



INFORMATION SHEET

Australian Pesticides & Veterinary Medicines Authority

Does the use of endosulfan interest you?

Yes! Then have your say about the future availability and approved uses of this chemical.

The APVMA has conducted an extensive review of the registration and approval of products containing endosulfan. The APVMA is keen to hear from affected producer industries to help it confirm whether potential residue risks associated with the use of endosulfan in cotton and other crops can be successfully managed, before making a final regulatory decision about the future availability and use of endosulfan.

What is endosulfan and what is it used for?

Endosulfan is a broad-spectrum organochlorine insecticide/acaricide that is registered in Australia for control of a large variety of insects and mites in horticultural and agricultural crops including cotton, cereals, oilseeds, fruit, vegetables and other crops. It has been widely used in Australia for over 35 years.

Why has the APVMA reviewed endosulfan?

The APVMA has reviewed the registration of endosulfan because of concerns relating to health, environment and residues in commodities and trade.

The APVMA has released a draft review report outlining the key issues influencing the continued use of endosulfan along with a number of other recommendations. The APVMA is now calling for producer industry and other input to help it determine the future uses of endosulfan.

How was the review conducted?

In November 1995, the APVMA announced its decision to review the registration of endosulfan. An interim report of this review was released in 1998.

During the period 1998 to 2001, the APVMA implemented a range of changes to the registrations and label approvals of endosulfan products. These changes were implemented to address risks associated with protection of the environment, worker safety and residues in commodities. Some of the principal changes included:

- declaring endosulfan products to be restricted chemical products;
- requiring users of endosulfan to undertake specified training;
- restricting the number of applications for endosulfan per season.

Subsequently, following reports of endosulfan residues in beef as a result of spray drift, the APVMA imposed mandatory buffer zones, required neighbourhood notification before application to cotton, and ultimately cancelled the registration of ultra-low-volume endosulfan products.

Further action by the APVMA in 2002 resulted in additional restrictions on the use of endosulfan products. These were given effect by suspending product registrations and label approvals, and issuing new instructions for the supply and use of the suspended products. These instructions included prohibited crop uses, some new withholding periods and numerous livestock feeding restraints. The suspensions are in place until 31 December 2004.

During the review, the APVMA also sought to investigate the potential for endosulfan to behave as an endocrine disruptor.

In undertaking the review the APVMA has received information from a number of sources including data packages submitted by registrants, submissions received from product users and the general public, published literature and international regulatory reports. The APVMA has consulted extensively with the registrants, representatives of affected industries and State environment and agriculture departments throughout the review. The APVMA has also kept abreast of approaches being taken by regulatory authorities overseas.

As part of the review the APVMA received advice from the Office of Chemical Safety in the Department of Health and Ageing, the Department of Environment and Heritage, and the National Occupational Health and Safety Commission.

What does the APVMA propose to do about products containing endosulfan?

The APVMA has completed an assessment of all the available information relating to the registration of endosulfan. Based on the review of the information, the APVMA has proposed a number of recommendations relating to the future use of endosulfan. Where data has been supplied that supports ongoing use a use will be retained. In instances where no data has been supplied to support ongoing use, uses will be deleted.

Consistent with the reasons for reviewing endosulfan, the findings of the review can be divided between the following headings.

- Health;
- Environment; and
- Residues

Health

Evaluation of the available occupational health and safety data found all registered nursery, orchard and broadacre uses to be within acceptable occupational exposure safety margins provided specified re-entry periods and new requirements for personal protective equipment (PPE) were observed. As a result, these uses will continue to be permitted conditional upon product

labels being amended to reflect these safety directions and re-entry periods.

An assessment of endosulfan toxicological data found that the endocrine disrupting potential of endosulfan is not a significant risk to public health under the existing management controls and health standards.

Environment

Previous assessments of endosulfan noted relatively high levels of endosulfan contamination of rivers in regions of intensive endosulfan use, such as cotton growing areas. However, subsequent environmental monitoring has shown a significant reduction since 1999. These results demonstrate that measures put in place by the APVMA and the cotton industry, along with other factors such as the introduction of genetically modified (insect resistant) cotton, have been effective in reducing endosulfan contamination.

Residues

The findings of the residues evaluation are that certain uses of endosulfan may result in residues that are harmful to human beings (through excessive dietary exposure to the chemical) or may pose an unacceptable risk to trade for Australian commodities (through the presence of unacceptable residues in produce). This may result in the deletion of some uses for broadacre crops, and uses for some horticulture crops (such as Brussel sprouts, lettuces, silverbeet, spinach, Chinese cabbage and sweetcorn).

