Australian Government

Australian Pesticides and Veterinary Medicines Authority

FIPRONIL – REVIEW SCOPE DOCUMENT

Part 2: Environmental considerations

Summary

JULY 2012

ISBN 978-0-9873529-5-8 (electronic)

Comments and enquiries can be made to:

The Manager, Public Affairs
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604
Australia

Telephone: +61 2 6210 4812
Email: communications@apvma.gov.au

In referencing this document the Australian Pesticides and Veterinary Medicines Authority should be cited as both author and publisher.

This publication is available from the APVMA website: www.apvma.gov.au

CONTENTS

LIST OF TABLES

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 Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Codes).

The APVMA can reconsider the approval of an active constituent, the registration of a chemical product or the approval of a label for a container for a chemical product at any time. This is outlined in Part 2, Division 4 of the Agvet Codes.

A reconsideration may be initiated when new research or evidence has raised concerns about the effectiveness or safety of a particular chemical, a product or its label.

The reconsideration process includes a call for information from a variety of sources, and a review of that information. The information and technical data required by the APVMA to review the safety of new and existing chemical products must be derived according to accepted scientific principles, as must the assessment methods. The APVMA reviews the information and technical data in close collaboration with its advisory agencies including the Office of Chemical Safety and Environmental Health (OCSEH) within the Department of Health and Ageing, the Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC) and state departments of agriculture, as well as other expert advisors.

The APVMA has a policy of maintaining transparency in its activities and encouraging community input to the reviews. To this end, the APVMA publishes the preliminary review findings and proposed regulatory decisions and invites public comment. Following a public consultation period, a decision is made about the future use of the chemical as well as products formulated containing that chemical. The APVMA then publishes the final review report and its regulatory decisions.

The APVMA makes these reports available to regulatory agencies of other countries as part of bilateral agreements. The APVMA recommends that countries receiving these reports should not utilise them for registration purposes unless they are also provided with the original data from relevant applicants.

The basis for the current reconsideration is whether the APVMA is satisfied that continued use of the active constituent fipronil and products containing fipronil in accordance with the instructions for their use will not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

The APVMA also considered whether product labels carry adequate instructions and warning statements.

This document defined the scope of the matters of concern to the APVMA and outlined the kinds of information the APVMA will use to conduct an assessment of the environmental impacts of selected fipronil-containing products and their labels.

The review scope document (Volume 1) and the technical assessment supporting the need to review fipronil are available on the APVMA web site <www.apvma.gov.au/>.

Submissions from the public are invited

The APVMA invites persons and organisations to submit their comments and suggestions on this review scope document directly to the APVMA. The comments will assist the APVMA with progressing the review.

Preparing your comments for submission

You may agree or disagree with or comment on as many elements of the review scope document as you wish.

When making your comments:

- clearly identify the issue and clearly state your point of view
- give reasons for your comments, if possible supporting them with relevant information and indicating the source of the information you have used
- suggest to the APVMA any alternative solution you may have for the issue.

Please try to structure your comments in point form, referring each point to the relevant section in the preliminary review findings. This will help the APVMA assemble and analyse all comments it receives.

Finally, please tell us if you allow the APVMA to quote your comments in part or in full.

Please note that subject to the *Freedom of Information Act 1982*, the *Privacy Act 1988* and the Agvet Codes, all submissions received may be made publicly available. They may be listed or referred to in any papers or reports prepared on this subject matter.

The APVMA reserves the right to reveal the identity of a respondent unless a request for anonymity accompanies the submission. If no request for anonymity is made, the respondent will be taken to have consented to the disclosure of their identity for the purposes of Information Privacy Principle 11 of the Privacy Act.

The contents of any submission will not be treated as confidential or confidential commercial information unless they are marked as such and the respondent has provided justification such that the material is capable of being classified as confidential or confidential commercial information in accordance with the Freedom of Information Act or the Agvet Codes as the case may be.

SUBMISSIONS MUST BE RECEIVED BY **31 AUGUST 2012**

Submissions can be sent by email to chemicalreview@apvma.gov.au or by mail to:

Manager Fipronil Environment Review
Australian Pesticides &Veterinary Medicines Authority
PO Box 6182 KINGSTON ACT 2604

Telephone: 61 2 6210 4749
Facsimile: 61 2 6210 4776
Email: chemicalreview@apvma.gov.au

SUMMARY

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has commenced a review of selected agricultural products containing fipronil, on the basis of environmental concerns. This is an extension to the scope of the current review for these fipronil products already under reconsideration.

The scope document outlines why this review is considered necessary, defines the scope of the matters of concern to the APVMA and outlines the kinds of information the APVMA requires to conduct a comprehensive scientific ecotoxicological assessment of fipronil.

Fipronil is a broad-spectrum insecticide used in agricultural and veterinary situations. It controls insect pests in a wide range of agricultural crops and is used as an insecticidal seed dressing and to control termites, cockroaches and ants in residential and commercial buildings. The control of locusts and grasshoppers is a major use of fipronil. In veterinary situations, fipronil products are used to control fleas, ticks and other ectoparasites on dogs and cats.

The APVMA commenced a review of products containing fipronil and their associated labels in 2003. Fipronil was nominated for review following reports of adverse experiences involving skin reactions in animals and humans. At the start of this review, environmental concerns were not identified as an issue that warranted consideration at the time.

Following the commencement of the current fipronil review in 2003, the Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC) subsequently nominated fipronil as a priority 1 chemical for environmental review. This followed the identification of new information, considered by international regulatory authorities (primarily the European Food Safety Authority in 2006), showing that fipronil and its metabolites are very highly toxic to organisms in the environment, particularly aquatic and terrestrial insects. These new studies also provided additional information on the toxicity of fipronil to fish and aquatic invertebrates, bees and non-target arthropods.

The scope document identifies some significant environmental concerns associated with continued use of selected fipronil agricultural products. Current uses of fipronil in Australia are quite diverse and have the potential for significant environmental exposure. Concerns over high application rates for termiticide uses, where the potential exists for contamination of aquatic areas via runoff, and those applications where spray drift and runoff into aquatic areas and impacts on non-target terrestrial species are considered very possible will be considered in the review.

DSEWPaC has identified concerns relating to the appropriateness of end points selected for previous assessments of fipronil. The new information suggests these previous assessments, which identified little risk to the environment from the use of fipronil products, may not accurately reflect risks associated with fipronil use in Australia.

The APVMA has thus determined that consideration of these environmental concerns is required and will be achieved by extending the scope of the current review for selected agricultural products. The review will not include household insecticide products, veterinary preparations, or products intended as baits or bait stations.

There are currently 28 registered agricultural products containing fipronil that will be considered under the extended review. These are listed in Appendix A.

The APVMA will review the following aspects of product registrations and label approvals for selected agricultural products containing fipronil, including but not limited to:

- aquatic degradation
- persistence in environmental media (soil, water and sediment)
- the partitioning in the environment, for example by deposition and adsorption
- toxicity to fish and aquatic invertebrates, sediment organisms, bees and non-target arthropods.

A decision on the reconsideration will be made once the APVMA has reviewed all data and other information provided to it for this purpose.

The public is invited to make submissions to the APVMA regarding any matters raised in the scope document (see Section 7).

1 INTRODUCTION

Section 31 of the Agvet Codes authorises the APVMA to reconsider:

a) the approval of an active constituent for a proposed or existing chemical product

b) the registration of a chemical product

c) the approval of a label for containers for a chemical product.

The APVMA has initiated the reconsideration of the registration of selected products containing fipronil and the approval of all associated labels. This document defines the scope of the matters of concern to the APVMA and outlines the kinds of information the APVMA will use to conduct a comprehensive scientific assessment of fipronil.

1.1 Regulatory history and status in Australia

Fipronil is a broad-spectrum insecticide first used in Australia in 1994 as an agricultural chemical product. The veterinary chemical use of fipronil has been registered since 1995. It is now widely used in agriculture as a seed dressing and to control locusts and a wide range of other insect pests in pasture, agricultural crops and domestic and commercial turf. Fipronil is also included in a number of household products and commercial building treatments such as cockroach baits and gels and in ant bait stations.

A targeted review of fipronil commenced in 2003. Reports of skin irritation and induction of skin sensitisation following use of veterinary fipronil formulations were the primary triggers for the review. The review is examining public health and occupational health and safety in relation to agricultural and veterinary products. Target animal safety is being reviewed in relation to veterinary products as are the adequacy of all label instructions. A *Preliminary Review Findings* report for the current fipronil review was released for public comment in June 2011. Environmental aspects were not considered as part of this review.

The initial environmental assessment of fipronil-containing flea and tick products for dogs and cats was conducted in 1995. While DSEWPaC (the Australian Government Department of Sustainability, Environment, Water, Population and Communities[1]) has considered fipronil over the years in registration and permit applications, these product assessments have focused on limited areas and have not addressed many aspects of the potential environmental impacts of fipronil.

[1] Formerly the Australian Government Department of Environment, Water, Heritage and the Arts.

1.2 Current use patterns in Australia

Fipronil is a broad-spectrum phenyl pyrazole insecticide acting on the nervous system of insects by contact or ingestion.

There are currently 28 registered agricultural products containing fipronil that will be subject to consideration under the extended review for environmental considerations. These are detailed in Appendix A.
This list and the extended scope do not include veterinary products formulated as baits or gels for ant or cockroach control, nor fly bait stations containing fipronil or termite dusts.

Labels describe use for a wide variety of agricultural and horticultural situations. Fipronil products can be used as foliar sprays, soil applications or seed treatments (sunflower, canola, sorghum). In agriculture, fipronil provides control of soil as well as selected foliar insect pests in bananas, brassicas, cotton, potatoes, grapes, sugarcane, pasture, sorghum and mushrooms. Fipronil is also used as an insecticidal seed dressing in rice, canola, sorghum and cotton to control mites, worm and thrips. It is also available in ultra-low volume sprays to control locusts in pasture and sorghum. A granular formulation is registered for use in recreational domestic and commercial turf.

Products containing fipronil are also used to protect structures from subterranean termite damage and to control subterranean termites around domestic and commercial structures.

Locust control

The control of locusts and grasshoppers is a major use of fipronil. Fipronil is one of the few chemicals relied upon by the Australian Plague Locust Commission (APLC) for its locust control program. The APLC monitors locust populations in inland eastern Australia and manages outbreaks with potential to inflict significant damage to agriculture in more than one member state (NSW, Vic, Qld, SA) as a result of population build-up and migration (http://www.daff.gov.au/animal-plant-health/locusts/role).

The ultra-low volume (ULV) formulations (three products) as well as the 200 g/L (grams per litre) soluble concentrate (SC) formulation are used by the APLC in its activities. The APLC adopts large buffer zones to protect sensitive areas and does not spray products containing fipronil within 5 km of beehives or crops being pollinated by bees. The APLC applies fipronil only by fixed winged aircraft.

The APLC also conducts various research programs investigating the impacts of fipronil on a wide variety of non-target species. Given the high species-specific variability in sensitivity to fipronil, it is extremely difficult to predict the toxicity of fipronil on unstudied species at high risk of exposure in the wild. Therefore, the APLC is researching the impacts of using fipronil under the current spraying protocols on a wide variety of non-target invertebrate species. The APLC is also working with the National Research Centre for Environmental Toxicology (EnTox) to develop passive samplers to monitor fipronil application during locust control.

The APLC is working with the University of Wollongong to determine the sensitivity of native birds at risk of exposure to fipronil from locust control operations. The APLC is also examining the ability of fipronil to affect the hatching and development of chicks from eggs laid by females exposed to fipronil. At this stage, the

studies indicate that fipronil can significantly affect hatching and growth, with a significant reduction in egg hatching rates and the successful development of chicks.

