Australian Pesticides &
Veterinary Medicines Authority

The Reconsideration of Approvals and Registrations Relating to Fenamiphos

REVIEW SCOPE DOCUMENT

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Australian Pesticides &
Veterinary Medicines Authority

Canberra
Australia

This scope document for the review of fenamiphos is published by the Australian Pesticides and Veterinary Medicines Authority. For further information about this review or the Pesticides Review Program, contact:

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Review Scope Document
Fenamiphos

FOREWORD

The APVMA is the National Registration Authority for Agricultural and Veterinary Chemicals. For information regarding the APVMA, please visit www.apvma.gov.au.

SUMMARY

The APVMA has initiated its reconsideration of the approvals of the active constituent fenamiphos, the registrations of products containing fenamiphos and the approvals of associated labels. This document 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 assessment of fenamiphos.

Approvals of the active constituent fenamiphos are being reconsidered because of concerns over a potential risk for acute and chronic toxicity to people. Products containing fenamiphos and all associated labels are being reviewed because of environmental, toxicological and occupational health and safety concerns.

The reconsiderations will be made after the APVMA assesses all the data and other information provided to it for this purpose – the assessment process is hereafter referred to as 'review'. It is anticipated that a draft report of the APVMA's review will be available for public comment late in 2004.

The APVMA will review the following aspects of active constituent approvals, product registrations and label approvals for fenamiphos:

- Toxicology, including:
  - the potential for acute and chronic effects on human health.

- Environment, including:
  - acute toxicity to birds; and
  - potential for groundwater contamination.

- Occupational health and safety, including:
  - the potential for hazards to worker; and
  - recent assessments conducted in the USA indicating concerns for worker safety when handling concentrate.

- Residues in food, including:
  - dietary estimates, both chronic and short term.

- Adequacy of label information.

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

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

The APVMA has decided to reconsider the approvals of the active constituent fenamiphos, the registrations of products containing fenamiphos and the approvals of associated labels, based on concerns over toxicology, environment, residues and occupational health and safety.

2 NOMINATION OF THE CHEMICAL

Fenamiphos (ethyl 3-methyl-4-(methylthio) phenyl (1-methylethyl) phosphoramidate) is an organophosphorus insecticide and nematicide widely used in agriculture to control soil pests, particularly nematodes. In October 1994 the APVMA invited the public to nominate active constituents, chemical products or labels for consideration for review. Of the 600 chemical nominations, 80 were prioritised for review, one of which was fenamiphos. Community groups, individual citizens and government agencies nominated fenamiphos for review.

The nomination of fenamiphos for review originally related to concerns over possible duck poisonings and the potential for environmental contamination of soil and waterways, particularly due to potential leaching. The details of the concerns that have been raised can be found in Sections 5 to 8 of this scope document.

Since 1994 the APVMA has received further letters from individuals regarding bird and fish deaths possibly associated with fenamiphos. Concerns raised regarding fenamiphos were investigated and fenamiphos was approved for review in 2001.

3 SCOPE OF THE REVIEW

The scope of the review has been defined taking into consideration the reasons for the nomination of fenamiphos, the information already available on this chemical and the way in which it is approved for use in Australia.

In light of concerns raised by:

- Environment Australia (EA) as detailed in Section 5,
- Therapeutic Goods Administration (TGA) as detailed in Section 6,
- National Occupational Health and Safety Commission (NOHSC) as detailed in Section 7 and
- APVMA Chemistry and Residues Evaluation Program (CREP) as detailed in Section 8,

it appears that the APVMA might not be able to maintain its satisfaction that the continued use of active constituent fenamiphos and products containing fenamiphos:

- would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues, and/or
- would not be likely to have an effect that is harmful to human beings; and/or
- would not have an unintended effect that is harmful to animals, plants and things or to the environment.

It also appears that the APVMA might not be able to maintain its satisfaction that labels for products containing fenamiphos contain adequate instructions.

On the basis of these concerns, it is appropriate that the registrations and approvals of fenamiphos be subject to reconsideration under Part 2, Division 4, of the Agvet Codes.

The APVMA will therefore review the following aspects of active constituent approvals, product registrations and label approvals for fenamiphos:

- Toxicology, including:
  - the potential for acute and chronic effects on human health.

- Environment, including:
  - acute toxicity to birds; and
  - potential for groundwater contamination.

