

## OTHER NOTICES

### APVMA Approach to Products Derived from Neem Tree

Various products derived from the neem tree (*Azadirachta indica*) are supplied and used in Australia for a variety of purposes, including in agriculture and as pesticides. These can take the form of seed, leaf, bark, gum, flowers, fruits presented in an unprocessed state or processed using various methods to produce neem oil, neem cake, neem coir or other. Some neem derived products and/or their stated or intended purpose (claims) of use are captured by the Agricultural and Veterinary Chemicals Code 1994 (Ag Vet Code (1994)) definition of an agricultural chemical product. To this extent, these products are of a direct regulatory interest to the APVMA. For Agvet Code definition of an agricultural chemical product, see the APVMA Website [www.apvma.gov.au](http://www.apvma.gov.au).

This notice outlines the APVMA's approach to neem derived products that are of regulatory interest and the principles guiding that approach.

#### Date of Effect of this Operational Notice: 1 July 2010

Proposed is a tiered approach based on the following guiding principles:

1. The scientific literature indicates Azadirachtin as the main recognised active constituent in neem products.
2. The scientific literature also indicates that for a neem product to have effective pesticidal properties, it must contain the recognised active constituent azadirachtin at a level of 850 ppm or more.
3. The regulatory focus will be on products that contain azadirachtin at 850ppm or more regardless of claims or type/fraction of neem that they comprise.
4. Any products containing azadirachtin at levels below 850 ppm are not considered effective as pesticides. Any claims of a pesticidal nature that are made about these therefore need regulatory scrutiny to check the validity of claims.
5. If such products (ie those containing azadirachtin at levels below 850ppm) make soil ameliorant or fertilizer claims only, (ie makes no direct or indirect claims of pest control) then these products could be considered as being subject to the AgVet Code exemptions available for soil ameliorants and fertilizers.
6. The APVMA reserves the right to consider the specific use pattern/situation of and claims of any 'neem' product that comes to its attention and take action, as it deems necessary.

The table below illustrates the approach, in terms of the product's azadirachtin content, claims made about the product and its registrability.

Fact*/Situation	Claims	Registrability
'neem' tree derived product (of any kind – i.e. seed, oil, cake, leaf, bark, gum, flowers, fruits) being supplied/ proposed for supply/use without registration		
Product contains azadirachtin @ 850ppm or above	Contains claims of interest to the APVMA	Product must be registered
Product contains azadirachtin @ 850ppm or above	Does not contain claims of interest to the APVMA	Product may need to be registered(Needs closer scrutiny to determine if product must be registered)

Fact*/Situation	Claims	Registrability
Product contains azadirachtin at less than 850 ppm	Contains claims of interest to the APVMA	Claims may be questionable(Needs closer scrutiny to check their validity)
Product contains azadirachtin at less than 850 ppm	No claims other than soil- ameliorant and/or fertilizer	Product not registrable. AgVet Code exemption to apply

\* - to be established including by product testing, where necessary.

The APVMA's intention is that this approach will be used initially for a two-year period from the date of the effect of this notice, to test its effectiveness. It is expected that at the end of that period any required further refinement will be made and the contents of the notice as it stands at that time will be included in the APVMA's Manual of Requirements and Guidelines (MORAG) for agricultural chemical products (Ag MORAG).

During this period the proponents of neem derived products that require registration should submit applications for registration to the APVMA. The usual data requirements as specified in the APVMA Guidelines for the Registration of Biological Agricultural Products (Biologicals Guideline) and Ag MORAG will apply to any neem derived product that is registrable.

The APVMA welcomes requests from prospective registrants for pre-registration meetings as a means to seek information regarding specific data requirements for the registration of their products.

If you require further information on registering neem products please contact:

Jay Kottege  
Principal Evaluator  
Pesticides Program  
Australian Pesticides and Veterinary Medicines Authority

T: 02 6210 4759  
E: jay.kottege@apvma.gov.au

The Australian Government has legislation namely, the Agricultural and Veterinary Chemicals Code (1994) in place to see that agricultural chemical products supplied to the marketplace are safe and effective. The supply of an unregistered chemical product is an offence under Section 78 of the Agricultural and Veterinary Chemicals Code (1994).

To report companies supplying or advertising unregistered neem products please utilise the Non-Compliance Report form found at <http://www.apvma.gov.au/compliance/report.php>

Or contact:

Compliance Contact Officer  
Ph: 1300 700 315  
Email: [compliance@apvma.gov.au](mailto:compliance@apvma.gov.au)