Progress report on the NRA review of sheep ectoparasiticides and related organophosphate reviews
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Summary
This paper presents a brief outline of the NRA’s chemical review program, the rationale for decisions to conduct reviews, and a brief outline and update of current reviews affecting sheep ectoparasiticide products.

Keywords
NRA, review, sheep ectoparasiticides, organophosphate

Background
The National Registration Authority for Agricultural and Veterinary Chemicals (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 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 (the Agvet Codes). For an overview of the activities of the NRA please refer to the paper by O’Brien (2001).

Before it can approve the use of a chemical, or register an agricultural or veterinary product, the NRA must be satisfied that the criteria specified in the Agvet Codes are met. The criteria specify that the NRA must be satisfied that the use is safe to humans, the environment, treated plants and animals and that the use will not adversely prejudice trade of treated produce. The NRA must by law remain satisfied that any product supplied in Australia meets the criteria set out in the legislation and registrants are required to bring to the NRA’s attention any new information likely to adversely affect the registration status of the product. Through the Chemical Review Program the NRA also responds to concerns raised by users and the community at large, as well as to changing standards.

When warranted, approvals and product registrations are reconsidered. Through its Chemical Review Program the NRA reconsiders the approval of chemicals and the registration status of agricultural and veterinary products in the Australian marketplace. A review can result from concerns raised over the safety of a chemical or to ensure that older chemicals that have been on the market for some time, continue to meet today’s standards.

The review process is an open one involving close consultation with all interested parties. Participants have the opportunity to submit evidence and/or argument in support of their views on a particular chemical. Submissions on issues such as product use practices and chemical adverse effects are invited from industry, government, academic institutions and concerns raised by other interested parties are also considered.

The NRA analyses the data gathered through submissions and conducts an analysis of national and international research. Technical advice is also sought from external agencies such as the Therapeutic Goods Administration (TGA), Environment Australia and the National Occupational Health and Safety Commission.
The NRA’s decision on which chemicals to include in its review program is based on concerns relating to human health, occupational health and safety, trade and environmental effects of the chemicals’ use.

Normal practice in the review process is for a draft report containing the NRA’s findings, conclusions and recommendations to be released for public comment. Interested persons are given a limited timeframe in which to respond. A final report is then prepared drawing on new information and supporting argument received in response to the draft report.

Chemical Review Program

Changes to the status of a registered chemical product or approved label that are imposed by the NRA must be initiated through the review process as described in the legislation. In general reviews are initiated when new information becomes available or when reports suggest chemicals or products are not meeting current standards.

It is important to appreciate that the NRA cannot do anything that it is not empowered to do by either the Agricultural and Veterinary Chemicals (Administration) Act 1992 or the Agvet Codes. Thus while the NRA is empowered by the Agvet Codes to register products once it is satisfied that they meet certain criteria specified in the Agvet Codes, it cannot deregister a product, or impose restricted uses on a product, unless the product has been subject to review and the product has failed to satisfy one or more of the legislative criteria. The NRA has to complete specific legal processes described in the Agvet Codes in reaching decisions, including appeal processes. As a result of the requirements of the program reviews can be lengthy.

The Sheep Ectoparasiticides Review

In 1998 the NRA completed a study of “The Residue Implications of Sheep Ectoparasiticides” (Savage, 1998). This study identified a number of key challenges associated with wool residues, and made a number of recommendations designed to respond to existing concerns about the occupational hazard of wool residues to shearsers and other wool handlers, as well as the environmental impact of wool residues when discharged to the environment in scouring effluent. The report also discussed anticipated trade problems likely to develop as overseas wool processors respond to changing environmental standards.

After considering the information contained in the Savage report, the NRA concluded that a limited review of a wide range of sheep ectoparasiticide products was warranted. This review was initiated in September 1999, and has been specifically targeted towards the concerns discussed in the Savage report.

The NRA’s review of sheep ectoparasiticide is now well underway. Draft component reports from Environment Australia and the National Occupational Health and Safety Commission are likely to be provided to the NRA within the next few months. The NRA will consider these component reports before the NRA releases its draft report for public comment. Specific regulatory outcomes will be developed that will take into consideration the Savage report, additional work undertaken and new chemicals/products/uses approved since the Savage report was published. The NRA’s report will also take into consideration the commitment of registrants and other stakeholders to undertake relevant initiatives and fill data gaps where applicable. If an undertaking is made to provide additional data, interim regulatory outcomes are likely to be applied.
The Diazinon and Chlorfenvinphos Reviews

The chlorfenvinphos review has now been finalised, while the diazinon review is nearing completion. The main proposals and outcomes of these reviews (NRA, 2000a; NRA, 2000b) that have affected or are likely to affect future use of these chemicals on sheep are as follows:

- Chlorfenvinphos sheep jetting products have been withdrawn from use due to occupational health and safety concerns. Chlorfenvinphos remains available for use on sheep as a flystrike/mulesing or wound-dressing product.

- It is proposed to withdraw the use of unstabilised emulsifiable concentrate (EC) diazinon formulations due to the risk of highly toxic breakdown products forming under certain conditions. Most currently registered EC diazinon products used on sheep now contain a stabiliser.

- Hand-jetting applications of diazinon have been identified as an occupational health and safety concern. Further data was provided in response to the public consultation phase of this review and discussion between the NRA and NOHSC is currently underway to define what additional data, if any, is now needed.

- Long wool backline treatment of sheep using diazinon has been identified as an occupational health and safety concern. The draft diazinon report has indicated that additional data will be required to support this use. This outcome may be affected by the sheep ectoparasiticide review.

- Additional OH&S statements to the labels of diazinon products have been proposed that will restrict use of such products if PPE cannot be worn in hot weather. This outcome may also be affected by the sheep ectoparasiticide review.

References


National Registration Authority (2000b). The NRA Review of Diazinon. Existing Chemical Review Program Review Series No 00. National Registration Authority for Agricultural and Veterinary Chemicals