- Occupational health and safety, including:
  - the potential for hazards to worker safety; and
  - recent assessments conducted in the USA indicating concerns for worker safety when handling concentrate.

- Residues in food, including:
  - dietary estimates, both chronic and short term.

- Adequacy of label information.

Registrants and approval holders will be required to undertake certain actions aimed at securing relevant data that might address these matters. However, the public is invited to make submissions to the APVMA regarding any of the matters raised in the scope document (see Section 10).

4 REGULATORY STATUS AND USE OF FENAMIPHOS IN AUSTRALIA

4.1 Active Constituent and Products

At the time of publication there were three (3) active constituent approvals for fenamiphos (Table 1) and four (4) registered products containing the active constituent fenamiphos (Table 2). Of the four registered products, two are granular formulations and two are emulsifiable concentrate (liquid) formulations.

Table 1: Active constituent approvals for fenamiphos.

Approval Number	Approval Holder
44171	Bayer Cropscience Pty Ltd
51157	Bayer Cropscience Pty Ltd
55043	4Farmers Pty Ltd

Table 2: Registered products containing fenamiphos.

Product Number	Product Name	Registrant	Label Approval Number(s)
33291	Bayer Nemacur Granular Nematicide	Bayer Cropscience Pty Ltd	33291/0103
33293	Nemacur 100G Nematicide	Bayer Cropscience Pty Ltd	33291/0198
33295	Nemacur 400 Nematicide Liquid	Bayer Cropscience Pty Ltd	33291/0198 33291/03
33296	Nemacur Turf Nematicide Liquid	Bayer Cropscience Pty Ltd	33291/1197

4.2 Current use patterns

Fenamiphos is a systemic and contact insecticide used primarily for the control of the major genera of nematodes and sucking insects including thrips and aphids that attack field crops, vegetables and turf. Products containing fenamiphos can be applied either by broadcast, in-the-row, in-band, by drench, before or at planting time, or to established plants, depending on the product. Products containing fenamiphos are approved for use on 45 crops, which include the pre-plant treatment for root vegetables crops, aloe vera, pineapples, bulbs and corms, vegetables, citrus, grapes, pineapples, strawberries, ornamentals, sugar cane, tobacco and turf (including golf greens). There is one granular product that is used in the home garden to control nematode in soils surrounding tomatoes, herbaceous ornamentals, crucifers and woody ornamentals.

5 ENVIRONMENTAL ISSUES

The major environmental issues to be examined during the review of fenamiphos are the potential for contamination of ground water, including contamination from the major metabolites (the sulfone and sulfoxide) and acute toxicity to birds as reflected in reported bird deaths in Australia and internationally.

Fenamiphos has been shown to be highly toxic to birds (Smith, 1993). The APVMA has received reports highlighting incidences where the application of fenamiphos products might have caused a number of duck poisonings, particularly after use on golf courses. In response to reports received in 1997, labels of fenamiphos products were changed. Despite this, duck poisoning incidents have continued to be received.

Fenamiphos is also of concern as research has demonstrated that heavy irrigation and rainfall can lead to leaching in certain circumstances (US EPA, 2001). Leaching of fenamiphos has been suggested as a possible cause of reported fish poisonings in the Swan River (Perth, Western Australia) after a fenamiphos product was applied to a racecourse. Fenamiphos has also been found at varying rates in soil (Kookana *et al*., 1997) and in groundwater (Di and Aylmore, 1997).

6 TOXICOLOGICAL ISSUES

Public health concerns relate to the acute and chronic toxicity of fenamiphos. The United States Environmental Protection Agency (US EPA) has completed a human health risk assessment for fenamiphos (US EPA, 1999). The report found that the acute and chronic dietary risk from food crops treated with fenamiphos was low, however, it also concluded that the dietary risk from drinking water was high.

The National Drugs and Poisons Scheduling Committee (NDPSC) and the Pesticide and Agricultural Chemicals Committee (PACC) have independently considered the toxicology and/or Maximum Reside Limits (MRLs) of fenamiphos on a number of occasions from 1971 to 1991. The NDPSC noted in 1988 that fenamiphos is highly acutely toxic and that inhibition of plasma cholinesterase (ChE) activity, with consequent cholinergic signs, was typical of repeat-dose studies in laboratory animals. The committee confirmed Schedule 6 (granular preparations containing 5% or less fenamiphos) and Schedule 7 entries in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). However, the committee was concerned that such an acutely toxic chemical was available in granular form for domestic use. The NDPSC recommended that home garden products containing fenamiphos be reviewed.

