



Australian Government  
Australian Pesticides and  
Veterinary Medicines Authority

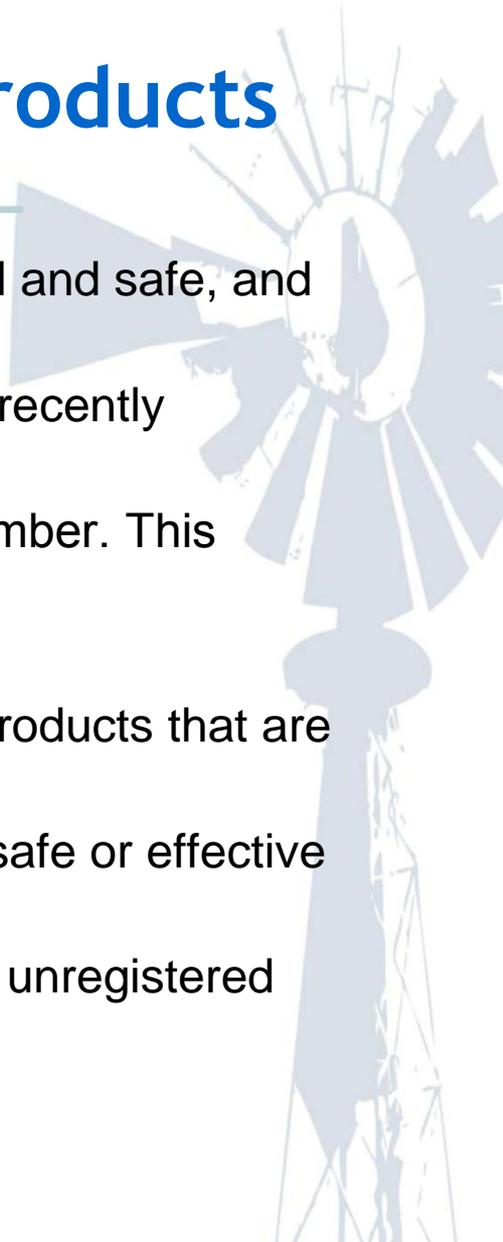
# Fenthion & Dimethoate Reviews : An overview



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**APVMA Chemical Review Section**

