



## **Chemicals**



## The NRA's role in the regulation of sheep ectoparasiticides

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### Summary

*This paper provides a general overview of the functions of the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) and its role in regulating agricultural and veterinary chemical products in the marketplace. It is one of four NRA papers to be presented at the FLICS conference and is designed to provide background information to the more focussed papers.*

### Keywords

NRA, regulation, sheep ectoparasiticides

### Who is the NRA?

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) operates the Australian system that evaluates, registers and regulates agricultural and veterinary chemicals.

The NRA was established in 1993 by Commonwealth, State and Territory Governments to manage the National Registration Scheme. The Scheme has achieved a consistent, national approach to agricultural and veterinary (agvet) chemical registration, combining the separate schemes previously operating in each of the States. The NRA operates in accordance with the *Agricultural and Veterinary Chemicals (Administration) Act 1992* and the *Agricultural and Veterinary Chemicals Code Act 1994*.

### What does the NRA do?

Through the National Registration Scheme, the NRA regulates agvet chemical products in the marketplace. It does this by assessing their safety and performance, ensuring there is no risk to human, animal or environmental health and that they won't jeopardise trade. If products meet these criteria, then they can be registered for use in Australia.

The NRA also reviews products that have been on the market for many years to ensure that they meet contemporary standards. It manages a national compliance program in partnership with the States and Territories to ensure products and their labels continue to meet the conditions of registration.

### The Registration Program

Before an agricultural or veterinary chemical product can enter the Australian market, it must go through the NRA's rigorous assessment process to ensure that it meets high standards of safety and effectiveness. Any changes to a product that is already on the market must also be referred to the NRA. Under the National Registration Scheme, companies must supply the NRA with extensive data about the product. These are independently evaluated to ensure that the product is safe for people, animals and the environment and that it won't pose any unacceptable risk to trade with other nations. If the product meets the NRA's standards it can be registered for use in Australia.

For specialist advice during the assessment process, the NRA receives input from three Commonwealth Agencies. The Chemicals and Non-prescription Medicines Branch of the Department of Health and Aged Care undertakes detailed assessment of toxicology and human health data. Environment Australia assesses the product's environmental implications. The National Occupational Health and Safety Commission assesses the data relating to occupational health and safety to ensure that risk to chemical users is avoided. Consultation with the States and Territories, other Commonwealth agencies and a range of expert panels or committees provides further advice when required.

A detailed description on the process of how a sheep ectoparasiticide product is registered by the NRA can be found in the paper by Moffatt and Bennet-Jenkins (these proceedings).

The Registration Program also administers the National Permits Scheme. A permit allows a person, under certain circumstances, to possess and use an unapproved active ingredient or unregistered product, or to use a registered product in a way not specified on the label and which would otherwise be illegal. Permits may be granted to exercise control over research chemicals, provide an emergency response to serious disease outbreaks or to approve chemicals for minor uses that do not normally appear on the product label.

### **The Policy and Public Affairs program**

The two key areas of the Policy and Public Affairs program are Chemical Review and Quality Assurance and Compliance. These areas re-assess and monitor products in the marketplace to ensure they meet contemporary standards of safety and effectiveness and to ensure products are supplied and used according to their registration guidelines.

#### ***Chemical Review***

Agricultural and veterinary chemicals are not registered indefinitely. The NRA's Chemical Review team reconsiders the registration of agricultural and veterinary chemicals in the marketplace where potential risks to safety and performance have been identified. Reviews are conducted to ensure that chemicals registered in the past meet today's standards. When the National Registration Scheme started in March 1995, the NRA inherited over 5000 chemical registrations granted under earlier arrangements in Australia's States and Territories. Some of these were issued as far back as the 1950s. Since registration was granted, new scientific data may have been generated that raise potential concerns over the chemical's use. Triggers for a review may include the findings of new research or concerns that have arisen about the use or safety of a particular chemical or product.