7 OCCUPATIONAL HEALTH AND SAFETY ISSUES

Outcomes of the US EPA Human Health Assessment for fenamiphos (US EPA, 1999), indicated concerns regarding worker exposure to fenamiphos concentrate when mixing/loading/applying products. Post-application exposure was also assessed and re-entry periods established.

To date there have only been limited occupational health and safety assessments conducted for fenamiphos products in Australia. Outcomes of the US EPA reassessment have raised concerns as to whether personal protective equipment (PPE) and re-entry period instructions that currently appear on product labels are adequate. As a result of recent concerns APVMA will review the adequacy of current OH&S label instructions.

8 RESIDUE ISSUES

The residues assessment of fenamiphos would focus primarily on short-term and chronic dietary estimates. These estimates will have regard to the ADI and ARfD established by the TGA. To allow a better estimate of Australian intake, registrants have been requested to provide residue data specifically for tomatoes, lettuce, strawberries and citrus, as well as animal transfer data for cattle and hens.

9 INTERNATIONAL REGULATORY STATUS OF FENAMIPHOS

The US EPA released (May 2002) an Interim Reregistration Eligibility Decision (IRED) document setting out the concerns of their review. These concerns relate to the possibility of fenamiphos leaching into drinking water sources from shallow water tables and vulnerable soils, to the safety of workers who mix, load and/or apply fenamiphos and to the risks associated with exposure of terrestrial, aquatic and endangered species to fenamiphos.

After releasing the IRED, the US EPA announced (27 September 2002) the voluntary cancellation of registration of all registered products containing fenamiphos, effective 31 May 2007. This action was apparently the result of a decision of the registrant to withdraw from the market, rather than meet the data requirements of the IRED.

10 NEXT STAGES IN THE REVIEW

The review will now commence and deal with the matters outlined in this scope document.

Interested parties are invited to provide information or data relevant to the issues raised in this scope document. These must reach the APVMA by no later than ***24 June 2003***. Submissions can be sent either by email to chemrev@apvma.gov.au or by mail to:

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10.1 Announcement of the review

The availability of the review scope document coincides with the APVMA's formal announcement of the review. Registrants have been separately advised of their responsibilities as part of this review.

10.2 Data assessment

Environment Australia, the Therapeutic Goods Administration, the National Occupational Health and Safety Commission and the APVMA will conduct the technical assessment of data submitted for the review of fenamiphos. These agencies will advise the APVMA regarding the concerns raised in Sections 5, 6, 7 and 8.

The data might lead agencies that provide expert advice to the APVMA to consider setting appropriate public health standards, which in this case might involve:

- the TGA revising the Acceptable Daily Intake (ADI);
- the NHMRC[1] revising the drinking water standard;
- the TGA establishing an acute reference dose (ARfD); and
- the NDPSC[2] revising the existing poisons schedule.

The APVMA will have regard to the appropriate public health standards in its reconsideration of approvals and registrations.

Depending on the findings of the technical assessment, a review can result in one of three broad outcomes.

- The APVMA is satisfied that active constituents and products containing fenamiphos continue to meet the conditions to which registration or approval are currently subject and confirms the registration and approvals; or
- The APVMA is satisfied that the conditions to which the registration or approval is currently subject can be varied in such a way that the requirements for continued registration or approval will be complied with, and varies the conditions of approval or registration; or
- The APVMA is not satisfied that the conditions continue to be met and suspends or cancels the registration or approvals.

10.3 Consultation throughout review process

From initiation of the review through to the implementation of the review outcomes, the APVMA will consult with relevant stakeholders and interested parties. Prior to finalisation of any report, comments from key stakeholders and the public will be sought.

The draft of the review summary along with proposed recommendations is intended to be made available to the stakeholders and public through the APVMA website or direct communication. A period will be allowed for the stakeholders and the public to comment on the draft.

[1] National Health and Medical Research Committee (NHMRC)
[2] National Drugs and Poisons Scheduling Committee (NDPSC)

The availability of both draft and final reports will be announced extensively through the media. Major stakeholders will be approached directly and all reports will be made available on the APVMA website.

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