**April 2010**

# Only use registered chemical products



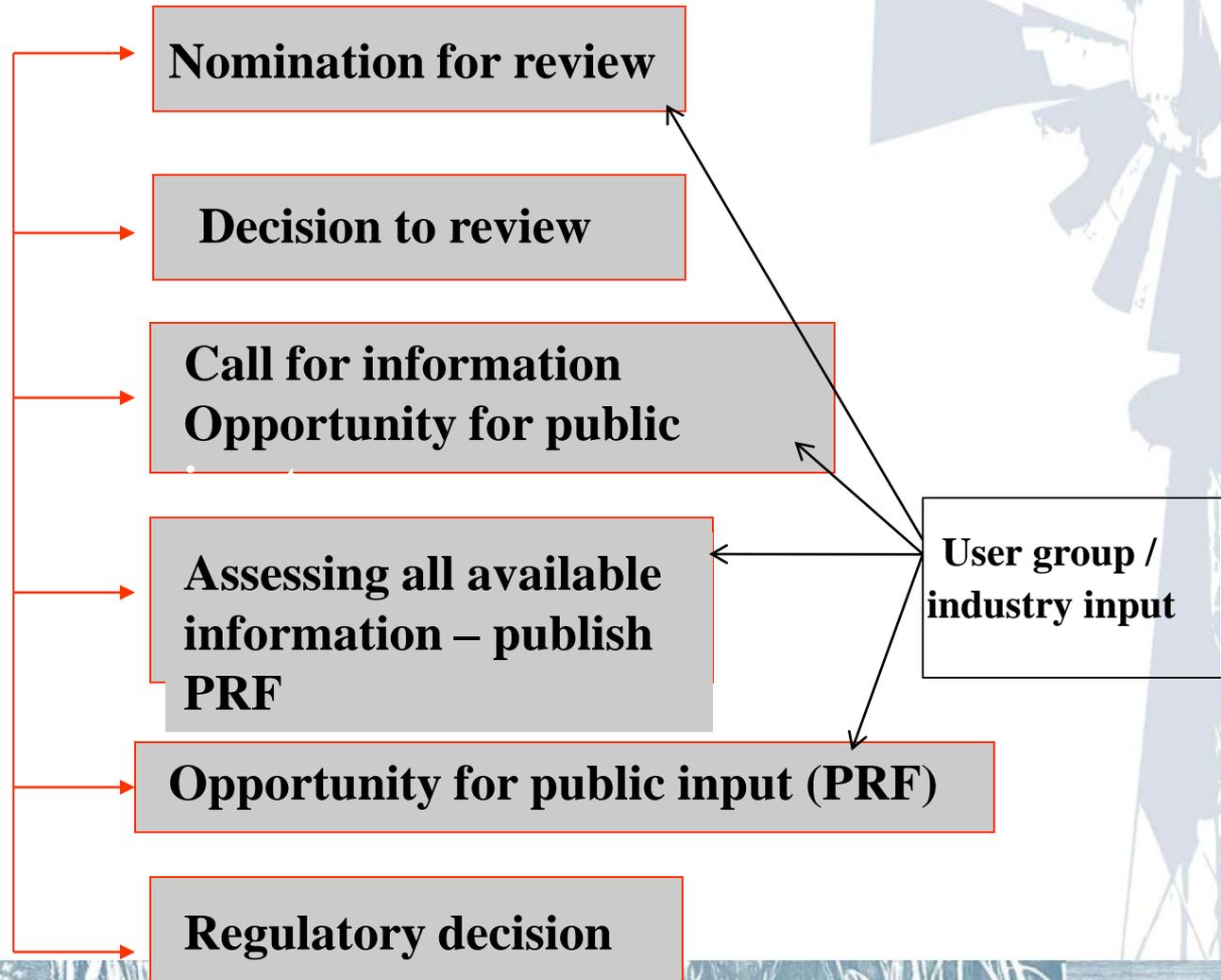
- You need to know that what you buy is tested, approved and safe, and does the job.
- Read the labels of any farm chemicals you buy or have recently bought.
- Make sure the label contains an “APVMA” or “NRA” number. This shows the product is registered.
- Or check the APVMA website (PUBCRIS) or Infopest
- There are people around who may try to sell chemical products that are illegally imported and unregistered for use in Australia.
- With these, you have no guarantee that they are either safe or effective for use in Australian conditions.
- The APVMA Compliance section investigates reports of unregistered farm chemicals being offered for sale

# *What does the APVMA do?*

- Approves active constituents
- Registers products
- Approves product labels
- Issues permits
- Reviews registered chemicals
- Considers **adverse experiences**
- Regulates chemical products up to the point of **retail sale.**  
**APVMA Compliance section.**



# *APVMA Chemical Review Process*



# Chemicals under review - current reviews

2,4-D

Fenamiphos

Omethoate

Fenitrothion

Azinphos-methyl

Fenthion

Paraquat

Fipronil

Parathion-methyl

Carbaryl

Polihexanide

Carbendazim

Macrolide antibiotics

Procymidone

Chlorfenvinphos

Maldison

Propetamphos

Chlorpyrifos

(Malathion)