Fipronil is also contained in a number of household products such as cockroach baits and gels and in ant bait stations as well as in veterinary products. Although these products are captured by the current human health and animal safety review, they will not be considered in the environmental assessment as the risk to the environment from these use patterns is considered low.

2 REASONS FOR REVIEW – ENVIRONMENTAL CONCERNS

Following the commencement of the current fipronil review in 2003, the Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC) subsequently nominated fipronil as a priority 1 chemical for environmental review. This followed the identification of new information, considered by international regulatory authorities (primarily the European Food Safety Authority (EFSA 2006)), showing that fipronil and its metabolites are very highly toxic to organisms in the environment, particularly aquatic and terrestrial insects. These new studies also provide additional information on the toxicity of fipronil to fish and aquatic invertebrates, bees and non-target arthropods.

DSEWPaC conducted a scoping assessment of fipronil to:

- investigate the areas of concern as they relate to the reasons for nomination
- justify why these concerns are relevant to the use of fipronil in Australia
- identify any additional data required to address these concerns.

Fipronil products are used for a wider range of applications in Australia than in other countries, and so the potential for environmental impacts is greater. Uses include termiticides with high application rates for which contamination of aquatic areas from runoff is a concern. Also of concern are ground-based and aerial spray applications to control locusts and other pests, where spray drift to aquatic areas has the potential to affect non-target terrestrial species.

The primary information source for the environmental assessment contained in this scope document is the European Food Safety Authority 2006 review, together with information provided for earlier fipronil applications (registration and permits) and other published studies. The studies in the European Food Safety Authority report are not held by DSEWPaC, but results from the EFSA assessment of these studies form the basis of the DSEWPaC proposal that fipronil be reviewed in detail for possible risks to the environment from its use.

The object of this scoping assessment was to use existing data to examine currently registered uses for fipronil. Where these data are available from the literature, the relevant studies were obtained and assessed by DSEWPaC. Where these data were only available in regulatory studies not provided to the APVMA, or became available after the registration assessments in Australia, the results have been taken by DSEWPaC as given in the scoping assessment. These have identified greater toxicity than previously understood and, therefore, greater environmental concern. Where the risk assessment concluded an acceptable risk, no further assessment by DSEWPaC was conducted. Where a risk was identified, DSEWPaC carried out a more refined risk characterisation.

Those studies considered critical—that is, the studies that result in a revision of the end points previously used in Australian assessments—are being requested as part of this current ecotoxicological review (see Section 4). In the case of additional unpublished regulatory studies, the results have been taken as reported in the EFSA review and used in the scoping assessment. However, where these results have resulted in changes to previous assessments of environmental risk, it is necessary they are obtained and independently reviewed for the fipronil review.

Conclusions and recommendations for this scoping assessment are restricted to:

- the additional regulatory studies that should be obtained for independent review by DSEWPaC
- currently registered agricultural use patterns of fipronil that can continue to be supported
- current agricultural use patterns of fipronil where the environmental risk is unacceptable in light of new information since their initial assessment, and that require further information to support the use pattern.

The information that follows in Appendices C to F is a summary only. The full technical components of the environmental assessment address environmental fate, environmental toxicity and a risk assessment. It provides in a step-wise format: the data available and relied on for different assessments of fipronil at the time; data that became available with later assessments but could not be applied to earlier assessments; and data that DSEWPaC is now aware of that will lead to a revision of the environmental risk of fipronil.

3 SCOPE OF THE REVIEW

Taking into consideration the findings from the DSEWPaC scoping assessment, the APVMA has extended the scope of the current review of fipronil to determine if it can be satisfied that continued use of or any other dealing with the selected agricultural products in accordance with the approved instructions for use will not have an unintended effect that is harmful to animals, plants and things or to the environment.

The APVMA will review the following aspects of selected fipronil agricultural products relating to environmental concerns including but not limited to:

- aquatic degradation
- persistence in environmental media (soil, water and sediment)
- the partitioning in the environment, for example through deposition and adsorption
- the toxicity to fish and aquatic invertebrates, sediment organisms, bees and non-target arthropods.

The APVMA will also consider if product labels carry adequate instructions and warning statements. These instructions include:

- 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-treatment interval for the product
- the withholding period after the use of the product
- the disposal of the product and its container
- the safe handling of the product and first aid in the event of an accident caused by handling the product
- any other matter prescribed by the regulations.

In its scoping assessment, DSEWPaC indicated there is minimal environmental impact posed by fruit fly baits, household insecticides, and 5 g/kg termiticide products. Hence no further assessment of these product types is required.

4 INFORMATION REQUIRED FOR ASSESSMENT

The scoping assessment for fipronil has identified concerns with its ongoing use in many situations. There is a possibility that continued use of fipronil may result in unintended negative environmental impacts.

The specific areas of concern are:

- aquatic degradation of fipronil
- persistence of fipronil in environmental media (soil, water and sediment)
- the partitioning of fipronil metabolites in the environment, such as by deposition or adsorption
- toxicity of fipronil (parent and metabolite) to fish and aquatic invertebrates, sediment organisms, bees and non-target arthropods.

DSEWPaC has identified 41 studies from the 2006 European Food Safety Authority (EFSA) report (not held by the APVMA or DSEWPaC) as important for the ecotoxicological assessment. Use of the EFSA data in the risk assessment conducted by DSEWPaC has resulted in different conclusions relating to the persistence of fipronil as well as its main metabolites than conclusions of earlier assessments of fipronil by DSEWPaC. However, to allow an independent conclusion, full reports of the studies need to be provided and assessed for the final fipronil review.

At this stage, and based on revised end points from as yet unreviewed studies, there are major concerns with fipronil. The APVMA seeks additional data on two levels. The first is provision of the identified regulatory studies that, based on their reported values, have resulted in amending the environmental (either fate or ecotoxicity) end point. DSEWPaC has advised it expects provision of this additional data is highly unlikely to result in any changes to the current calculations. Rather, it is most likely the data will allow confirmation of the values as reported.

The second level of data being sought relates to industry information in regard to specific uses of fipronil that, if acceptable, may allow refinement of exposure calculations and therefore risk quotients.

Specific data requirements are noted below.

4.1 Existing regulatory studies to be submitted

The available regulatory studies addressing environmental fate and environmental toxicity are considered sufficient to change the end points used in initial assessments in Australia. Where the prediction of environmental risk from certain use patterns is increased as a result, copies of the studies are required as part of any assessment. They are listed below but described in full in the environmental technical reports.

Environmental fate studies

The following studies related to photodegradation of fipronil are new data that may assist in further mitigation of risks and their possible characterisation:

- Mackie J 2000c, 'A brief investigation into the photodegradation of (^{14}C)-fipronil in natural water under artificial sunlight', Document No. C010475, Aventis CropScience, 1 November 2000.
- Keirs D 2001a, 'Artificial sunlight photodegradation of (^{14}C)-M&B045950 in buffered aqueous solution', Aventis CropScience, Document No. C010619, 17 November 2001.
- Keirs D 2001b, 'Artificial sunlight photodegradation of (^{14}C)-M&B046136 in buffered aqueous solution', Aventis CropScience, Document No. C010620, 17 November 2001.
- Keirs D 2001c, 'Artificial sunlight photodegradation of (^{14}C)-M&B046513 in buffered aqueous solution', Aventis CropScience, Document No. C010621, 01 January 2001.

The following studies provide new information relating to the persistence of fipronil and its metabolites in environmental media (soil, water and sediment) not previously available. These show that fipronil and its metabolites exceed Australian PBT criteria, and may exceed persistent organic pollutants criteria (POPs criteria—outlined in Annex D to the Stockholm Convention):

- Fitzmaurice M and Mackenzie E 2002, '[^{14}C]-Fipronil: degradation in four soils at 20^{o}C and two soils at 10^{o}C (AE F124964)', Document No. C018800, Aventis CropScience UK Limited, 17 January 2002.
- Feung C and Yenne S 1997, 'Fipronil – aerobic aquatic metabolism', Document No. R010598, Rhone-Poulenc, 27 March 1997.
- Ayliffe J 1998. '[^{14}C]-Fipronil degradation and retention in two water/sediment systems', Document No R010604, Rhone-Poulenc Agriculture Ltd, 24 February 1998.
- Roohi A and Buntain I 2002, '(^{14}C)-Fipronil: degradation in two water/sediment systems (AE F124964)', Document No. C0166696, Aventis CropScience GmbH, DEU, 25 February 2002.
- Lowden P and Mahay N 2000, '[^{14}C]-MB 46513 – Degradation in two water/sediment systems', Rhone-Poulenc; Aventis CropScience UK Limited, Document No: R016124, 23 March 2000. Unpublished.

The following studies provide new information on the partitioning behaviour of fipronil metabolites in the environment and will allow further revision of predicted environmental concentrations:

- Burr C 1997, '[^{14}C]-M&B45950: Adsorption/desorption to and from four soils and one sediment', Document No. R010601, Rhone-Poulenc Agriculture Ltd, 19 November 1997.
- McMillan-Staff S 1997a, '[^{14}C]-M&B46136: Adsorption/desorption to and from four soils and one sediment', Document No. R010600, Rhone-Poulenc Agriculture Ltd, 14 November 1997.
- Feung C and Mislankar S 1996, 'Fipronil metabolite MB46513: Soil adsorption/desorption', Document No. R010593, Rhone-Poulenc, 31 May 1996.

Environmental toxicity studies

The following chronic fish toxicity studies are required as they indicate the need for a lowering of the previous chronic fish end point used in fipronil registration assessments in Australia:

- Sousa J 1998, 'Fipronil technical – early life-stage toxicity test with sheepshead minnow (*Cyprinodon variegatus*)', Springborn Laboratories Inc, Document No. R010540, 8 June 1998.

- Dionne E 2000, 'Fipronil – Chronic toxicity to the sheepshead minnow *(Cyprinodon variegatus*) during a full life-cycle exposure', Springborn Laboratories Inc, Document No. B003064, 28 September 2000.

The following acute aquatic invertebrate metabolite toxicity data indicate significantly lower LC50 values for metabolites than DSEWPaC was previously aware of for fipronil registration assessments in Australia:

- Putt A 2000a, '[^{14}C]MB45950 – acute toxicity to mysids (*Mysidopsis bahia*) under static conditions', Springborn Laboratories Inc, Document No. B002875, 17 May 2000.
- Putt A 2000b, '[^{14}C]MB46136 – acute toxicity to mysids (*Mysidopsis bahia*) under static conditions', Springborn Laboratories Inc, Document No. B002876, 18 May 2000.
- Putt A 2000c, '[^{14}C]MB46513 – acute toxicity to mysids (*Mysidopsis bahia*) under static acute conditions: MB46513', Springborn Laboratories Inc, Document No. B002794, 7 January 2000.

The following chronic aquatic invertebrate toxicity data indicate there are more sensitive chronic toxicity end points than previously considered in fipronil registration assessments in Australia:

- Machado M 1995, 'Fipronil – chronic toxicity to mysids (*Mysidopsis bahia*) under flow-through conditions', Springborn Laboratories Inc, Document No. R010517, 18 May 1995.
- Lima W 2000a, '[^{14}C]MB45950 – life cycle toxicity test with mysids (*Mysidopsis bahia*)', Springborn Laboratories Inc, Document No. B003049, 25 September 2000.
- Lima W 2000b, '[^{14}C]MB46136 – Life cycle toxicity test with mysids (*Mysidopsis bahia*)', Springborn Laboratories Inc, Document No. B003055, 3 October 2000.

