Registration by reference to APVMA registration

Registration by reference is part of an ongoing work programme with the Australian Pesticides and Veterinary Medicines Authority (APVMA) to align regulatory standards and authorisation requirements between Australia and New Zealand.

It is a new pathway for registering veterinary medicines in New Zealand for use on non food-producing animals. (This includes products for cats, dogs, reptiles, pigeons, aviary birds, game birds, aquaria animals, mustelids, lagomorphs and rodents.) Such a product registered in Australia can be submitted for registration in New Zealand through this registration by reference pathway. Veterinary medicines submitted for registration by reference must be identical to the APVMA registered product, including the trade name. This means the product must be manufactured as approved by APVMA.

Registration by reference should reduce the time needed to process applications and costs associated with registration in New Zealand. This could potentially encourage a greater range of products to be registered in the New Zealand market, particularly for products with a limited demand, where costs of registration may have acted as a deterrent.

This is not a mutual recognition initiative. APVMA assessments will be used by MAF as the baseline for considering applications for registration, but the reverse arrangement has not been made. Differences in environment and production systems, as well as differing use patterns for agricultural compounds, make the mutual recognition of every regulatory decision in the two countries difficult.

ACVM registration by reference to APVMA registration: ACVM Information Requirements 18 (63 KB PDF)

ACVM registration by reference to APVMA registration: ACVM Operational Interpretation 192 (79 KB PDF)

Label claim to control PSA in kiwifruit

If you wish to register a new trade name product (TNP) or request a variation to an already registered product with a label claim for PSA control in kiwifruit, the following should help to clarify information requirements. This advice is in addition to the normal information we expect for any application for registration or variation to an existing registration. Therefore, read this paper in conjunction with the ACVM Registration Information Requirements for Agricultural Chemicals (link below).

Efficacy and crop safety data

Any person who wishes to sell or promote a TNP with a label claim for control of PSA in kiwifruit would require efficacy and crop safety data for this claim in addition to other information requirements. This position was taken after discussion within MAF and taking into consideration the requirements in the document Risk Assessment under the ACVM
Act (link below), in particular the risk thresholds and criteria for the agricultural security risk.

For a number of products, efficacy information immediately available to support a claim for PSA control in kiwifruit is limited. Therefore, to facilitate claims, we have introduced a flexible approach to the information requirements on efficacy and crop safety. This flexibility means a PSA claim will be recognised under one of the three categories outlined below.

Full claim
Our expectation is that efficacy data should be collated from New Zealand field trial work that shows the TNP provides a level of PSA control that is commercially acceptable. We appreciate that currently there are no commercial standards for comparison purposes, so there will be a higher level of subjectivity than usual on what the industry would consider commercially acceptable level of control. The public information provided in the delegate decision (on the public register) will provide information for users.

In the absence of data from New Zealand generated field efficacy trial work, relevant overseas efficacy data would be considered on the basis that:

- the disease is the same as in New Zealand and its epidemiology is similar;
- climate and environmental conditions are similar to New Zealand;
- grower cultural practices are similar;
- the use pattern (for example, application rates and timing) is similar to that proposed in New Zealand.

However, note that overseas efficacy data are normally considered supplementary to support data from New Zealand efficacy trials. You would have to make a strong technical case to support overseas efficacy data for a full label claim.

Limited claim
Generation of efficacy data from New Zealand field trial work will take time. In the intervening period, there is a need to have information out in the marketplace to indicate which TNPs offer some degree of activity against PSA. One of the best sources of this is information on the label, but we will consider other methods of communication to users.

In this instance, we will consider a lesser amount of efficacy data to support limited label claims. This is with the expectation that further efficacy data will be submitted at a later stage to support either a full label claim or “aid in the control” claims for the TNP.

Under this scenario we will consider efficacy data from:

- laboratory and/or glasshouse trials undertaken in New Zealand; and/or
- relevant overseas trial work.

Aid in the control claim
There could be TNPs that provide a level of control which is less than what the industry would normally consider commercially acceptable. In the past, the ACVM Group has not generally accepted these claims. However, in the absence of other products with full claims we consider that these are likely to be of interest to the growers.
This claim differs from a limited claim (mentioned above) in that the efficacy data to support such a claim is complete but indicates the TNP is only partially effective against PSA. The type of efficacy data required would be similar to that required for a full claim (mentioned above).

