



OPERATIONAL NOTICE

Label claims for efficacy against pests and diseases which are exotic to Australia

The APVMA occasionally receives applications for registration of agricultural and veterinary chemical products which have a label claim for efficacy against pests or diseases which are exotic to Australia, or where there have been only very limited incursions of the pests and diseases. Examples of such pests and diseases are foot and mouth disease, avian influenza, rabies, sugarcane smut, citrus canker and fire blight.

In the past, the APVMA has occasionally approved label claims for efficacy against exotic pests and diseases, in some instances with the modifying statement “This pest does not currently occur in Australia.”

From the date of this notice, the APVMA will not grant approval of label claims for efficacy against pests and diseases which are exotic to Australia, for the following reasons:

- granting a label claim of this nature may give the impression that the disease or pest occurs, or is reasonably likely to occur, in Australia. This may prejudice Australia’s international disease-free status and may subsequently also prejudice trade or commerce
- the APVMA has not established data requirements or criteria for efficacy for such exotic pests or diseases
- relevant Australian efficacy data are usually not available.

Incursion of exotic pests and diseases

The APVMA can authorise the use of products to combat incursions of exotic pests and diseases by issue of an emergency use permit. The Agvet Code Regulations define an emergency use as:

“...a use of the product or constituent arising from an emergency in which there is a genuinely believed need for the use of the product or constituent.”

Applicants may submit relevant data under application category 22 for consideration by the APVMA for issue of an emergency use permit. This may be done before such incursions occur so that the APVMA has finalised relevant assessments in advance of any need to issue an emergency use permit. A permit can then quickly be issued should an incursion of the exotic pest or disease occur.

‘Shelf’ product registrations or approved labels

The APVMA will consider allowing label claims for efficacy against exotic pests and diseases by the registration of ‘shelf’ products, or approval of labels which will be supplied and used only under official direction in the event of an incursion of an exotic pest or disease. The product must then be used only in accordance with the approved label directions/instructions or as specified under official direction.

Multivalent or multifunctional vaccines which contain an antigen for a disease organism which is exotic to Australia

There is a trend in the animal health industry towards producing multivalent or multifunctional vaccines at global production facilities to suit global markets. For this reason, an applicant may wish to register an animal vaccine manufactured overseas which contains an antigen for a disease organism which is exotic to Australia.

The APVMA will consider granting registration of products of this nature provided that:

- the disease is not one against which AQIS normally takes preventive quarantine action, or is otherwise not a biosecurity risk to Australia
- the product label does not make specific efficacy claims with respect to the disease antigen which is exotic to Australia.

The APVMA will consider each application on its merits.

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APVMA January 2008