The sediment toxicity data below provides new information on the toxicity of fipronil metabolites to sediment organisms. Given new data suggesting that aquatic invertebrates may be more sensitive to fipronil and its main metabolites than previously recognised, these studies are required to be submitted:

- Putt A 2000d, 'Toxicity to midge (*Chironomus tentans*) during a 10 day sediment exposure: [^{14}C]MB45950', Springborn Laboratories Inc, Document No. B002839, 24 March 2000.
- Putt A 2000e, '[^{14}C]MB46136 toxicity to midge (*Chironomus tentans*) during a 10 day sediment exposure', Springborn Laboratories Inc, Document No. B002960. 10 July 2000.
- Putt A 2001, '[^{14}C]MB46513 – toxicity to midge (*Chironomus tentans*) during a 10 day sediment exposure', Springborn Laboratories Inc, Document No. B003240, 21 March 2001.

New data are also available for fipronil toxicity to bees, significantly lowering previous assessment end points used in fipronil registration assessments in Australia:

- Maurin 1999a, 'Effects of seed treatment with Regent TS on honeybees during sunflower bloom. Part 1: tunnel tests', ACTA, Paris. Document No: C019707.
- Maurin 1999b, 'Effects of seed treatment with Regent TS on honeybees during sunflower bloom. Part 2: field study', ACTA, Paris. Document No: C019707.
- Maurin 1999c, 'Effects of seed treatment with Regent TS on honeybees during sunflower bloom. Part 3: sample taking', ACTA, Paris. Document No: C019707.

- Maurin 2001, 'Effet du traitement de sol EXP61829 (0.5% de Fipronil), vis a vis des abeilles, evalue sous tunnels, pendant la floraison du tournesol', ACTA Laboratories, Document No: C018874.
- Giffard H 2001, 'Evaluation of impact of EXP60720A on honey bees (insect proof tunnels on sunflowers)', Testapi, Gennes, Document No: C013759.

The following new data for non-target terrestrial arthropods have identified the need to revise the end points from previous fipronil registration assessments in Australia:

- Drexler A 2001, 'Effects of EXP60720A on the reproduction of rove beetles *Aleochara bilineata* Gyll. (Coleoptera, Staphylinidae) in the laboratory', Aventis CropScience, Document No. C015353, 30 July 2001.
- Drexler A 2002, 'Effects of EXP60720A on the reproduction of rove beetles *Aleochara bilineata* – extended laboratory study', Aventis CropScience, Document No. C019532, 13 March 2002.
- Gossmann A 2001a, 'Effects of EXP60720A on the predatory mite *Typhlodromus pyri* Scheuten (Acri, Phytoseiidae) in the laboratory – dose response design', Aventis CropScience, Document No. C012342, 30 March 2001.
- Gossmann A 2001b, 'Effects of EXP60720A on the predatory mite *Typhlodromus pyri* Scheuten (Acri, Phytoseiidae) – extended laboratory study (dose response test)', Aventis CropScience, Document No. C014582, 5 July 2001.
- Moll M and Büetzler R 2001a, 'Effects of EXP60720A on the parasitoid *Aphidius rhopalosiphi* (Hymenoptera, braconidae) in the laboratory – dose response test', Aventis CropScience Document No. C013159, 26 April 2001.
- Moll M and Büetzler R 2001b, 'Effects of EXP60720A on the parasitoid *Aphidius rhopalosiphi* (Hymenoptera, braconidae) extended laboratory test – dose range test', Aventis CropScience, Document No. C013577, 21 May 2001.
- Meister A 2002, 'Effects of EXP60720A on reproduction of *Folsomia candida* in artificial soil', Aventis CropScience, Document No. C019002, 11 March 2002.
- Mead-Briggs M 1996, 'A laboratory evaluation of the side-effects of the insecticide EXP60720A (an 80% w/w wettable granule formulation of fipronil) on lycosid spiders of the genus *Pardosa'*, Rhone-Poulenc, Document No. R010527, 22 November 1996.
- Waltersdorfer A 2002a, 'Toxicity to the ground dwelling predator *Poecilus cupreus* L. (Coleoptera, Carabidae) in the laboratory. Fipronil water dispersible granule Code: AE F124964 00 WG80 A201 (EXP60720A)', Aventis CropScience, Document No. C019600, 6 March 2002.
- Waltersdorfer A 2002b, 'Exposure of the ground dwelling carabid beetle *Poecilus cupreus* L. (Coleoptera, Carabidae) in the laboratory to soil samples taken from the field after application of EXP60720A. Code: AE F124964 00 WG80 A201 (EXP60720A)', Aventis CropScience, Document No. C019601. 12 March 2002.
- Klepka S and Groer M 1997, 'Effects of EXP80415A on the carabid beetle *Poecilus cupreus* L. (Coleoptera, Carabidae) in the laboratory', Rhone-Poulenc, Document No. R010536.
- Goβmann A 1997, 'Effects of EXP80415A on the reproduction of rove beetles *Aleochara bilineata* Gyll. (Coleoptera, Staphylinidae) in the laboratory', Rhone-Poulenc, Document No. R010538.

- Goβmann A 1998, 'Effects of EXP80415A on the reproduction of rove beetles *Aleochara bilineata* Gyll. (Coleoptera, Staphylinidae) – extended laboratory study', Rhone-Poulenc, Document No. R010537.

4.2 Additional data - sediment toxicity

The current scoping assessment was performed using available results (listed above), whether or not the studies underlying those results were evaluated in detail.

There is also a need for other data about sediment toxicity, as the scoping assessment was based on the literature value for acute toxicity of fipronil and its metabolites to a single sediment organism.
There are unpublished regulatory studies for acute toxicity of fipronil metabolites that show lower toxicity than values obtained from the literature.

The following additional information in relation to sediment toxicity should be provided:

- Acute toxicity of fipronil to Chironomid in spiked water and spiked sediment tests in accordance with OECD or other accepted guidelines.
- Chronic toxicity of fipronil, MB45950 and MB46136 to Chironomid in spiked water and spiked sediment tests in accordance with OECD or other accepted guidelines. (NOTE: these were requested from sponsors in the European Food Safety Authority review from 2006. These studies may already be available, in which case they should be submitted).

4.3 Use pattern specific information and recommendations

For some use patterns, the refined risk assessment is based on an assumption the end points based on as-yet unreviewed studies are correct. The assessment has still resulted in an unacceptable risk to one or more areas of the environment. To further refine the risk in these areas, additional industry information is required to allow further refinement of exposure calculations and therefore risk quotients (see Table 1).

The underlying reasons for the further data requirements identified here have been discussed in more detail in the technical report during the refinement of the risk characterisation for these uses.

Table 1: Additional requirements for continued assessment

USE PATTERN	PRODUCT GROUPS AFFECTED	USE PATTERN ACCEPTABLE	ADDITIONAL REQUIREMENTS
Pasture/sorghum (locust)	1, 2, 3, 4	No	Requirement 1, 2
Forestry	1*	No	Requirement 1, 2
Mushrooms	1, 2	Yes	None
Wine grapevines	1, 2	No	Requirement 2, 3, 4§
Cotton	1, 2	No	Requirement 2, 3, 4§

USE PATTERN	PRODUCT GROUPS AFFECTED	USE PATTERN ACCEPTABLE	ADDITIONAL REQUIREMENTS
Asparagus	1*	No	Requirement 2, 3, 4§
Brassicas	1, 2	No	Requirement 2, 3, 4§
Swede and turnip	1*	No	Requirement 2, 3, 4§
Sugarcane	1, 2	No	Requirement 2, 3, 4§
Ginger	1*	No	Requirement 2, 3, 4§
Potatoes	1, 2	No	Requirement 2, 3, 4§
Bananas	1, 2	No	Requirement 2, 3, 4, 5§
Seed treatment	5	No	Requirement 2, 6
Turf	6	No	Requirement 3, 7§
Termiticide (100 g/L)	7	No	Requirement 8

** Uses only registered on product numbers 60284 and 62236.*

§ Not possible to recommend practical buffer zones for these use patterns.

Requirement 1 - Buffer zones

It should be noted, Requirement 1 relates to buffer zones. Downwind buffer zones were calculated in the technical report for all broadacre applications applied by either aerial or ground boom spray. However, for uses where application rates exceeded 2.5 g ac/ha, the buffers were well beyond the validated range of the models (more than 800 metres for aerial spray and more than 300 metres for ground boom spray). Given this, it is not possible to recommend practical buffer zones for these use patterns (indicated above by the symbol §) and they are thus not subject to Requirement 1 in Table1. Alternative drift-reducing technologies could be considered but were not included in this assessment.

Pasture and sorghum

Use in these situations is for control of plague locusts. Products in Groups 1 and 2 are registered for a range of situations other than just pasture and sorghum. Products in Groups 3 and 4 are registered for this use only and are applied as ULV formulations under conditions designed to facilitate spray drift to cover a large area.

Final recommendations will be subject to information from industry relating to the coarsest spray quality that can be used efficaciously for Group 1 and 2 products when applying to pasture and sorghum to control plague locusts.

Aquatic systems

The main risk to aquatic ecosystems from runoff may be from use of the product on steeper slopes, not on gentle slopes. New toxicity data for the parent compound as well as its main metabolites show very high

toxicity to aquatic invertebrates (mysid shrimp). Therefore, the need for downwind aquatic buffer zones is required. These buffers will be a function of the spray quality used, the wind speed at the time of application and the type of aircraft used for application. Buffer zones (in terms of absolute values for this scoping report) are shown in the technical report.

Terrestrial systems

The application rates are sufficiently low (1.25 g ac/ha) that risk to terrestrial vertebrates is acceptable from downwind spray drift, as is risk to non-target terrestrial arthropods, earthworms and soil microorganisms.

Forestry

Forestry use is only registered for two products, 60284 and 62236. The registered rate is 2.5 g ac/ha, and the comments for pasture and sorghum (above), with respect to buffer zones, are applicable in this situation.

Requirement 2 – Hazard to bees and other pollinators

The data available on toxicity to bees following spray application are limited to one literature study examining mortality over time when bees were exposed to aged residues on foliage. The impact of fipronil on bees cannot be adequately determined due to a lack of available data on spray formulations (data based on seed dressings only). Given new concerns about the extremely high toxicity of fipronil to bees, new information or field trial results should be provided to address this data gap.

Suggested methodology is available from activities of the European and Mediterranean Plant Protection Organisation (EPPO) relating to honeybees, with the following observations required:

- The number of foraging bees in the crop, behaviour of bees on crop and around hives, mortality of bees (using dead-bee traps).
- An estimation of pollen collection (using pollen traps) and pollen in collected honey. Given the likely persistence of fipronil in honey and potential impacts on the colony, it is considered necessary to estimate the number of bees on frames, brood status in frames, and to study residues in dead bees, pollen, wax and honey. Brood status should always be assessed at test initiation and test termination.
- The likelihood that foraging bees will be exposed through the identified use pattern, including likelihood of weeds flowering during treatment.
- For uses where bees may be exposed, a detailed characterisation of exposure is important, and should consider such factors of the spatial scale of application compared to foraging area of bees.
- For use patterns where bees could be exposed, the likely residues of fipronil and its metabolites in nectar and pollen following application.
- Persistence of fipronil and its metabolites in nectar or pollen contaminated by spray drift.
- Toxicity of the main metabolites to bees (in the absence of such data, it will be assumed they are as toxic as the parent molecule).

Group 1, 2, 3 and 4 products

Based on new information relating to the high hazard of fipronil to bees, the refined risk assessment identified a potential risk to bees from several fipronil use patterns. At this stage, no further refinement of the risk assessment is considered possible, and the scoping assessment concludes that the risk to bees is not acceptable from spray uses of fipronil. To further refine this in any further fipronil review, new bee toxicity data listed above should be provided.

