Provisional Registration in New Zealand

ACVM Information Requirements No 4

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WEBSITE

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1 Introduction

The purpose of provisional registration**,** which is required under section 27 of the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act), is to enable an applicant to carry out trial work with a trade name product in order to obtain:

- further information (eg efficacy, safety, residue trials) on that product and to determine whether it should be registered in New Zealand, or
- information other than that required for registration of the product in New Zealand, ie general research on the product or trials required for registration of the product in another country.

Provisional registration is necessary only for trial work on trade name products that are agricultural compounds that are (or intended to be) identified and packaged under a trade name for a specified use or uses. The characteristics of a trade name product are:

- it is in the formulation (or not materially different from the formulation) that will be specified in an application to register
- it has or is intended to have a specified trade name under which it will be marketed
- it is packaged or has (or will have) packaging specifications for marketing in New Zealand.

Provisional registration is **not** required where:

- the substances being used in the trials do not have the characteristics of a trade name product, or
- the trade name products being used are registered in New Zealand and they are being used in a manner that is consistent with the conditions of registration.

The information required by the ACVM Group in this document is compulsory in all cases where a provisional registration is sought.

Applicants should note that they are responsible for providing all information required by the ACVM Group to make a decision on the application. If applications do not contain the required information the ACVM Group will either decline the application or impose conditions to address the uncertainty created by the lack of information. If further advice is required, applicants are advised to contract the services of an appropriate consultant prior to submitting the application.

1.1 Scope

This document must be followed by all persons applying to provisionally register a designated or trade name product or a product characterised as an end use formulation where experimental animals or plants are to be sold and have the potential to enter the food chain.

This document provides specifications for:

- general requirements
- documentation and fees
- identification of the investigational product
- security
- approval for sale of treated produce
- variations to terms and conditions of a provisional registration.

1.2 Definitions and abbreviations

Definitions and abbreviations in the Approvals and ACVM Group Glossary apply.

1.3 References

ACVM Information Requirements for Research Approval

ACVM Registration Information Requirements for Veterinary Medicines in New Zealand

ACVM Registration Information Requirements for Agricultural Chemicals (Plant Compounds) in New Zealand

ACVM Registration Information Requirements for Vertebrate Toxic Agents in New Zealand

ACVM Registration Standard and Guideline for Determination of a Residue Withholding Period for Veterinary Medicines

ACVM Registration Standard for Residue Data

ACVM Registration Guideline for Residue Data: Agricultural Chemicals (Plant Compounds)

2 General

2.1 Relevant documents

This document must be read in conjunction with:

- *ACVM Registration Information Requirements for Veterinary Medicines in New Zealand and/or*
- *ACVM Registration Information Requirements for Vertebrate Toxic Agents in New Zealand and/or*
- *ACVM Registration Information Requirements for Agricultural Chemicals (Plant Compounds) in New Zealand*
- *ACVM Information Requirements for Research Approval*

These documents contain information, including definitions, that applies to both registration and provisional registration.

2.2 Data

Granting of a provisional registration does not indicate acceptance of the data obtained during the studies to support any future application. It is the responsibility of the applicant to ensure that the proposed study is able to support the intended outcome. It should be noted that it is a requirement that studies submitted in support of an application for registration must be undertaken in accordance with the appropriate ACVM standards. Where data have been provided, eg residue data, for a provisional registration that could be used for a future application for registration, cross-referencing may be requested. In that case, reference to the data held under that provisional registration must be made in the application for registration.

2.3 Advertising/Sale

Trade name products or other formulations registered under a provisional registration in New Zealand must not be advertised for sale or sold in New Zealand.

2.4 Animals

All studies involving animals must be conducted in accordance with the Animal Welfare Act 1999, Part 6. Evidence of this will be in the form of an approval from a valid Animal Ethics Committee (AEC), or a

letter stating that in principle the AEC accepts the protocol and will issue approval upon provisional registration being granted by the ACVM Group. **Where AEC approvals are yet to be obtained, a condition may be placed on the provisional registration requiring AEC approvals to be supplied as soon as they are available.**

2.5 Conditions

Conditions detailed on the provisional registration must be given in writing and adhered to by any person using the product to which that document pertains.

2.6 Approval for sale

Treated animals and plants or their produce must not be sold without an approval for sale of treated produce as detailed in section 4. For vertebrate toxic agents, carcases of treated species must not enter the food chain. In addition, see section 5 for introduction of non-target animals into the trial site after trial has been completed.

2.7 Time limit

Provisional registrations are issued for a fixed time sufficient only to achieve the purpose of the provisional registration. Requests for extension to that time must be made as an application for a variation to the registration (see section 6).

2.8 Study documentation

Information submitted in support of an application for a provisional registration must form part of the researcher's own study documentation (which will necessarily contain more detail). This study documentation will form the basis of any audit undertaken.

2.9 Approval to import

If the investigational product is to be imported, an ACVM Approval to Import Veterinary Medicines or Agricultural Chemicals (Plant Compounds) or Vertebrate Toxic Agents will be required for clearance of goods by MAF Quarantine Services. The applicant must indicate if they require this document to be sent out with the provisional registration. (See part B, section 9 of the application form.)

3 Information Requirements

3.1 Documentation and fees

The following must be provided:

- a covering letter
- a completed application form (available on the website), signed and dated by the applicant or authorised agent or consultant
- Animals Ethics Committee approval documentation or letter (see point 2.4 above) where applicable
- the appropriate fee (check the website).