Note that limited claims and “aid in the control” claims are likely to have conditions on registration relating to the submission of extra data or information to assist in the future review of the product and its claims.

**Crop safety information requirements**

Any efficacy trials undertaken, regardless of the type of claim, should include a crop safety component. This needs to be included because crop damage caused by the product may have a significant adverse impact on kiwifruit that is already under stress from PSA.

[ACVM registration information requirements for agricultural chemicals in New Zealand: ACVM Information Requirements 2](#) (163 KB PDF)

[Risk assessment under the ACVM Act](#) (157 KB PDF)

**Exempt or not exempt?**

**Review of class determination welfare thresholds for products exempt from registration**

We have reviewed our policy for determining if veterinary medicines and oral nutritional compounds (ONCs) require registration, based on claims made about the product. The review has resulted in some minor policy changes that may affect the determination of some products.

These changes relate to interpretation of claims that may have previously been determined to be for the treatment or prevention of diseases characterised by moderate pain and distress in animals. This interpretation resulted in a determination that the product was not exempt from registration under the ACVM Act.

Changes are in the following areas:

- If there is a clear nutritional context and the product is not actually claiming to treat a disease, an exempt from registration determination is likely to be made. Claims for treatment of painful conditions such as arthritis will not be acceptable for an exempt determination, but a nutritional claim that states a food is an appropriate choice for a dog with arthritis may be. (For example: “Food suitable for dogs with reduced joint flexibility. Provides nutrients for joint health and aids maintenance of a healthy weight”.)

- For conditions that legitimately have minor forms that are unlikely to escalate rapidly into a condition of moderate pain or distress, then the determination may be exempt from registration. The description of the condition will need to make it readily apparent that the product is only for treatment of minor forms of the condition. (For example: “For minor cases of mud fever”.)

- If labels have borderline claims and the distributor cannot readily change the labels, the addition of a suitable disclaimer may be acceptable if the disclaimer alters the claims so that the product now fits an exemption category. (For example, a shampoo with claims for promoting healthy skin and treating mild skin infections would need a disclaimer to the effect of: “Skin infections can rapidly escalate to a severe condition. Seek veterinary advice in severe cases or if the condition fails to respond to treatment”.)
• Flea repellent claims will be considered suitable for exemption provided no claims are made to:
  – treat diseases of pain or distress caused by fleas;
  – control current infestations.

**Regulatory control of animal feeds and dietary supplements**

We have also reviewed the assessment of oral nutritional compounds (ONCs) with respect to class determination requests and regulatory control. As a result, the operational interpretations used in ONC evaluations have been revised. The following policies will now apply to the assessment of ONCs.

**Use of the GRAS list for feed additives**

All applications for registration and requests for class determinations for products that contain feed additives not currently on the GRAS (generally recognised as safe) list will also be considered as requests to add the relevant additive to the list. The additive will be GRAS unless there is evidence against its safety. Approval of the ingredient as a feed additive in the country of origin can be used as evidence of safety even if the full formulation is not available. If the feed additive cannot be uniquely identified, a determination of “not able to be considered GRAS” will be made.

**Safety of nutrients in ONCs**

To ensure the safety of the target animal species, a safety threshold will be established for nutrients where there is a level above which harmful side effects or toxicity can develop. The maximum level of nutrient will be set by either assessment of all available information in the target species or by use of known safety thresholds. These thresholds will be used to evaluate the absolute concentration of the nutrient in the ONC or the total concentration (that is, the sum of unsupplemented nutrient + supplemented nutrient + environmental sources) ingested by the animal, whichever is more applicable.

**ONCs with expressly stated or obviously implied pharmacological claims**

These products are not considered exempt and will still require data to support the stated or implied claims.

**ONCs without expressly stated or obviously implied pharmacological claims**

The Register of Allowable Nutrients with Known Therapeutic Uses in Exempt Oral Nutritional Compounds will no longer be used to determine exemption status. Nutrients formerly included on that register, including those not a part of the animal’s natural diet, will now be evaluated solely on safety and pharmacological thresholds as applicable.