Methamidophos

Sheep

Diquat

Methidathion

Ectoparasiticides

Diuron

Methiocarb

Temephos

Diazinon

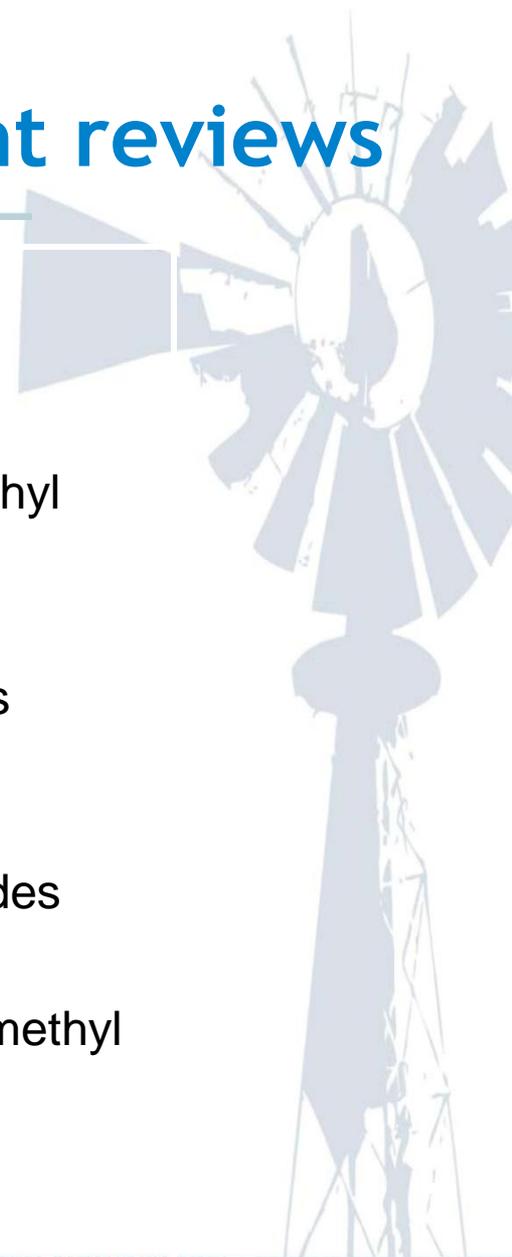
Molinate

Thiophanate-methyl

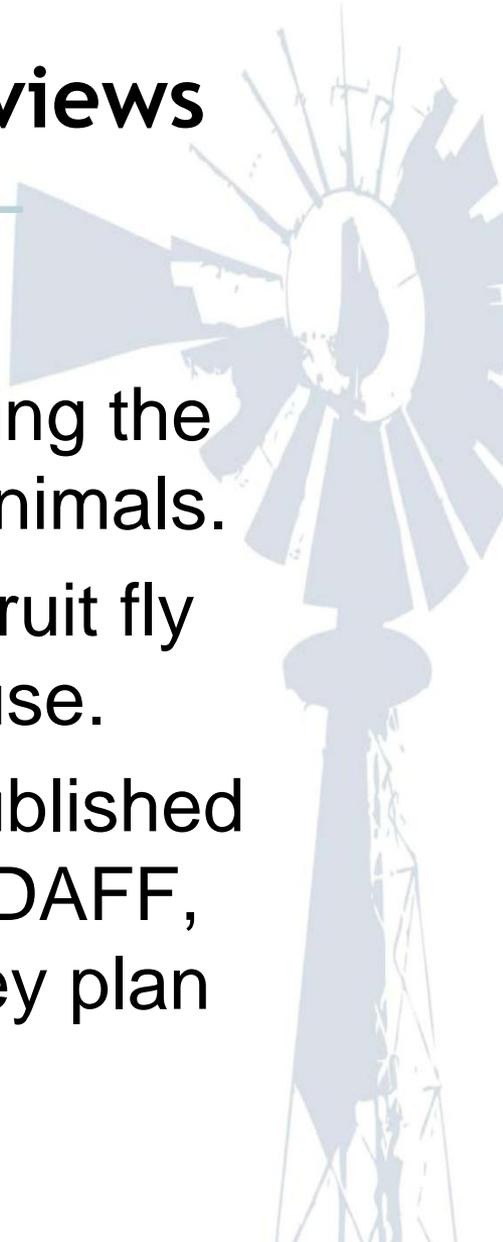
Dichlorvos

Dimethoate

Neomycin



# The Fenthion & Dimethoate Reviews

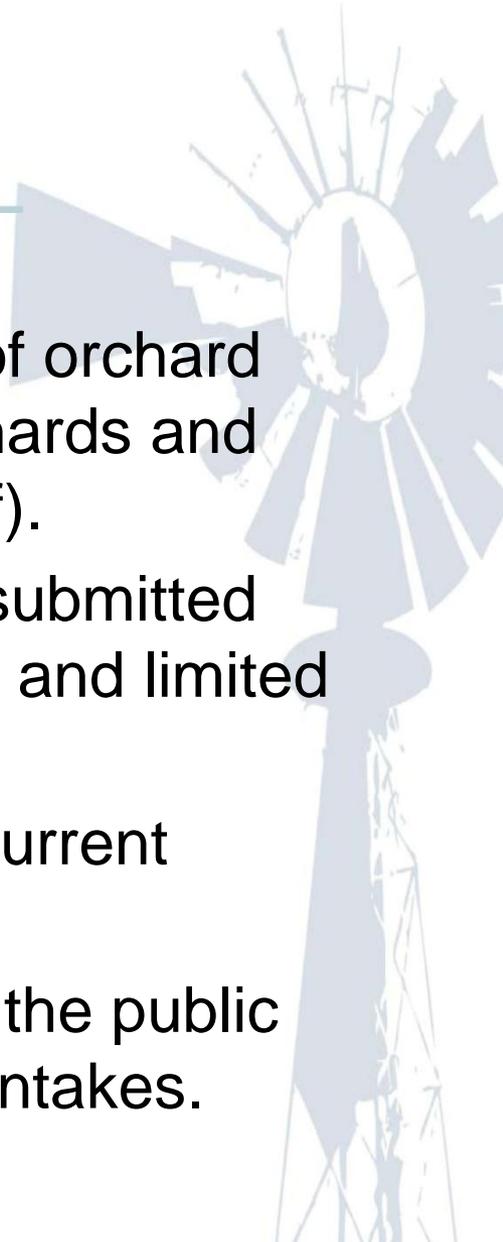


- Fenthion and dimethoate are organophosphate insecticides – affecting the nervous system of insects and other animals.
- Separate reviews – similar impact on fruit fly control and trade of any restriction of use.
- Preliminary Review Findings will be published next. The APVMA is cooperating with DAFF, States/Territories and industries as they plan their response to these reviews.

# Fenthion Review Update

- All aspects of the chemical; toxicology and OH&S (occupational health and safety), residues, trade and environment
- Divided into Non-Food uses (Part 1) and Food uses (Part 2). Part 1 close to finalisation
- The toxicology assessment is complete. OH&S, residues and environmental assessments for Food Uses are underway
- The next stage is publication of preliminary review findings followed by a period of public comment

# Fenthion Review Update



- Concerns with the environmental impact of orchard uses of fenthion (exposure of birds in orchards and aquatic animals via spray drift and run-off).
- Residue assessment found that the data submitted was older (not meeting current standards) and limited to few crops.
- More data is being generated to support current uses. This is expected in May 2010.
- Once received it will be assessed against the public health standards using estimated dietary intakes.

# Dimethoate Review Update

- Dimethoate Review is considering residues, trade, toxicology and OH&S (Human Health) . It commenced April 2004.
- Toxicological and OH&S assessments underway