Group 5 products

To properly assess this aspect of risk to bees when used as a seed treatment, specific field or semi-field studies listed above need to be provided. A more refined risk assessment for this issue is likely to be required at that stage.

It is also necessary to have data provided on fipronil concentrations in nectar and pollen where fipronil is used as a seed treatment in canola, sorghum and sunflowers in Australia. These data should be generated with a suitably low limit of quantification.

Requirement 3 – Industry information on use patterns

To further refine risk, the use patterns of fipronil need to be better characterised for exposure. Without this, it will be difficult to refine the current assessments. Such information can include:

- drift reducing technology used for spray application (shielded sprayers, directed sprays)
- expected areas (hectares) of use for different use patterns, and their likely attributes (slopes, estimate of cropping area treated, geographic region)
- the specific spray droplet category must be nominated that will appear on product labels (APVMA operational notice effective from 1 March 2010)
- the likelihood of multiple applications where allowed on labels.

Requirement 4 – Sediment toxicity data

Sediment toxicity data are required.

Requirement 5 – Data specific to bananas (Group 1 and 2 products)

The available toxicity data for reptiles has become available since the first application of fipronil to bananas, so this end point should be considered. However, without further data relating to information on the occurrence of native lizards in banana plantations, their likely diet, how much of their diet is likely consumed from contaminated food, and information on food intake rates, no firmer conclusions about the risk can be determined. Further, if an acute risk is found for these organisms, additional data relating to chronic toxicity should be provided.

Requirement 6 – Specific requirements for rice

Industry information on the likelihood and extent of rice bay water release, where it is released to (receiving streams, or retained on farm for additional agricultural use), and likely levels of dilution in the event rice water is released to natural receiving waters (creeks, streams, rivers) is required.

Requirement 7 – Specific requirements for Group 6 turf products

Information should be provided relating to the efficiency of incorporation if carried out according to label instructions. This information will be used in conjunction with a more appropriate turf runoff model to refine the risks associated with these uses.

Requirement 8 – Specific requirements for Group 7 termiticide products

There are international monitoring data demonstrating the movement of fipronil from its area of use as a structural pest control agent in urban areas to receiving surface waters, and these detections suggest levels exceed ecotoxicity thresholds for water as well as sediment. There are no equivalent Australian monitoring data that can dispute or support these findings.

Additional information for the use of fipronil as a surface barrier spray for termite and ant control around new and existing buildings and structures to allow a further mitigation of this risk assessment is required. This information should include any available relevant monitoring data attributed to these use patterns, volumes of use of fipronil for this use pattern over the last 5 years, the main geographical areas of use and characterisation of areas of use (for example, the amount of treated area around ‘typical’ buildings or the number of likely treated buildings in a wider location, such as in housing estates) to allow a better modelling approach to estimating runoff concentrations.

5 INTERNATIONAL REGULATORY REPORTS AND REGISTRATION STATUS OF FIPRONIL

5.1 Joint FAO/WHO Meeting on Pesticide Residues (JMPR)

Fipronil was first reviewed by the 1997 JMPR for toxicology only, and was identified as a candidate for residue evaluation by the 2000 JMPR by the 1998 CCPR (ALINORM 99/24). The residue evaluation was postponed to the 2001 JMPR and included a review of its metabolism in animals and the environmental fate of fipronil.

5.2 Europe

Action was taken in France in 2004 to ban the use of fipronil because of concerns about bee toxicity and the involvement of fipronil in Colony Collapse Disorder.

The European Food Safety Authority conducted a review of fipronil in 2006, with the purpose of obtaining an inclusion of this fipronil into Annex I according to Directive 91/414/EEC. France was the Rapporteur Member State.

Fate and ecotoxicity data for the active constituent and metabolites and for various formulations were assessed in that review. However, the risk assessment considered only representative uses as an insecticide applied as a seed dressing formulation (the 500FS, 'suspension concentrate for seeds') to control soil insects and wireworms in sunflower and maize. These uses involve application rates up to 30 g ac/ha for sunflower (up to 5 g ac/kg seed) and up to 50 g ac/ha for maize (up to 2.5 g/kg seed). The applicant had changed and the new applicant no longer supported some representative uses for the review.

The overall conclusion from this assessment was that only uses as insecticide for use as seed treatment may be authorised. The seed coating shall only be performed in professional seed-treatment facilities. These facilities must apply the best available techniques to ensure no release of fipronil dust occurs during storage, transport and application.

In implementing this decision, Member States must pay particular attention to:

- the packaging of the marketed products to avoid the generation of photodegradation products of concern
- the potential for groundwater contamination, especially from metabolites which are more persistent than the parent compound, when the active substance is applied in regions with vulnerable soil and/or climatic conditions
- the protection of granivorous birds and mammals, aquatic organisms, non-target arthropods and honey bees (especially bee brood embryo or egg, larva and pup stages)
- the use of adequate equipment ensuring a high degree of incorporation in soil and a minimisation of spillage during application.

Conditions of authorisation should include risk mitigation measures, where appropriate. The concerned Member States shall request the submission of further studies to confirm the risk assessment for granivorous birds and mammals, and honey bees, especially bee brood. They shall ensure that the notifier at whose request fipronil has been included in this Annex provide such studies to the Commission within one year from the entry into force of this Directive.'

5.3 United States of America

In the United States of America (USA), a range of products containing fipronil are registered for similarly diverse purposes to those in Australia. Fipronil was first registered in the USA in 1995. Fipronil is contained in granular turf control products, seed treatments, topical pet care products, gel baits and liquid termiticides, and is for general agricultural use.

A technical fact sheet on fipronil prepared by the National Pesticide Information Center (NPIC, a cooperative agreement between Oregon State University and the United States Environmental Protection Agency (US EPA), see <http://npic.orst.edu/index.html>) indicates that a range of products containing fipronil are registered for similarly diverse purposes to those in Australia. However, uses differ considerable between states. For example, there are currently no agricultural crop uses in California, where the wide range of urban use scenarios includes animals, buildings (indoors and outdoors), lawns/turf, food/feed areas, large outdoor areas, and vehicles (ships, trains, aircraft, buses) and transport facilities.

Fipronil has not been listed under the US EPA Pesticide Re-registration Review Program. Use on rice seed was voluntarily cancelled in 2004 because of concerns over impacts on crayfish and non-target invertebrates (specific to the types of application in rice in the USA, not comparable to Australian uses).

California

The Californian Department of Pesticide Regulation (CDPR) of the California Environmental Protection Agency initiated a risk assessment process to address toxicological concerns for products containing fipronil in late 2001 (CDPR, California Notice 2001–11). In March 2008 this review was at the 'hazard identification and exposure assessment stages' (CDPR, Prioritization and status of active ingredients for risk characterization: Report 50, 21 March 2008). It appears this review is not yet finalised.

Two reviews of the environmental fate of fipronil have been conducted by the Environmental Monitoring Branch of the California Environmental Protection Agency:

- Connelly P 2001, *Environmental fate of fipronil,* Environmental Monitoring Branch, Department of Pesticide Regulation, California Environmental Protection Agency, Environmental Fate Review for the California Department of Pesticide Regulation Red Imported Fire Ant Project, Internet January 2009: <http://www.cdpr.ca.gov/docs/emon/pubs/fatememo/fipronil.pdf>.
- Gunasekara AS and Troung T 2007, *Environmental fate of fipronil*, Environmental Monitoring Branch, Department of Pesticide Regulation, California Environmental Protection Agency, www.cdpr.ca.gov/docs/emon/pubs/fatememo/fipronilrev.pdf.

A review of the use of fipronil in California, current information on the aquatic toxicity and fate of fipronil and its degradates, and levels of fipronil and its degradates detected in water and sediment was reported by Moran (2007). This was presented in a memorandum to the Urban Pesticides Committee (described as 'a nationally unique statewide network of more than 150 agencies, non-profits, industry, and other stakeholders that are working to solve water quality problems from pesticides' (see <http://www.up3project.org/up3_about.shtml>, available from February 2009). It provided 'recommendations for California water quality agencies and other entities involved in management of pesticides and water quality', as follows:

1. Continue to exercise discretion in use or recommendation of fipronil for urban outdoor above ground application in California – avoid above-ground outdoor application of un-containerised fipronil products, and encourage integrated pest management-based methods that minimise releases to surface waters (such as containerised baits and barriers like caulking); underground injection is considered unlikely to pose a threat to surface water quality.
2. Fill aquatic toxicity data gaps – need to obtain sediment toxicity data for fipronil and its primary degradates and fill gaps for standard aquatic toxicity testing species (including chronic toxicity data), measure cumulative toxicity of fipronil and its degradates, explore potential for synergism with other pesticides commonly present in surface waters.
3. Fill environmental fate data gaps – major gaps include the aquatic sediment half-life for fipronil degradates and basic characterisation data for degradates.
4. Support activities to improve chemical analytical capabilities for fipronil in surface water (water column and sediment), urban runoff, and municipal wastewater treatment plant effluent and biosolids. The United States Geological Survey (USGS) has developed methods which need to be transferred to commercial laboratories; the recommended detection limits (0.5 × lowest aquatic toxicity data point) for fipronil and degradates in water and sediment are 0.002 µg/L and 30 µg/kg, respectively.
5. Support activities to develop toxicity identification evaluation capabilities for fipronil in water and sediment samples to identify whether fipronil is causing toxicity when toxicity is found.
6. Include fipronil and its degradates in water quality monitoring – in surface water and sediment monitoring programs for waters receiving urban runoff, and to investigate whether environmentally meaningful levels occur in municipal wastewaters effluent or biosolids.

Louisiana

In the USA, fipronil was widely used on rice seed to control the rice water weevil from 1999, replacing carbofuran. Under the particular field-rotation and farming practices used in the Mermentau River Basin of Louisiana (which differ markedly from those used in Australia), rice and crawfish (crayfish – *Procambarus spp*.) are grown in rotation on the same fields, and water drained from rice fields may enter downstream rice or crawfish fields. It was alleged that low crawfish production in Louisiana in 2000 was associated with the use of fipronil. Various studies and evaluations were conducted of the residues of fipronil and its metabolites present in water and soil/sediment, and of the toxicity of fipronil and metabolites to Procambarus species. Potential effects on non-target invertebrates in Louisiana wetlands visited by migratory birds were also considered. These literature reports are identified below, and have been used where appropriate in the scoping assessment.

The farmers filed suit against the manufacturers and sellers of the pesticide 'Icon' (active ingredient fipronil) for losses in their pond-grown crawfish crops allegedly caused by the pesticide, and a US$45 million settlement was reached in 2004 (see <http://www.lieffcabraser.com/crawfish-lawsuit.htm>, published February 2009). USA registrations for three products containing fipronil for use on rice or rice seed (Icon 80WG, Icon 6.2FS and Icon 6.2SC) were voluntarily cancelled (US EPA Federal Register, 1 July 2004, Volume 69, Number 126, pp 39927–39928).

