

MAF Food Assurance Authority

**Agricultural Compounds and
Veterinary Medicines Group
Operational Policy**

**REGISTRATION / LICENSING
OF
PESTICIDES / ANIMAL REMEDIES**

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Approval

Author: Chris Boland Special Advisor Technical Policy	Quality Manager: Erin Daldry	Business Manager: Allen Bryce National Manager (ACVM Approvals)
Date:	Date:	Date:

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ACVM GROUP OPERATIONAL POLICY - REGISTRATION / LICENSING OF PESTICIDES / ANIMAL REMEDIES

1 BACKGROUND

The purpose of this policy is to establish the decision-making criteria for registering pesticides and licensing animal remedies. The options are to approve or decline an application for registration/licensing. Under certain circumstances a decision cannot be made because further evaluation must be deferred until some specified action is taken. This policy specifies the decision-making criteria for each of the options. The policy must be read in conjunction with the relevant ACVM registration standards, guidelines and information requirement documents.

In all cases the applicant must be kept informed of not only the decision but also the rationale for the decision.

2 DEFINITIONS

Risk areas

Those areas relevant to the regulatory control of pesticides and animal remedies under the Animal Remedies Act 1967 and the Pesticides Act 1979 respectively. They are risks to:

- trade in primary produce;
- public health (of both the user of products and the consumer of treated produce);
- animal welfare;
- agricultural security; and
- the environment in general.

3 POLICY

The prescreening process identifies obvious deficiencies in applications and these are returned to the applicant with advice on the deficiencies. No assessment of the information is carried out at the prescreening stage.

Hazard assessment should be done within the context of existing policy and the guidelines for hazard analysis. Decisions in regard to registration/licensing of products will be based on a consistent application of the following rules.

3.1 Approval of registration/licensing

- 3.1.1 An application for registration/licensing must be approved when:
- a) the information on the product complies with the ACVM registration standards;
 - b) the information adequately supports registration/licensing (for the uses specified by the applicant); and
 - c) all hazards that could cause harm in any of the relevant risk areas have been addressed and no tolerable endpoints have been exceeded, or conditions can be imposed to manage the hazards; and
 - d) the application complies with all other MAF policies, Board policies and other statutory obligations.
- 3.1.2 Conditions should be imposed on the registration/licence where necessary to ensure that hazards are managed adequately. In all cases the purpose of each condition and the person or group responsible for complying with the condition must be specified.

The following kinds of conditions may have to be imposed.

- a) Conditions specifying the characteristics of the product to ensure that the product is marketed with the same chemistry and manufacturing specifications and for the same uses as are specified in the registration/licence. It is the responsibility of the registrant/licensee to comply with these conditions.
- b) Conditions limiting access to the product to specified individuals or groups to ensure that the product is sold or distributed to specified competent persons. It is the responsibility of seller/distributor of the product to comply with these conditions.
- c) Conditions placing an obligation on specified persons to provide specified information. The responsibility to comply with such conditions will fall on whoever has been specified in the registration/licence.
- d) Conditions limiting use to ensure that the product is used correctly and under the appropriate circumstance. It is the responsibility of the user to comply with these conditions. The conditions may include specifications for appropriate measures to be taken to:
 - properly prescribe the product;
 - avoid unnecessary pain or distress in treated animals;
 - avoid jeopardising pest management programmes or jeopardising national productivity;
 - prevent environmental damage or toxicity to non-target species;
 - avoid harm to the user or handler of the product;
 - prevent breaches in the domestic food residue standards or any relevant specified trade maximum residue limit;
 - comply with any other regulatory obligations.

MAF has the following responsibilities:

- To provide the registration standards and set tolerable endpoints where possible. These will be reviewed regularly and adjusted if necessary.
- Review and evaluation of applications to register or vary the registration of trade name products.
- Responsibility for agricultural compound groups considered to be candidates for exemption from registration under section 75(a) of the Agricultural Compounds and Veterinary Medicines Act 1997 according to its regulatory control principles.

- 3.1.3 Some conditions imposed on the registration/licence of a product may not have been anticipated by the applicant. The conditions may materially alter the characteristics of the product or place limitations on its use. Where conditions would materially alter the characteristics or uses as specified by applicant, the applicant must be consulted before the registration/licence is approved and given the option of withdrawing the application.

3.2 Declining registration/licensing

- 3.2.1 An application to register/license a product should be declined if:
- a) information on the product does not comply with the ACVM registration standards in a material way that prevents a proper assessment of the hazards posed by the product;
 - b) information does not adequately address all hazards that could cause harm in any of the relevant risk areas, and therefore, is insufficient to support registration/licensing for the uses specified by the applicant;
 - c) information provided indicates that any of the hazards cannot be managed to reduce the risks down to an acceptable level;
 - d) registration/licensing for the use(s) specified by the applicant is incompatible with existing policy; or
 - e) the application does not comply with all other MAF policies or other statutory obligations.
- 3.2.2 The applicant must be advised of the rationale for declining an application. The advice should be comprehensive and in sufficient detail for the applicant to understand the reasons for the decline and, if necessary, address the issues.

3.3 Deferral of further evaluation of an application

- 3.3.1 Evaluation and formulation of recommendations on an application should be deferred if:
- a) clarification of the information provided on any material issues raised in the assessment of the hazards posed by the product is required from the applicant;
 - b) crucial information has not been provided in the application;
 - c) conditions that would have to be imposed would materially alter the characteristics of the product or limit its uses in a way that may not have been anticipated by the applicant (see 3.1.3 above);
 - d) there is any existing directive that requires a decision to be deferred at that time, e.g. a Board-directed moratorium; or
 - e) the existing policy does not provide an adequate context in which to evaluate the product.
- 3.3.2 A deferral of a decision is appropriate if, after discussions with the applicant, it becomes apparent that the applicant already has the information needed to address a particular issue. A decision should not be deferred to allow the applicant to gather more information or to change the characteristics of the product or to specify different uses. These are changes that should be dealt with in a new application.

- 3.3.3 In cases in which clarification is required or missing information must be provided, an applicant should be given 30 working days to provide the information. A request for extension should be accepted for a finite and agreed period of time if, within 30 working days, the applicant requests an extension on the grounds that:
- there is a logistical reason why the information cannot be provided within the 30 working days; or
 - the information must be put into a form that is consistent with ACVM information requirements, and this cannot be done within the 30 working days.
- 3.3.4 If existing policy provides an adequate context in which to assess the hazards posed by a product, the decision to approve or decline must be based on that existing policy.
- 3.3.5 If existing policy has inadequacies, but the inadequacies have not resulted in, or are not expected to result in significant harm or losses, the decision must be based on existing policy. The inadequacies of the policy should be addressed within the ACVM Group's priorities and resources. Once the policy changes have been made, all products affected, including the one that prompted the review of the policy, should be reassessed and registrations/licences adjusted accordingly.
- 3.3.6 If existing policy is inadequate and there is sufficient justification for immediate development of new policy to avoid harm or losses associated with a product, further evaluation of the application on that product should be deferred until the necessary policy can be developed. The registration/licences of other products affected by the policy should be suspended if necessary to avoid harm or losses. Those products should be reassessed in light of the new policy and within the same timeframe as the product that prompted the review of the policy.
- 3.3.7 Whatever the reasons for deferring further evaluation, the applicant must be advised of the action, the reason for taking the action, the likely consequences of the action, and what is expected of the applicant.

4 REFERENCES

ACVM – Registration Standards and Guidelines
Animal Remedies Board and Pesticides Board policies
ACVM Operational Policy on Operational Definitions of Agricultural Compounds and Prescribed Risk Areas