS. KEEP AWAY FROM DOGS. KEEP DOGS AWAY FROM TREATED AREAS.

Ensure pets do not have access to this box by locking it in a safe place.

Symptoms of pet poisoning may include (but are not limited to) constricted pupils, hyper salivation, vomiting, diarrhoea, difficulty in breathing, coughing and seizures.

IF POISONING IS SUSPECTED, TAKE THE PET TO A VETERINARIAN IMMEDIATELY.

A veterinary treatment advice for pets that have ingested Baysol is available.

Do not give dogs Ipecac Syrup.

DO NOT treat areas on which poultry graze.

Protection

DO NOT apply to edible crops. Clean up spilled pellets immediately so they are not eaten by animals and birds. DO NOT allow chemical containers or products to get into drains, sewers, streams or ponds. KEEP AWAY FROM DOMESTIC PETS.

Safety directions

Harmful if swallowed. May irritate the eyes. Avoid contact with eyes and skin. Do not touch bait except when wearing disposable gloves. If dust is present, wear disposable dust face mask covering mouth and nose. If on skin and after each baiting, wash thoroughly with soap and water. Wash hands after use.

First aid instructions

~~If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (phone Australia 131 126) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.~~ If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131 126, New Zealand 0800 764 766.

ABBREVIATIONS

ADI	Acceptable daily intake (for humans), a level of intake of a chemical that can be ingested daily over an entire lifetime without any appreciable risk to health
Agvet Code	Agricultural and Veterinary Chemicals Code Act 1994
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARfD	Acute reference dose, the estimated amount of a substance in food or drinking-water, (expressed on a body weight basis), that can be ingested or absorbed over 24 hours or less, without appreciable health risk
bw	Body weight
CCI	Confidential Commercial Information
ChE	Cholinesterase
d	Day
DEWHA	Department of the Environment, Water, Heritage and the Arts
DotE	Department of the Environment
EPA	Environmental Protection Agency
EU	European Union
FAISD	First Aid Instruction and Safety Directions
FAO	Food and Agriculture Organisation
FSANZ	Food Standards Australia New Zealand
kg	kilogram
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LD_{50}	Lethal Dose 50 (Median Lethal Dose)—the dose level at which 50% of the test animals died
LOQ	Limit of Quantitation
mg	milligrams
MOE	Margin of Exposure
MORAG	Manual of Requirements and Guidelines
MRL	maximum residue limit
NEDI	National estimated daily intake (of chemical)
NESTI	National Estimated Short-Term Intake
NOAEL	no observable adverse effect level
NOEL	no observed effect level
OCS	Office of Chemical Safety within the Australian Government Department of Health
OHS	occupational health and safety

PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	Parts per million
PRD	Proposed Regulatory Decision
PRF	Preliminary Review Findings
SC	suspension concentrate
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons (formerly the Standard for the Uniform Scheduling of Drugs and Poisons)
US	United States
US EPA	United States Environmental Protection Agency
WHO	Word Health Organisation
WP	wettable powder