- Bedient PB, Horsak RD, Schlenk D, Hovinga RM and Pierson JD 2005, 'Environmental impact of fipronil to the Louisiana crawfish industry', *Environmental Forensics* 6(3):289–299.
- Biever RC, Hoberg JR, Jacobson B, Dionne E, Sulaiman M and McCahon P 2003, 'ICON® rice seed treatment toxicity to crayfish (*Procambarus clarkii*) in experimental rice paddies', *Environmental Toxicology and Chemistry* 22(1):167–174.
- Demcheck DK and Skrobialowski SC 2003, *Fipronil and degradation products in the rice-producing areas of the Mermentau River Basin, Louisiana, February–September 2000*, National Water Quality Assessment Program. U.S. Dept. of the Interior, U.S. Geological Survey Fact Sheet (Geological Survey (U.S.)); FS-03-010. Cited only in DSEWPaC's recent assessment for Wolsit T-35.
- Mize SV, Porter SD and Demcheck DK 2008, 'Influence of fipronil compounds and rice-cultivation land-use intensity on macroinvertebrate communities in streams of southwestern Louisiana, USA', *Environmental Pollution* 152(2):491–503.
- Schlenk D, Huggett DB, Allgood J, Bennett E, Rimoldi J, Beeler AB, Block D, Holder AW, Hovinga R and Bedient P 2001, 'Toxicity of fipronil and its degradation products to Procambarus sp.: field and laboratory studies', *Archives of Environmental Contamination & Toxicology* 41(3):325–332.
- US EPA Region 6 2002, *Total Maximum Daily Load (TMDL) for the pesticide fipronil in the Calcasieu River Basin*, <http://d.scribd.com/docs/k653edji8gtou1oa9zf.pdf>, accessed March 2009.

5.4 Madagascar

Large-scale operations to control a migratory locust plague occurred in Madagascar from 1997 to 2000 (note the practices used were quite different to those followed for Australian locust control operations). The widespread use of pesticides (repeated aerial and ground application over more than 42,000 km^2) in an area described as a 'biodiversity hotspot' (including fipronil by full-cover spray and by barrier treatments) raised concerns about hazards to wildlife. Therefore studies were conducted to monitor the effects of insecticides on key non-target organisms. These included a study which focused on the mound-building harvester termite *Coarctotermes clepsydra* and its endemic vertebrate predators, the lesser hedgehog tenrec *Echinops telfairi*, and two lizard species (see the Peveling et al. 2003 study, listed below). Fipronil caused a large reduction in activity of the termites, culminating in high mortality (about 80% colony mortality within spray barriers 6 months post-spraying at one site, and about 90% colony mortality within spray barriers 10 months after spraying at another). Declines in the relative abundance of the two lizard species were also observed, and the lesser hedgehog tenrec was not found in fipronil plots, though it was frequent in the control and deltamethrin plots.

The investigators concluded the study provided evidence of food chain perturbations induced by fipronil, which has important implications for the management of locust control operations in Madagascar and other

countries. They recommended that full-cover spraying for locusts should not be used and that further investigations of the long-term ecological effects of barrier sprays were needed, particularly to examine the consequences of substantial termite mortality. The severe and long-lasting effects of fipronil on termite populations also presents a long-term risk to nutrient cycling and soil fertility where termites are important in these ecological processes. There were also claims there may have been harmful effects on certain birds and other species (see the Kirby 2000 and Thomas et al. 2000 studies listed below). Various references discussing the widespread use of fipronil for locust control in Madagascar at this time and exploration of its consequences include the following, and have been used in the scoping assessment:

- Dinham B 2000, 'Poisoning an island? Locust control in Madagascar', *Pesticides News* 48:3–6.
- Kirby A 2000, 'Anti-locust drive 'created havoc',' *BBC News* 27 June 2000, <http://news.bbc.co.uk/1/hi/sci/tech/806641.stm>, accessed March 2009.
- Peveling R 2000, 'Toxicity of fungal and chemical locust control agents to lizards', *Advances in Applied Acridology* 2000, AAAI, p 17.
- Peveling R and Demba SA 1997, 'Effect of Metarhizium flavoride, chlorpyrifos, and fipronil on *Acanthodactylus dumerli* (Milne Edwards, 1829) (Squamata: Lacertidae),' LUBILOSA bioassays in Akjoujt, Mauritania, November 1996 to February 1997, first draft July 1997.
- Peveling R and Demba SA 2003, 'Toxicity and pathogenicity of *Metarhizium anisopliae* var acridum (Deuteromycotina, Hypomycetes) and fipronil to the fringe-toed lizard *Acanthodactylus dumerili* (Squamata, Lacertidae)', *Environmental Toxicology and Chemistry* 22: 1437–1447.
- Peveling R, McWilliam AN, Nagel P, Rasolomanana H, Rakotomianina RL, Ravoninjatovo A, Dewhurst CF, Gibson G, Rafanomezana S and Tingle CCD 2003, 'Impact of locust control on harvester termites and endemic vertebrate predators in Madagascar', *Journal of Applied Ecology* 40(4):729–741.
- Peveling R, Rasolomanana H, Raholijaona RR, Ravoninjatovo A, Randimbison L, Rakotondravelo M, Raveloson A, Rakotoarivony H, Bezaka S, Ranaivoson N & Rafanomezantsoa J-J 2001, 'Effets des traitements aériens de fipronil et de deltaméthrine en couverture totale sur la chaîne alimentaire', In: Zehrer W. (Ed.) 'La Lutte Antiacridienne à Madagascar', Tome III: Ecotoxicologie. DPV/GTZ, Ministère de l'Agriculture, Antananarivo, Madagascar pp 525–572. Unpublished report cited by Tingle et al. (2000), not seen by DEWHA but we have cited it from that source.
- Thomas M, Klass J and Blanford S 2000, 'The year of the locust', *Pesticide Outlook* 11(5):192–195.
- Tingle CCD and McWilliam AN 1999, 'Evaluation of short-term impact on nontarget organisms of two pesticides used in emergency locust control in Madagascar', Final Report to DFID. NRI, Chatham, UK. 28+9+6+5+12+xxix pp. Unpublished report cited by Tingle et al. (2000), not seen by DEWHA but we have cited it from that source.
- Tingle CCD, Rother JA, Dewhurst CF, Lauer S and King WJ 2000, *Health and environmental effects of fipronil.* Briefing Paper AI1, Pesticide Action Network UK, November 2000. <www.pan-uk.org/briefing/fipronil.pdf>.

5.5 China

On 1 February 2009, the Ministry of Agriculture of China announced it would no longer register or certify the production of fipronil-containing pesticide formulations (except those to be applied for hygiene, or as a drought-resistance seed-coating agent and for exports), effective 1 July 2009. The existing fipronil technical material manufacturers were allowed to produce fipronil-containing pesticides formulations only for export. Fipronil-containing pesticides formulations were not to be sold or used in China for any other purposes. All existing registrations and certificates for other purposes were to be revoked. The manufacturers were required to strengthen their management of production, marketing and use, and to establish a traceability system. Shortly after that, on 25 February 2009, the Ministry of Agriculture, the Ministry of Industry and Information Technology and the Ministry of Environmental Protection jointly issued Announcement 1157 and set 1 October 2009 as the date to ban the use of fipronil-containing pesticides formulations, which means fipronil products have already been completely banned from use in China (for more information see <http://www.highbeam.com/doc/1G1-222024808.html>).

In its March 2009 bulletin, AGROW Asia/Australasia reported that China's Ministry of Agriculture had placed these restrictions on fipronil in light of the high risk it posed to aquatic crustaceans and bees, and its slow rate of degradation in water and soil (Agrow bulletin no. 564, 27 March 2009).

5.6 Uruguay

In August 2009 restrictions were placed on fipronil to avoid harm to beneficial insects in Uruguay. The new rules only allow seed treatments and granular baits for control of ants.

6 DATA ASSESSMENT AND POSSIBLE OUTCOMES

The APVMA will refine its technical assessment of fipronil taking into consideration the information provided in response to the review announcement.

The review can result in one of three broad outcomes:

1. The APVMA remains satisfied that products containing fipronil continue to meet the conditions to which registration or approval are currently subject, and affirms the registrations and approvals.
2. The APVMA is satisfied the conditions to which the registration or approval is currently subject can be varied in such a way that the requirements for continued registration or approval will be complied with, and varies the conditions of approval or registration.
3. The APVMA is not satisfied the conditions to which the registration or approval is currently subject continue to be met and suspends or cancels the registration or approvals.

7 CONSULTATION AND INVITATION TO MAKE A SUBMISSION

7.1 Consultation throughout the review process

From initiation of the review through to implementation of the review outcomes, the APVMA will consult with relevant stakeholders and interested parties.

7.2 Submissions from the public are invited

Interested groups or individuals are invited to make a submission or provide data relevant to the concerns raised in this scope document. Submissions must reach the APVMA by no later than **31 August 2012**. Submissions can be sent either by email or by mail to:

Manager Fipronil Environmental Review
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Telephone: 61 2 6210 4749
Facsimile: 61 2 6210 4776

Email: chemicalreview@apvma.gov.au

Please note that subject to the *Freedom of Information Act 1982*, the *Privacy Act 1988* and the Agvet Codes all submissions received may be made publicly available. They may be listed or referred to in any papers or reports prepared on this subject matter.

The APVMA reserves the right to reveal the identity of a respondent unless a request for anonymity accompanies the submission. If no request for anonymity is made, the respondent will be taken to have consented to the disclosure of their identity for the purposes of Information Privacy Principle 11 of the Privacy Act.

The contents of any submission will not be treated as confidential or confidential commercial information unless they are marked as such and the respondent has provided justification that the material is capable of being classified as confidential or confidential commercial information in accordance with the Freedom of Information Act or the Agvet Codes as the case may be.

APPENDIXES

APPENDIX A – FIPRONIL PRODUCTS TO BE CONSIDERED FOR ENVIRONMENTAL IMPACTS

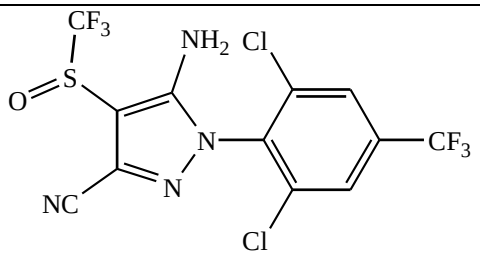
PRODUCT NO,	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS
46793	REGENT 200SC INSECTICIDE	BASF Australia Ltd	46793/01 46793/03 46793/0399 46793/0402 46793/0403 46793/0499 46793/0501 46793/0605 46793/0901 46793/0997 46793/0999 46793/1099 46793/1199
47407	REGENT 800WG INSECTICIDE	BASF Australia Ltd	47407/0399 47407/0402 47407/0403 47407/0499 47407/0501 47407/0605 47407/0901 47407/0997 47407/1199
49434	COSMOS INSECTICIDAL SEED TREATMENT	BASF Australia Ltd	49434/0403 49434/0499 49434/0598 49434/0699 49434/0798 49434/0899 49434/0997 49434/1100 49434/1101 49434/1204
50285	ADONIS 8.5UL INSECTICIDE	BASF Australia Ltd	50285/0403 50285/1199
53156	ADONIS 3UL INSECTICIDE	BASF Australia Ltd	53156/0403 53156/0900
54624	TERMIDOR RESIDUAL TERMITICIDE AND INSECTICIDE	BASF Australia Ltd	54624/0204 54624/0403 54624/0806 54624/0808 54624/0809 54624/1002 54624/1004 54624/1007
57764	IMPEDE INSECTICIDE	BASF Australia Ltd	57764/0503
58884	NUFARM IMPEDE INSECTICIDE	Nufarm Australia Limited	58884/0604