Under its legislation the NRA has the power to conduct reviews of registered chemicals. In broad terms, these powers include the authority to reconsider the registration of active ingredients, products and labels, and to require relevant information to be provided. Relevant trial work can be requested to generate results needed for consideration, and additional information can be requested for delivery within specific timeframes. The NRA has the power to suspend or cancel the registration of active ingredients, products and labels.

As a part of each review, a substantial amount of time is made available for public and industry consultation to ensure that the review process is open and transparent. Submissions from farmers, householders, local government authorities, pest controllers and other chemical users help the NRA to construct a picture of chemical use, problems or concerns, and implications if a chemical is to be withdrawn.

The NRA's Chemical Review team makes objective, scientifically-based recommendations about the future registration of chemicals under review. Depending on a review's findings, chemicals (and the products containing them) might be:

- confirmed as safe and appropriate for registered use;
- restricted in use;
- required to be reformulated;
- required to change labelling to limit the situations in which product(s) may be used; or
- suspended, cancelled or withdrawn from the market.

In recent years a number of sheep ectoparasiticides have been the focus of reviews. For more detailed information on these reviews please refer to the paper by Ashton and O'Brien (these proceedings).

### ***Quality Assurance and Compliance***

After registration, products in the marketplace are subject to ongoing scrutiny by the Quality Assurance and Compliance Section through its compliance and surveillance programs, as well as a licensing scheme for manufacturers of veterinary chemical products and an Adverse Experience Reporting Program.

Market place surveillance is undertaken through a risk-based compliance program, which targets the importation and supply of unregistered products and unapproved active constituents. The Compliance Group processes about 400 reports each year relating to the non-compliance of agvet products and labels. Non-compliance includes unapproved labels, deficient formulations, fraudulent applications to the NRA, unlicensed manufacture and supply of date-expired products.

The Compliance program aims to create greater awareness and understanding of the registration and approval processes for agvet chemicals, while at the same time taking more stringent action such as prosecution or recall where there is a high risk to the community, the environment or the integrity of the National Registration Scheme.

The Manufacturers Licensing Scheme ensures that veterinary chemical products are manufactured to a consistently high standard. It does this by requiring Australian manufacturers to be regularly inspected by NRA authorised auditors for compliance with the relevant Code of Good Manufacturing Practice (GMP). Manufacturing premises that comply are licensed, and products can only be made in a licensed or otherwise approved premises. It is an offence under the Agvet Codes to make a veterinary chemical product in unlicensed premises. Overseas manufacturers are required to provide evidence that their products are manufactured to a standard comparable with the Australian Veterinary Code of GMP before the products can be registered in Australia.

The Adverse Experience Reporting Program is a post-registration quality assurance program that requires manufacturers to report any adverse effects of veterinary chemical products. It also enables product users and members of the public to voluntarily notify the NRA of any unexpected adverse effect experienced as a result of using a veterinary chemical product.

### **Conclusion**

The NRA contributes to the ongoing prosperity of Australia's primary production industries by helping to ensure the continuing safety of chemicals to users and the environment.

### **References and where to go for further information**

This paper is one of four NRA papers presented at the FLICS conference. It is designed to provide a very brief overview of the functions of the NRA. The other three NRA papers to be presented are:

Moffatt L. and Bennet-Jenkins E. (2001). The Registration and Label Approval Process for Sheep Ectoparasiticides. (*these proceedings*)

Ashton J. and O'Brien K. (2001). Progress Report on the NRA Review of Sheep Ectoparasiticides and Related Organophosphate Reviews. (*these proceedings*)

Ashton J. and Savage G. (2001). Integrating “Best Practice” Chemicals Use and Residues Management with Regulation – a Challenge for both the Wool Industry and the NRA. (*these proceedings*)

Further information on the NRA can be obtained from the NRA’s website at [www.nra.gov.au](http://www.nra.gov.au)