- Residues and trade assessments commenced
- Similar residue 'gaps' been identified. Trial data due for submission to APVMA in May 2010
- After assessments are complete then preliminary review findings will be published.

# Possible outcomes of a review



- **Affirm** the products as safe for use
- **Vary the conditions** under which products may be used
- **Vary label** instructions and safety directions
- **Cancel** some or all uses
- **Cancel active** constituent approval (includes all product registrations)
- **Interim actions** such as suspension (with new instructions for use).

# Review Legislation

- Section 34 of the AgVet Code Act (1994)\*
- Can only allow continued use if the APVMA is satisfied that it:
  - 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*
  - Would not be likely to have an effect that is harmful to **human beings**; *and*
  - Would not be likely to have an unintended effect that is harmful to **plants, animals or things or to the environment**; *and*
  - Would not unduly prejudice **trade or commerce** between Australia and places outside Australia; *and*
  - Would be **effective** according to criteria determined by the APVMA.

\* S.34, (1)(a)(i), (ii), (iii) and (iv) and (b)



## Agricultural and Veterinary Chemicals Code Act 1994

Act No. 47 of 1994 as amended

This compilation was prepared on 6 December 2004 taking into account amendments up to Act No. 120 of 2004

[Note: The amendments made by Schedule 2 (items 1 and 3–21) of the *US Free Trade Agreement Implementation Act 2004* (Act No. 120 of 2004) are not in force. These provisions will commence on 1 January 2005.

The amendments made by the *US Free Trade Agreement Implementation Act 2004* (Act No. 120 of 2004) have been incorporated in this compilation for the convenience of users.]