PRODUCT NO,	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS
58885	NUFARM ADONIS 3UL INSECTICIDE	Nufarm Australia Limited	58885/0307 58885/0604 58885/0605 58885/1006
60284	NUFARM REGENT 200SC INSECTICIDE	Nufarm Australia Limited	60284/0406 60284/0809 60284/1005 60284/1208
61345	CROP CARE COSMOS INSECTICIDAL SEED TREATMENT	Crop Care Australasia Pty Ltd	61345/1106
61632	NUFARM GARD INSECTICIDE	Nufarm Australia Limited	61632/0107
61820	IMTRADE REGAL 800 WG INSECTICIDE	Imtrade Australia Pty Ltd	61820/0309 61820/0909 61820/51738
62236	LEGION 200SC INSECTICIDE	Crop Care Australasia Pty Ltd	62236/0609 62236/0707
63435	BARMAC FIPRO FORCE RESIDUAL TERMITICIDE	Barmac Industries Pty Ltd	63435/1108
63581	SUREFIRE VISTA 200SC INSECTICIDE	PCT Holdings Pty Ltd	63581/0309 63581/50826
63600	TRANSFER TERMITICIDE	Garrards Pty Ltd	63600/0309
63789	FIPFORCE AQUA TERMITICDE	Sherwood Chemicals Public Company Limited	63789/46493
63960	CAMPBELL KAISER 200SC INSECTICIDE	Colin Campbell (Chemicals) Pty Ltd	63960/1209
64449	ULTRATHOR WATER BASED TERMITICIDE	Ensystex Australasia Pty Ltd	64449/50519
64884	COUNTRY FIPRONIL RESIDUAL TERMITICIDE	Accensi Pty ltd	64884/49532
65313	ENVIROMAX FIPRONIL 200 SC INSECTICIDE	Enviromax Technologies Pty Ltd	65313/52624
65356	AW FLAK INSECTICIDE	Agri West Pty Limited	65356/50745 65356/52702
65389	RHYME INSECTICIDE	Ospray Pty ltd	65389/50808
65878	4FARMERS FIPRONIL 800 WG INSECTICIDE	4 Farmers Pty Ltd	65878/52214
66873	SHERWOOD FIPRONIL 200 INSECTICIDE	Sherwood Chemicals Public Company Limited	66873/54589
67352	MISSION FIPRONIL 800 WG INSECTICIDE	Mission Bell Holdings Pty Ltd	67352/55857

PRODUCT NO,	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS
67463	TAURUS RESIDUAL TERMITICIDE	Farmoz Pty Limited	67463/56083

APPENDIX B – FIPRONIL CHEMICAL IDENTITY AND PHYSICOCHEMICAL PROPERTIES

Table 2: Chemical identity of fipronil

COMMON NAME	FIPRONIL
Chemical name – CAS	(±)-5-Amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl)-4-[(trifluoromethyl)sulfinyl]-1H-pyrazole-3-carbonitrile
Other names	RM1601 – Rhône Mérieux CodeMB46030 – Rhône-Poulenc Code
CAS Registry Number	120068-37-3
Molecular formula	C12H4Cl2F6N4OS
Molecular mass	437.14
Structural formula	

The chemical structures for selected fipronil metabolites are provided at appendix G

Table 3: Summary of physicochemical properties

ACTIVE CONSTITUENT	
Colour/physical state	White powder with mouldy smell
Melting point	195.5–203ºC
Relative density	1.471-1.626 at 20ºC
pKa	Not provided. As an amine, fipronil would be expected to be basic, but the lack of variation of solubility with pH suggests the degree of dissociation in aqueous media is not significant.
Vapour pressure	3.7 x 10-4 millipascals at 25ºC
Henry's Law constant	-
Solubility in water	1.9 (distilled water), 2.4 (pH 5), 2.2 (pH 9) mg/L
Solubility in other solvents	hexane 28.0 mg/L, acetone 545.9 mg/L, toluene 3000 mg/L, octanol 12.2 g/L
Octanol/Water Partition Coefficient:	logPow = 4.0 at 20°C

APPENDIX C – ENVIRONMENTAL EXPOSURE

As at June 2011, there were 49 fipronil products registered for use in Australia. Household insecticides (5), companion animal products (19), wood preservative (1), cockroach gel (1) and vertebrate poisons (2) are not considered in relation to environmental impacts. The remaining 21 products are registered for pest control in a wide range of agricultural, turf and termiticide situations. These products have been grouped based on product type (Table 4).

Table 4: Fipronil Insecticide label use patterns and grouping

GROUP	FIPRONIL CONCENTRATION	USE PATTERN	PRODUCT NUMBERS
1	200 g/L	Cropping situations, locust control in pasture and sorghum; some labels have a forestry use	46793, 60284, 62236, 63581, 63960
2	800 g/kg	Cropping situations, locust control in pasture and sorghum	47407, 61820, 62372, 53156, 58885
3	3 g/L	Locust control in pasture and sorghum	
4	8.5 g/L	Locust/grasshopper control in pasture and sorghum	80285
5	500 g/L	Seed treatment (canola, sorghum, sunflowers)	49434, 61345
6	1 g/kg	Recreational, domestic and commercial turf	57764, 58884, 61632
7	100g/L	Protection from/control of subterranean termites around domestic and commercial structures	54624, 63435, 63600
8*	3.4 g/kg	Fruit fly baits	58478, 60664
9**	5	Termiticide	60654

**Group 8 fipronil fruit fly bait products contain 0.02 g/station fipronil with up to 16 stations per hectare used for fruit fly susceptible fruit crops. This equates to a maximum rate of 0.32 g/ha in the 16 discrete bait stations. Overall environmental exposure will be very limited from use of these products. No further risk assessment for these products is therefore proposed.*

***Group 9: The single product in this group is a termite dust formulation (fipronil at 5 g/kg), for the treatment of termite nests in trees, stumps, posts, power poles, timber bridges and wharves, mounds and wall cavities. The application rate is up to 5 g of dust per nest (25 mg fipronil/nest). It appears that DSEWPaC never assessed the environmental risk of this product. It is not possible to undertake a quantitative assessment of risk for this product, even at the screening level, given its likely intermittent (and scarce) use within any given area. However, the small pack sizes (3 X 5 g containers sold as a 15 g unit), and low application rates (25 mg/nest) suggest that overall environmental exposure would be limited. Therefore no further risk assessment for this product is proposed.*

Fipronil use patterns and application rates

Group 1 products

Table 5: Group 1 products

Crop	Application type	Maximum rate	Applications per year
Asparagus*	Ground boom	40 g ac/ha	6
Bananas	Butt application	30 g ac/100 L** (0.15 g ac/stool)	Up to 2
	Band application	8 g ac/100 m^2 (800 g ac/ha in the treated area)	
Brassicas	Ground boom	50 g ac/ha	Up to 4
Cotton	Ground boom and air	25 g ac/ha	2
Mushrooms	-	3.2 g ac per 300 L bale***	1
Potatoes	Ground boom	100 g ac/ha (incorporated)	1
Wine grapevines	Hand held equipment only	0.05 g ac/vine (directed spray)	1
Pasture/sorghum	Ground boom and air	1.25 g ac/ha	2
Sugarcane	Ground (directed spray)	1.14 g ac/100 m row (75 g ac/ha in the treated area)	1
Forestry*	Ground boom and air	2.5 g ac/ha	1
Ginger*	Ground boom	100 g ac/ha (incorporated)	1
Swede and turnip*	Ground boom	50 g ac/ha	4

See page 45 for an explanation of the units of measure in this table

** Only product numbers 60284 and 62236 were registered for these uses in this group.*

*** Application is by a fine spray to ensure thorough coverage of the stem and suckers to a height of 30 cm and surrounding trash and soil on a 30 cm radius. The application rate is 0.15 g ac per banana stool, which equates to 225 g ac/ha.*

**** Presto Mushroom Insecticide is thoroughly mixed with each 300 L bale of peatmoss during the preparation of the casing for mushroom cultivation.*

Group 2 products

Table 6: Group 2 products

CROP	APPLICATION TYPE	MAXIMUM RATE	APPLICATIONS PER YEAR
Bananas	Butt application	30 g ac/100 L* (0.15 g ac/stool)	Up to 2
	Band application	8 g ac/100 m2 (800 g ac/ha in the treated area)	
Brassicas	Ground boom	48 g ac/ha	Up to 4
Cotton	Ground boom and air	24 g ac/ha	2
Mushrooms	-	3.2 g ac per 300 L bale**	1
Potatoes	Ground boom	100 g ac/ha (incorporated)	1
Wine grapevines	Hand held equipment only	20 g ac/ha (directed spray)	1
Pasture/sorghum	Ground boom and air	1.20 g ac/ha	2
Sugarcane	Ground (directed spray)	1.12 g ac/100-m row (75 g ac/ha in the treated area)	1

See page 45 for an explanation of the units of measure in this table

** Application is by a fine spray to ensure thorough coverage of the stem and suckers to a height of 30 cm, and surrounding trash and soil on a 30 cm radius. The application rate is 0.15 g ac per banana stool which equates to 225 g ac/ha.*

*** Presto Mushroom Insecticide is thoroughly mixed with each 300 L bale of peatmoss during the preparation of the casing for mushroom cultivation.*

The environmental exposure from use in mushrooms is not expected to be significant. This use pattern will not be considered further in the risk assessment.

Group 3 and 4 products

The three products in Groups 3 and 4 are registered only for the control of Australian plague locusts and spur throated locusts in pasture and sorghum at a single rate of 1.25 g ac/ha (grams of active constituent per hectare). The labels carry explicit application instructions relating to spray release (8–10 metres height) with wind speeds ranging from around 7 km p/hr to almost 30 km p/hr, although at wind speeds approaching this highest speed, the release height should be reduced to 5 metres.

This product will only be applied in undiluted form by aircraft through ULV spray units.

Group 5 products

The two products in Group 5 are registered for seed treatment use on canola (200 g ac per 100 kg of seed), rice (10 g per 100 kg of seed), sorghum (75 g per 100 kg of seed) and sunflowers (75 g per 100 kg of seed).

Group 6 products

Products in this group are registered for use in recreation turf (bowling greens, golf courses, parks and playing fields), domestic turf and commercial turf farm. When initially registered for use on turf, which entails application to the surface of turf by granule applicator, application rates were 15–30 kg of product per hectare (equivalent to 15–30 g ac/ha). Current turf labels (three products) now have more than twice this rate registered: application rates are 30–75 g ac/ha, depending on the target pest. Applications are to be followed immediately by incorporation using at least 6 millimetres (mm) overhead irrigation or rainfall.

It is unclear if DSEWPaC ever re-evaluated fipronil-associated risks at the higher registered rates.

Group 7 products

Termite products contain fipronil at 100 g/L and are registered as conventional termite soil chemical barrier treatments around existing buildings and structures. The products are mixed at a dilution rate of 600 mL product in 100 L of water and applied at the rate of 100 L of mixed solution per cubic metre of soil (60 g ac/m^3) or 5 L per square metre surface area of soil (3 g of active ingredient).

Application equipment could be either by conventional spraying such as hand-sprayer lance delivering a low pressure, high volume spray, or soil injection equipment such as trenching and backfill or soil rodding. All this will be applied directly to the soil. There should be no need for any re-treatment for at least 4 years unless the barrier is disturbed.

While all three products in this group are registered for this use around existing buildings and structures, one of them (product number 54624) is also registered for pre-construction use. The application rates and methods are the same as for existing buildings. However, this product is also registered for application by reticulation systems.

All three products are also registered for treatment of poles and fence posts in contact with soil. For existing posts, a continuous barrier 450 mm deep and 150 mm wide around the post or pole should be created, either by soil injection or rodding, or trench and puddle treating backfill. One hundred litres of prepared spray per cubic metre of soil around the pole, post or stump should be used. If new posts are being installed, the bottom of the hole and the backfill should be treated at installation.

Only product 54624 is registered for other termite control situations, including nests in poles and trees (600 mL in 100 L water); wall cavity treatment (6 mL/L water); and for control of nuisance ants in external areas and surrounds of buildings and structures (6 mL/L water).