A number of broadacre crops that endosulfan is registered for use in are used as livestock feed (eg. cereals and pastures), potentially leading to endosulfan meat residue violations. For those crops grown primarily or substantially for livestock feed it is proposed that some endosulfan uses no longer be permitted, where they present an undue risk to trade.

Future use of endosulfan in cotton.

A key issue from the review is the potential for by-products of cotton (fodder, stubble and trash) that has been treated with endosulfan to be fed to livestock and cause residue violations in the meat. Cotton is not grown primarily for feed purposes. In fact, the feeding of cotton fodder, stubble and trash to livestock is not considered to be good agricultural practice, although it is claimed to occur, particularly in drought conditions.

Cotton production has previously been linked to endosulfan residues in beef, as a result of contaminated feeds, spray drift and other poor management practices. Significant measures have been put in place by the APVMA, the cotton industry and the meat industry to achieve good agricultural practice aimed at, amongst other things, preventing violative endosulfan residues in meat commodities, with a high level of success.

The review proposes that the future use of endosulfan in cotton can only be continued provided the APVMA can be assured that appropriate and effective safeguards can and will be put in place to protect against violative residues in meat.

The APVMA is therefore seeking feedback on whether such safeguards can be implemented and whether they are likely to be effective. If these safeguards are not likely to be effective, the future use of endosulfan on cotton is unlikely to continue.

Are there alternative products to endosulfan?

Alternative products are available for all use patterns, although endosulfan has a number of important advantages in that it is inexpensive, is soft on beneficial insects, and provides a different chemistry useful in resistance management. It is anticipated that increasing use of genetically modified cotton will continue to reduce reliance on pesticides such as endosulfan in the future.

How can I have my say on the recommendations of the review

Before the APVMA makes a final decision about the future availability and use of endosulfan it is seeking industry comment on the draft review report. The APVMA is particularly keen to hear from affected producers as to the impact that approval or not of the use of endosulfan in cotton may have. All comments must be received by 30 July 2004.

A copy of the draft review report and all other documents related to the review of endosulfan can be found on the APVMA website (<http://www.apvma.gov.au>).

Your comments should be forwarded to:

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What is the Australian Pesticides and Veterinary Medicines Authority (APVMA)?

The APVMA is the Australian Government statutory authority responsible for the regulation of pesticides and veterinary medicines up to the point of retail sale.

All pesticides and veterinary medicines must be registered and their labels approved by the APVMA prior to being supplied, sold or used throughout Australia.

Pesticides include products that are used around the home garden and those used for commercial or agricultural purposes.

The APVMA used to be called the National Registration Authority (NRA).

What is product registration?

Registration means that the pesticide or veterinary medicine has been rigorously assessed to ensure that it works, is safe for people, animals and the environment, has been manufactured to appropriate standards and does not pose an unacceptable risk to Australia's trade with other countries.

All registered products have an approved label that includes instructions for correct use and relevant safety information. Only registered products have a distinguishing number on the label APVMA Approval no. xxxxx/ or NRA Approval No. xxxxx/.

What is a chemical review?

The APVMA also has a program for reviewing the registration of older chemicals that are currently on the market. Reviews are undertaken when there is new information that raises concerns about a chemical's ongoing use, suggesting that its registration should be reassessed. This is the process being undertaken for products containing endosulfan.

Reviews can be triggered by new research or other evidence that has raised concerns about one or more of the following:

- the safety of people using the chemical or the product;
- an effect that is harmful to public health;
- an unintended effect that is harmful to animals, plants or to the environment;
- a prejudice to trade or commerce between Australia and places outside Australia;
- whether the product is effective when used as instructed by the label; and
- labels instructions for the safe and effective use of the product.



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Veterinary Medicines Authority

When the APVMA decides to reconsider the registration of a chemical it calls for any relevant new information from registrants and the public; it may also require registrants to conduct new studies. The APVMA then assesses all the information and publishes a review report that details its findings. The assessment also forms the basis for decisions about the future availability of the chemical or how it is used.

There are three possible outcomes from a review:

1. The APVMA is satisfied that the chemicals are safe and effective and chemical use can continue based on existing instructions;
2. The APVMA has identified that some aspect of the chemical or its use may not be safe and therefore makes changes to the conditions of registration and/or the label instructions; or
3. The APVMA is not satisfied that continued use of the chemicals will be safe and effective and suspends or cancels the chemical's registration and/or label approval.

Contacting the APVMA

Want More Information?

If you would like to know more about the APVMA or any of its services please contact us.

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