A functional nutrient is a nutrient known to have a pharmacological action when ingested, and inclusion of that nutrient above a certain concentration will result in, or is likely to result in, a pharmacological effect. When it is considered necessary, and when there is robust and specific scientific evidence of the pharmacological effect, a pharmacological threshold will be set for functional nutrients.

A functional nutrient with a set pharmacological threshold can be included in an ONC up to that threshold and its inclusion will still be considered nutritional. As long as no pharmacological claims are expressly stated or obviously implied, a pharmacological claim...
will not be presumed unless the threshold is exceeded. The maximum safe level of the nutrient will still apply and cannot be exceeded.

If no pharmacological threshold has been set for a particular functional nutrient, and an application for registration is submitted with robust technical evidence to support a pharmacological claim, that data can be used to set a pharmacological threshold applicable to all products containing that nutrient. Again, the safety threshold for the nutrient cannot be exceeded.

**Currently registered ONCs**

Some ONCs currently registered, especially those products that required registration because they contain ingredients above acceptable levels listed on the register, may now be considered exempt from registration. If you are a registrant of these products, you may request re-evaluation to determine if your products are eligible for cancellation of registration. Otherwise, ONCs will be re-evaluated as they are submitted for registration renewal and their registrations will be cancelled if applicable.

**Avoiding rejection of applications at pre-screen**

We continue to have applications that are not accepted at pre-screen. You can often avoid rejection if you take care with some simple aspects. For example:

- Submit a cover letter that clearly details the applications you are submitting and lists the data you have enclosed.
- Fully complete the correct application form.
- Supply all necessary data (for Smart Tracks, pay particular attention to section 6).
- Ensure that there are no conflict of interest issues in relation to the data assessor you use.
- Address all non-conformances raised during data assessment.

**Sterility testing**

Sterility of sterile products must be tested at the end of the shelf life. If you apply for an extension of the currently approved shelf life for a sterile product, sterility is one of the parameters that must be tested at the end of the new shelf life you are requesting.

**Revised information requirements**

**Agricultural chemicals**

Information requirements for registered agricultural chemicals have been updated and the revised document is available on the website now. The revision is minor—the new version includes a section on resistance statements.

[ACVM registration information requirements for agricultural chemicals in New Zealand: ACVM Information Requirements 2](#) (163 KB PDF)

**Labelling requirements for veterinary medicines**

The labelling guide for registered veterinary medicines has also been updated and is available on the website. Unlike the previous version, the updated version excludes
information relating to advertising. (This will be covered in a separate document to be published soon.)

Some of the other changes in the new version are:

- required regulatory statements covering compliance by the user;
- statement relating to restricted veterinary medicines (RVMs), which replaces the prescription animal remedy statement;
- information that dose/volume tables for sheep and cattle anthelmintics should start from 15kg and 50kg bodyweight, respectively;
- statements for anthelmintic products intended for horses;
- information on APVMA harmonised labels.

ACVM labelling requirements for veterinary medicines requiring registration: ACVM Information Requirements 16 (113 KB PDF)

Staff update

New manager appointed
We are happy to announce that Glen Bradbury, who used to be with the Production, Processing and Sales side of the Approvals and ACVM Group, has been appointed Manager in the Programmes and Appraisals area. He will take up his new position at the end of May and will introduce himself in the next issue of News and Views.

Farewell to veterinary adviser
Lucy Johnston (adviser, veterinary medicines) is leaving us at the end of the month to work with MAF Animal Imports. Her new work will involve Import Health Standards and issuing clearances for animals and products into New Zealand under the Biosecurity Act. Lucy has been with us for several years and has been a valuable member of the ACVM Group. We wish her well and look forward to continuing to work with her in her new role.

Mini OE coming up
Approvals Operations Manager Maree Zinzley will be away from 27 May-15 July. While she is enjoying the European summer, Linley Thorburn will oversee the Operations area. You can contact Linley by email (linley.thorburn@maf.govt.nz).

New postal and courier delivery addresses
By the time you read this issue of News and Views, we will have moved to the MAF head office. This does not affect our telephone/fax numbers, but it does affect postal and courier delivery addresses.

Our new postal address is PO Box 2526, Wellington, 6140

Courier parcels/items should be delivered to:
Approvals and ACVM Group, Ministry of Agriculture and Forestry
Pastoral House, 25 The Terrace, Wellington
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