Earlier considerations of these products assumed the average house in Australia has a perimeter of 75 metres. When applied in accordance with the Australian Standard (AS3660.2), the soil barrier that is created around a structure is a minimum of 150 mm wide and installed to a minimum depth of 50 mm (applied as a vertical barrier). Assuming 300 mm as a worst-case scenario, the average surface area of soil that would be treated around a building would therefore be approximately 75 x 0.3 m = 22.5 m^2 (or equivalent to about 100 to 120 L of mixed product). The rest of the treatment that would occur around footings, piers or other support structures under the house may also involve injection through the slab in some cases. An average volume used for a house is estimated as 400–500 L of mixed solution, thus about 240–300 g of active ingredient per

house would be used. This is the highest proposed rate of any use. When used as a pre-construction treatment, it is a relatively high rate compared with other uses, and it would be higher still if several houses in close proximity needed treatment at the same time.

APPENDIX D – ENVIRONMENTAL FATE

The full technical evaluation of environmental fate data is provided in the environmental technical reports.

Degradation rates and routes

Fipronil is hydrolytically stable under neutral and acidic conditions, but it undergoes hydrolysis of its nitrile substituent (the amide, RPA 200766) under alkaline conditions (half-life about 1 month at pH 9).
The main metabolites, the sulfone (MB46136), sulphide (MB45950) and desulfinyl (MB46513) were all stable at neutral and acidic pHs, but did hydrolyse at pH 9 with corresponding half-lives of 50 days (25^{o}C), 11 days (50^{o}C) and 10.9 days (25^{o}C).

Photochemical breakdown in aqueous solution results in production of the desulfinyl metabolite (MB46513) as the main photodegradation product (more than 50%). The aqueous photoloysis half-life of fipronil is around half a day or less, and MB46513 is more persistent with an aqueous photolysis half-life of 120 hours or more. Photolysis on soil seems a slower process, and although MB46513 still remains the dominant photolysis product, it is formed at lower rates (less than 10% after 30 days). In one soil photolysis study, the irradiation half-life was 34 days compared with 49 days in dark samples.

More recent reliable data available for aerobic soil degradation of fipronil bring into doubt previous assessment information used. In four soils at 20^{o}C, fipronil degraded to form the amide (RPA 200766) at maximum levels of 19–38% of applied radioactivity (AR), the sulfone (MB46136) at maximum levels of 11–34% and the sulphide (MB45950) at maximum levels of 2–17%. The rate of fipronil degradation was dependent on temperature and soil microbial biomass, being more rapid at 20^{o}C and more rapid with higher microbial biomass. At 20^{o}C, the soil half-lives of fipronil (linear, first order kinetics) ranged from 42 to 382 days. In two of the four soils, the half-lives exceeded 6 months. Applying the Australian PBT (persistent, bioaccumulative, toxic) criteria, and those outlined in Annex D to the Stockholm Convention for persistent organic pollutants, this indicates fipronil is very persistent in soils. In the field, half-lives from 3–7 months appear typical under temperate conditions; the longer half-lives prevail at colder locations. Limited evidence indicates half-lives are very short in the tropics. Half-lives of less than 1 month have been reported in established turf plots, and half-lives are of a similar order in rice paddies, probably reflecting higher microbial activity.

New aerobic aquatic metabolism data are available. In four systems, MB45950 was the dominant metabolite in water and sediment. In water, levels could approach 10% of AR; much higher (up to 80% AR) levels were found after at least 60 days in sediment. No sulfone (MB46136) or desulfinyl (MB46513) metabolite was found in any system in water or sediment except for one minor detection of MB46513 in one sediment at two sampling times. Small amounts of the amide (RPA 200766) were found in water (generally less than 10%) and sediment (generally less than 5%). Loss of radioactivity tended to follow first order kinetics. Fipronil-only half-lives ranged from 14.4 to 93.6 days in water and from 16.3 to 119.5 days in the whole system. However, when total residues were considered (which is appropriate given the biological activity of the main metabolites), water half-lives were 18 to 122 days, and whole-system half-lives exceeded 6 months. Half-lives greater than 2 months in water and 6 months in sediment exceed Australian PBT (persistence, bioaccumulation potential and toxicity) criteria and those outlined in Annex D to the Stockholm Convention for persistent organic pollutants. One study testing metabolism of the main photolysis product, MB46513, in

two water–sediment systems showed this compound to be persistent, both in water (half-life 78–92 days) and the whole system (half-life 533–770 days).

Anaerobic degradation principally involves reduction of the sulfoxide linkage, in which an initial half-life of about 4 months in the single soil studied under flooded conditions was observed. In a non-standard study, MB45950 was also the dominant metabolite and was found with almost stoichiometric production from initial fipronil levels. The half-life of fipronil in sediment slurries was 35–40 days. In terms of total residues, the overall half-life was much slower, but not able to be calculated.

Mobility

Results from conventional adsorption–desorption tests in five soils indicate that fipronil is moderately to slightly mobile in soils. K_{oc} values ranged from 427 to 1248 L/kg. This mobility conclusion is supported by a batch equilibrium study of eight South Australian soils, though direct comparison is difficult due to the use of solvents in the aqueous media.

The sulphide (MB45050), was less mobile, with K_{oc} values in five soils of 1695–5621 L/kg. Similar K_{oc} values were found for the sulfone (MB46136) with values five soils of 1448–6745 L/kg. The desulfinyl (MB46513) was less mobile than these two metabolites and only slightly less mobile than the parent compound. In five soils, the K_{oc} values were 1150–1498 L/kg. The amide (RPA 200766) was much more mobile with a range of K_{oc} values of 96–203 L/kg in five soils.

In leaching studies on packed columns and field dissipation studies at four sites in Europe and four in the USA, an absence of significant leaching potential for fipronil and its sulfide and sulfone metabolites was confirmed. The amide metabolite is more mobile and was detected to 90 cm depth, at concentrations below 5 µg/kg (micrograms per kilogram), in one soil that became saturated with water during the spring thaw.

Bioaccumulation

Fipronil is not expected to bioaccumulate.

Environmental monitoring (USA)

Since the initial assessments of fipronil in Australia, monitoring in the USA has detected fipronil in surface waters and sediments in association with different use patterns. In the rice producing areas of the Mermentau River Basin in Louisiana during 2000, fipronil was found in 79% of samples, while MB46513, MB45950 and MB46136 were found in 99–100% of samples (from 17 sites; n = 91). Fipronil concentrations ranged from 0.004 to 5.29 µg/L (90th percentile = 2.69 µg/L) in surface water. In bed sediment, fipronil was not found; however, MB45950 and MB46513 were found at all sites with MB45950 found at concentrations of 0.636–24.8 µg/kg.

The US Geological Survey has demonstrated the presence of fipronil and its major metabolites (in the low µg/L range) in water bodies in urban and agricultural areas throughout the USA (data from 2002 to 2006). The highest recorded concentration for fipronil was found in Louisiana (0.117 µg/L). For MB46136, MB46513, MB45950 and RPA200766, the highest detections were 0.038 µg/L (Colorado), 0.015 µg/L

(Louisiana), 0.158 µg/L (California), and 0.011 µg/L (Louisiana) respectively. The Louisiana detections were made in surface water from mainly agricultural areas.

In Orange County, California, where fipronil is used for structural pest control in urban areas, almost 100% of samples contained fipronil in a 2008 survey. In dry weather runoff, the median concentration was 0.091 µg/L and the maximum was 10 µg/L; in wet weather runoff the median concentration was 0.183 µg/L and the maximum 1.1 µg/L.

APPENDIX E – ENVIRONMENTAL EFFECTS

Fipronil and its metabolites are very highly toxic to organisms in the environment, particularly aquatic and terrestrial insects. Table 7 summarises the lowest ecotoxicity values for the various environmental organisms used in the risk assessment. The highlighted cells indicate those end points that have changed from previous assessments performed by DSEWPaC as a result of consideration of the new information.

Table 7: Summary of most sensitive environmental organisms

GROUP	SPECIES	STANDARD	ECOTOXITY VALUE	
AQUATIC ORGANISMS (PARENT FIPRONIL)				
Fish – acute	Bluegill sunfish	LC_{50}	85	µg/L
Fish – chronic	Sheepshead minnow*	NOEC	2.8	µg/L
Aq. invertebrates acute	Mysid shrimp	LC_{50}	0.14	µg/L
Aq. invertebrates chronic	Mysid shrimp*	NOEC	0.0077	µg/L
Algae/aquatic plants acute	Green algae	EC_{50}	68	µg/L
Algae/aquatic plants chronic	Green algae	NOEC	40	µg/L
Sediment organisms	*Chironomus tentans**	10-day LC_{50}	0.90	µg/kg
AQUATIC ORGANISMS (METABOLITES)				
Fish – acute	MB45950, Rainbow trout*	LC_{50}	29.5	µg/L
	MB46513, Bluegill sunfish**	LC_{50}	20	µg/L
	MB46136, Bluegill sunfish**	LC_{50}	25	µg/L
Aq. invertebrates – acute	MB45950, Mysid shrimp*	LC_{50}	0.077	µg/L
	MB46513, Mysid shrimp*	LC_{50}	1.5	µg/L
	MB46136, Mysid shrimp*	LC_{50}	0.056	µg/L
Aq. invertebrates chronic	MB45950, Mysid shrimp*	NOEC	0.0046	µg/L
	MB46513, Daphnia magna**	NOEC	6.3	µg/L
	MB46136, Mysid shrimp*	NOEC	0.0051	µg/L
Sediment organisms	MB45950, *Chironomus tentans**	10-day LC_{50}	1.1	µg/kg
	MB46136, *Chironomus tentans**	10-day LC_{50}	0.83	µg/kg
Terrestrial organisms				
Birds, acute oral	Bobwhite quail	LD_{50}	11.3	mg/kg bw

GROUP	SPECIES	STANDARD	ECOTOXITY VALUE	
Birds, short term, dietary	Bobwhite quail	LC_{50}	48	ppm diet
Birds, chronic, reproduction	Bobwhite quail	NOEC	10	ppm diet
Bees (oral toxicity) Bees (contact)	New data are available showing the highly sensitive nature of bees to fipronil. A higher tier risk assess for bees is required based on these data.*			
Non-target terrestrial arthropods	(Exposure through spray)	LD50*	0.106	g ac/ha
	(Exposure through soil) - Collembola	NOEC*	0.04	mg/kg dw
Earthworms	(based on soil concentration)	NOEC	1000	mg/kg dw
Soil microorganisms	(<25% effects at day 28)	NOEC*	0.667	mg/kg dw
Non-target terrestrial plants	(end point based on plant height data)	EC25		g ac/ha

* *New data not previously available to DSEWPaC.*

** *Available for fipronil assessments by DSEWPaC from 1998, therefore leading to a revision of assessments prior to this.*

APPENDIX F – ENVIRONMENTAL RISK ASSESSMENT

For fipronil products, the risk assessment was performed in two tiers. The first, a screening level assessment, calculated worst-case exposure concentrations and derived corresponding risk-quotients for the various environmental organisms. This Tier 1 risk assessment is provided in the technical report. Where this risk assessment concluded an acceptable risk, no further refinement was required.

Where a risk was identified through the screening level assessment, a more refined, second-tier risk assessment was performed in which further consideration was given to refining exposure calculations and ecotoxicity thresholds as appropriate. This Tier 2 (refined) risk assessment is provided in the technical report. In this part of the report, the main findings from these components of the assessment are provided.