The operation of amendments that have been incorporated may be affected by application provisions that are set out in the Notes section

Prepared by the Office of Legislative Drafting and Publishing, Attorney-General's Department, Canberra

# Human Health

- The Office of Chemical Safety and Environmental Health, (Department of Health and Ageing)

## Toxicological Assessment

- Determines if a **chemical** is likely to have **any** adverse health effects in humans. May use animal studies.
- Sets health standards for continual exposure...  
“Acceptable Daily Intake (ADI)”
- and single exposures “Acute Reference Dose (ARfD)”  
(if a single exposure can cause harm)
- Uses safety factors of 100x or greater.

## Occupational Health & Safety Assessment

- Likely exposure of users compared to these standards.  
May require Personal Protective Equipment (PPE).

# Residues assessment

- Likely residues in foods are compared to national surveys of average long-term intake and maximum likely short-term intake of foods.
- The amount of chemical in the diet must not exceed the health standards for long-term (ADI) and short-term intake (ARfD).
- The Maximum Residue levels are set based on the results of trials using Good Agricultural Practice.
- They are then compared to the health standards and food intake to see if that use is acceptable.

# Spray Drift - Changes to Labels

- APVMA has a website specifically dedicated to spray drift issues at [http://www.apvma.gov.au/use\\_safely/spray\\_drift/index.php](http://www.apvma.gov.au/use_safely/spray_drift/index.php)
- In 2008 the APVMA published a policy document setting out how spray drift regulation would be done. These Operating Principles were developed over a period of five years, four rounds of public consultation and two national forums.
- The new spray drift regulatory framework is currently being implemented on all new products. A priority list of older chemicals that will be assessed for spray drift risk has also been published.
- Based on the data available for environmental, crop or human health risks the labels for products will include 'no spray' **downwind** buffer zones, recommendation for spray droplet types ( coarse, medium or fine) and other restrictions.
- Spraying in still air or nil wind is NOT recommended.

# Adverse Experience Reporting Program (AERP)

- The APVMA investigates reports of adverse experiences with agricultural and veterinary chemical products in Australia.
- An adverse experience is an unintended or unexpected effect of a product when used according to the label instructions. This includes impacts on human beings, animals and crops, damage to the environment, or lack of efficacy.
- Written, emailed, telephone or on-line reports are accepted  
[http://www.apvma.gov.au/use\\_safely/index.php](http://www.apvma.gov.au/use_safely/index.php)

# APVMA's Website - Technical and Regulatory Information

- APVMA's website is at <http://www.apvma.gov.au>
- Contains information about agricultural and veterinary chemicals in Australia, including:-
  - a list of approved active constituents (ACs);
  - a list of all products formulated from those ACs and copies of their labels;
  - summary information about new chemicals registered in Australia;
  - List of Maximum Residue Limits (MRLs);
  - information about older chemicals which have been reviewed, are under review, or are to be reviewed.
- Other information.
  - The APVMA's risk assessment framework for spray drift - *APVMA Operating Principles in Relation to Spray Drift Risk*.
  - Contacts for AERP and Compliance
  - 'Our View', 'Community Questions' and 'Regulatory Information' (on Home page).



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REGULATORY NEWS



12 APRIL 2010 Chemical regulator suspends agricultural chemical because of dioxin contamination

14 APRIL 2010 APVMA Online Services unavailable today, 5:00 - 7:00pm

17 MARCH 2010 Media Release: Chemical Regulator Snares Noncompliant Paint Company

9 MARCH 2010 Canadian regulator re-registers simazine after evaluation

26 FEBRUARY 2010 New registration application and label requirements in relation to spray drift management

See also: Media Releases | View more News...

OUR VIEW



22 MARCH 2010 APVMA Response to 60 Minutes program

9 MARCH 2010 APVMA to have atrazine studies formally assessed

View more Topics...

COMMUNITY QUESTIONS

- Why are endosulfan and carbendazim still registered in Australia?
What is the APVMA doing about the incidents at the Sunland Fish Hatchery in Noosa?
Are Australian fruit and vegetables safe to eat?
Why didn't the APVMA appear on the recent 60 Minutes program?

About Community Questions...

I want to...

- Find out about the NRS review
Register for the Veterinary Medicines Symposium
Submit an EARS application
Report an adverse experience
See chemicals under review
Pay fees or levies

Chemicals in the news

- Atrazine
Carbendazim
Endosulfan

Search registered Chemical products (PUBCRIS)

Registration Requirements and Guidelines (MORAG)

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