The conclusions made in the assessment relate only to the parent fipronil, and have considered only a single application of this insecticide. Where an acceptable risk from fipronil was determined at the screening level, risk was also considered to be acceptable for fipronil's main metabolites. Outcomes of the risks assessment are shown in Table 8 as 'Y' for risk being acceptable, and 'N' for not-acceptable thereby requiring a refined risk assessment.

The screening level risk assessment was based on new data that have become available since previous fipronil environmental assessments in Australia. The results showed that for the broadacre spray uses (Groups 1 and 2), a refined risk assessment was needed for all organisms except soil microorganisms and earthworms. For products registered for plague locust control only (Groups 3 and 4), the refined risk assessment was required to focus on aquatic invertebrates and sediment organisms (aquatic organisms) and bees and non-target arthropods exposed through spray (terrestrial organisms).

For all other product groups, the risk to the terrestrial compartment was deemed acceptable. However, some further refinement of aquatic risk was required for seed treatment uses (Group 5), turf uses (Group 6) and termiticide uses (Group 7).

Based on the screening level risk assessment, uses of products from Group 8 (fruit fly baits, product numbers 58478 and 60664) and Group 9 (termiticide dust, product number 60654) remain acceptable with no further refinement of the risk assessment required.

Table 8: Matrix of results of screening level risk assessment

AQUATIC ORGANISMS	PRODUCT GROUP NUMBER								
	1	2	3	4	5	6	7	8	9
Fish – acute	N	N	Y	Y	Y	Y	N	Y	Y
Fish – chronic	N	N	Y	Y	N	Y	N	Y	Y
Aquatic invertebrates – acute	N	N	N	N	N	N	N	Y	Y
Aquatic invertebrates – chronic	N	N	N	N	N	N	N	Y	Y

AQUATIC ORGANISMS	PRODUCT GROUP NUMBER								
	1	2	3	4	5	6	7	8	9
Algae/aquatic plants	N	N	Y	Y	Y	Y	N	Y	Y
Sediment organisms (acute)	N	N	N	N	N	N	N	Y	Y
Birds, mammals and reptiles									
Birds, acute/dietary	N	N	Y	Y	Y	Y	Y	Y	Y
Mammals, acute	N	N	Y	Y	Y	Y	Y	Y	Y
Reptiles, acute	N	N	Y	Y	Y	Y	Y	Y	Y
Birds, chronic/reproduction	N	N	Y	Y	Y	Y	Y	Y	Y
Other non-target terrestrial organisms									
Bees	N	N	N	N	N	Y	Y	Y	Y
Non-target arthropods, exposure through spray	N	N	N	N	Y	Y	Y	Y	Y
Soil dwelling arthropods, exposure through soil	N	N	Y	Y	Y	Y	Y	Y	Y
Earthworms	Y	Y	Y	Y	Y	Y	Y	Y	Y
Soil microorganisms	Y	Y	Y	Y	Y	Y	Y	Y	Y
Non-target terrestrial plants	No plant toxicity data available								

Y = acceptable; N = not acceptable

Outcomes of the refined risk assessment

The refined risk assessment is reported in detail in the environmental technical reports. The following provides a summary of its findings.

Group 1 and 2 products

Aerial application - spray drift

Use patterns where aerial application is expected include pasture, sorghum (plague locust control), forestry and cotton. Downwind aquatic buffer zones can be implemented to mitigate risk to aquatic organisms aerial

spray drift from application to pasture, sorghum and in forestry, but by large are impractical at the high cotton use rates.

There is no statement precluding aerial application for several crops, but application rates in these cases would exceed those in cotton, and buffer zones would be impractically large if applied.

Ground application – spray drift

Downwind aquatic buffer zones can be implemented to mitigate risk to aquatic organisms from aerial spray drift for pasture, sorghum and forestry, but are outside the model capabilities (more than 300 metres) for other cropping situations. No suitable model exists to predict downwind drift in grapevines and sugarcane.

Runoff

Risk to aquatic organisms from runoff is acceptable for uses in pasture, sorghum and forestry on gentle slopes, but it may be unacceptable for use on steeper slopes. Additional information, including industry practices and sediment toxicity data, is required to mitigate the risk for other uses. At this stage, the risk remains unacceptable.

Bees

The risk to bees is not acceptable for any Group 1 and 2 use patterns. Further information is required to allow additional mitigation measures to be considered in the risk assessment.

Non-target terrestrial arthropods

The risk from use in pasture, sorghum and forestry is expected to be limited. Adverse effects on non-target terrestrial invertebrates could occur for significant distances downwind at application rates for other uses.

Reptiles

Based on current information, a risk has been identified to reptiles through application in bananas. The available toxicity data for reptiles is new since the first application of fipronil to bananas, so this end point should be considered. Additional information is required to assess this risk this risk.

Group 3 and 4 products

Aerial and ground application – spray drift

Downwind aquatic buffer zones can be implemented to mitigate risk to aquatic organisms through aerial spray drift for plague locust control in pasture and sorghum.

Bees

The risk to bees is not acceptable for Group 3 and 4 products with further information required to allow additional mitigation measures to be considered in the risk assessment.

Group 5 products

Aquatic organisms – runoff

Seed treatment uses of fipronil for canola, sorghum and sunflowers were acceptable. New information on fipronil toxicity to aquatic invertebrates, and the formation and corresponding toxicity of metabolites, resulted in further consideration of the potential for non-target receiving waters to be exposed when rice bay water may be released. Further information to potentially allow mitigation in this area is required.

Bees

The risk to bees is not acceptable with further information required to allow additional mitigation.

Group 6 products

Runoff

Risk to aquatic organisms from runoff is currently unacceptable, with further information required to allow mitigation of this risk.

Group 7 products

Runoff

Risk to aquatic organisms from runoff is currently unacceptable, with further information required to allow mitigation of this risk.

Groundwater

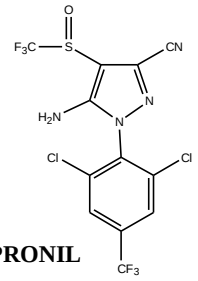
Groundwater exposure has not been covered specifically for use patterns in the screening level or refined risk assessments. The properties of fipronil are such that the potential for leaching to groundwater could exist.

As a worst case, the groundwater concentration was assumed to equal to soil pore-water concentration, which in turn was calculated based on the predicted soil concentration (Environmental Protection and Heritage Council 2009). However, this method neglects transformation and dilution in deeper soils. It was demonstrated in the technical reports that predicted soil concentrations for the range of agricultural uses range from 0.0008 mg/kg to 0.067 mg/kg, with a higher concentration of 0.53 mg/kg in the treated area for bananas. Applying the methods outlined in EPHC (2009), corresponding groundwater concentrations would be predicted to be 0.094–7.8 µg/L, with a higher level of 62 µg/L predicted from banana application (single applications only). All these concentrations exceed the chronic aquatic invertebrate end point (0.0077 µg/L) and would therefore result in a prediction of risk.

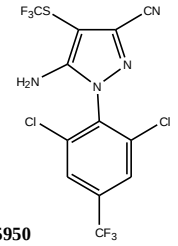
However, from leaching studies and field dissipation studies, including application of fipronil at extremely high (termiticide use) rates of 30 kg/ha, it was apparent that neither fipronil nor its biologically active metabolites move vertically through a range of soils in any appreciable amounts. Therefore, it is not anticipated that fipronil will leach to groundwater if these test data are given preference over the low-tier modelling approach

APPENDIX G- STRUCTURAL FORMULAE FOR FIPRONIL AND ITS METABOLITES.

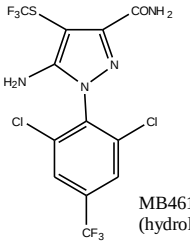
Below are the structural formulae for fipronil and its metabolites. Separate environmental fate and/or ecotoxicity studies have been conducted with the major metabolites shown in block letters. The origin of these metabolites is indicated, with the assistance of summary information in the European Food Safety Authority review as well as our previous assessments.



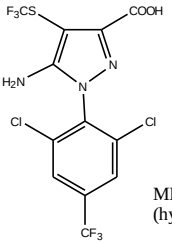
FIPRONIL



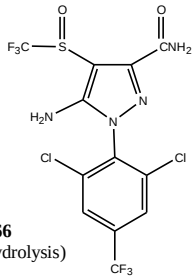
MB45950
(sulfide - reduction in soil)



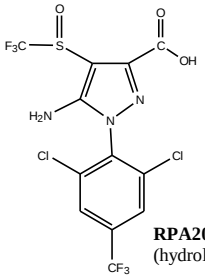
MB46126
(hydrolysis of MB45950)



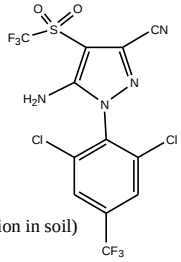
MB46233
(hydrolysis of MB46126)



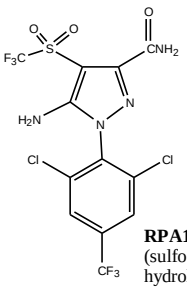
RPA200766
(amide - hydrolysis)



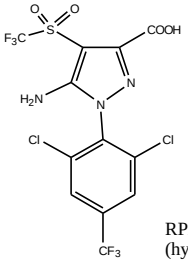
RPA200761
(hydrolysis of RPA200766)



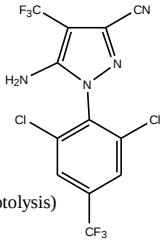
MB46136
(sulfone - oxidation in soil)



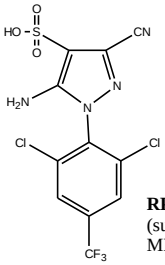
RPA105320
(sulfone-amide - hydrolysis of MB46136)



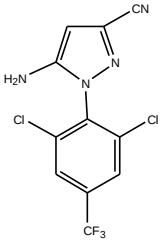
RPA106681
(hydrolysis of RPA105320)



MB46513
(desulfinyl - photolysis)



RPA104615
(sulfonate - photolysis of MB46136)



MB45897
(displacement product, possibly from RPA104615)

ABBREVIATIONS AND ACRONYMS

LENGTH/DEPTH		WEIGHT	
km	kilometre	kg	kilogram
cm	centimetre	g	gram
m	metre	mg	milligram
mm	millimetre	µg	microgram
		wt	weight
		bw	body weight
APPLICATION RATES/DOSAGES			
g ac/ha	grams of active ingredient per hectare		
mg/kg bw	milligrams per kilogram of bodyweight		
g/ha	grams per hectare		
VOLUME		CONCENTRATION	
L	litre	ppm	parts per million
mL	millilitre	µg/kg	microgram per kilogram
		µg/L	microgram per litre

OTHER ABBREVIATIONS AND ACRONYMS

ac	active ingredient
AERP	Adverse Experience Reporting Program
APVMA	Australian Pesticides and Veterinary Medicines Authority
Adverse Experience Reporting Program	Australian Plague Locust Commission
AR	applied radioactivity
CDPR	Californian Department of Pesticide Regulation
DSEWPaC	Australian Government Department of Sustainability, Environment, Water, Population and Communities (formerly the Australian Government Department of Environment, Water, Heritage and the Arts
EC_{50}	median effective concentration – the median concentration required to cause death to half the exposed population)
EFSA	European Food Safety Authority
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC_{50}	lethal concentration – the concentration in water that causes death to half the population being exposed

LD_{50}	median lethal dose
NOEC	No Observed Effect Concentration
OCSEH	Office of Chemical Safety and Environmental Health
PBT criteria	persistence, bioaccumulation potential and toxicity criteria
POP criteria	persistent organic pollutants criteria
SC	soluble concentrate
US EPA	United States Environmental Protection Authority
ULV	Ultra-low volume