Note that, although the ACVM Group can process an application and approve the provisional registration, the registration cannot be issued for that designated or trade name product unless one of the following is supplied:

- a signed declaration from the applicant stating that the designated or trade name product as formulated is not a hazardous substance, ie does not exceed any thresholds prescribed in the Hazardous Substances Minimum Degrees of Hazard Regulations 2001 (a copy of the required non-hazardous declaration is attached to this document), or
- a determination from ERMA NZ that the trade name product is not a hazardous substance, or
- an appropriate ERMA NZ approval (if the designated or trade name product is a hazardous substance).

3.2 Identification of the investigational product

The following information must be supplied:

- trade name or company designation for the product
- biosecurity clearance if a product being imported contains an ingredient of biological origin
- amount of the product to be used in the study

- justification for the amount (ie dose regimes and number of animals to be treated, or application rates and areas treated – ensure amount and numbers allow for all contingencies)
- product type (eg fungicide, antibiotic, vertebrate toxic agent)
- application or administration method
- formulation type or types
- species/target host.

Provide names, CAS numbers and functions of the active ingredients and formulants. Concentration(s) of the active ingredient(s) must also be provided.

Where an application is made for an approval for sale of treated produce (see section 4), the full formulation details are required.

3.3 Security

3.3.1 Information to be provided

The applicant must supply sufficient information to satisfy the ACVM Group that the security of the investigational product, and that of any animals or plants that have been treated with it, will not be compromised. This information should include:

3.3.1.1 Name of the study director.

3.3.1.2 Purpose of the study and the period of time for which the provisional registration is sought to achieve this purpose. Include the start date of the study.

3.3.1.3 Site and systems information that covers:

a. The study location

- the study location(s)
- the method used to select it
- the means by which access to it is limited.

If the study location is not known at the time of application, information must be provided detailing criteria for selection of the location, as well as means by which access to it is limited. Locations must be advised to the ACVM Group as soon as they are known.

b. Assurance that persons who have access to the product are suitably qualified or trained to use it.

c. Precautions taken to prevent environmental contamination, eg buffer zones, special methods of application/administration, protection of waterways where necessary.

d. Measures taken to ensure that the study site is left free of residues that might compromise further use of the site, including the period of time for which the site will remain secure to avoid residues affecting its further use.

e. Method of disposal of any unused investigational product.

f. Method of disposal of animal or plant wastes.

g. Method of disposal of any animals or plants or their produce that have been treated with the investigational product. If an approval for sale of treated produce is sought, refer to section 4. If such an approval is not gained, the produce must not be sold at any time. A written declaration that the produce will not be sold must be given to the ACVM Group.

h. Introduction of non-target species into trial site for VTAs, refer to section 5.

3.3.2 References to be provided

In addition to providing the information specified above on the application form, the following information must be held in the researcher's study documentation, and references to it must be specified on the application form.

3.3.2.1 Names of personnel involved in the study and their responsibilities.

3.3.2.2 Measures taken to limit access to the investigational product, including:

- where the product is stored and how access to that storage is limited
- personnel who have access to the product
- how stocks of the product will be reconciled, from arrival to disposal.

3.3.2.3 Measures taken to limit exposure to the investigational product specifically to the animals or plants intended to be treated, including:

- identification of treated plants or animals, eg method of marking out study plots, eartagging
- identification of any treated water or feed to be administered
- stockproofing of treated plots.

4 Approval for Sale of Treated Produce

4.1 Information to be provided

For treated animals or plants (or their produce) to be assessed for approval to be sold, the applicant must provide the following information:

4.1.1 Formulation

The complete formulation (or formulations) of the product under investigation for either case in 4.1.2 and 4.1.3 below.

4.1.2 Proposed method of disposal

The proposed method of disposal (including proposed sale) of treated animals or plants (or their produce) supported by data that meets the appropriate ACVM standard for residue data initial data package as well as any other information the ACVM Group may require in order to set a withholding period, or

4.1.3 Withholding period

Where the active ingredient has previously been assessed by the ACVM Group, the applicant may provide information to support the use of a default withholding period (as listed in the appendix). Specific argument with supporting information must be submitted to support any other withholding period.

Note: This option applies only to treated animals or their produce. No default withholding times have been set for treated plants.

4.2 Withholding period sale restriction

Applicants should note that treated animals or plants or their produce must not be sold until the withholding period has elapsed. This is so that the measures implemented for their security are maintained until possible entry into the food chain. (Note: requirements under other legislation, eg Food Act, Animal Products Act etc, may apply.)

4.3 Sale other than to slaughter

If approval for ongoing sale of animals, other than to slaughter is sought, this must be applied for separately. Consideration in the risk analysis should be given to any features of the formulation, eg capsules, that pose risks with uncontrolled entry into the food chain.

5 Introduction of Non-Target Animals (Vertebrate Toxic Agents only)

5.1 Information to be provided

For introduction of non-target animals into the trial site after the trial has been completed the applicant must provide the following information:

5.1.1 Formulation

The complete formulation (or formulations) of the product under investigation for either case in 5.1.2 below**.**

5.1.2 Where bait has been applied aerially or broadcast:

- information on the breakdown of the bait, including residue decay of the active ingredient
- information on the persistence of the active ingredient in the soil.

5.1.3 Where the VTA is applied in discrete bait stations:

The applicant must provide information on the measures taken after the trial to ensure no bait remains in the trial site.

6 Variations to Terms and Conditions of a Provisional Registration

6.1 New application

The following variations to a product for which a provisional registration is held are considered to constitute a new application:

- variation to formulation beyond the range approved
- variation to formulation type beyond those approved
- variation to product type
- variation to trade name, or
- reinstatement after expiry.

The following information must be supplied:

- an application letter detailing the requested variation and reasons for it
- a completed application form (available on the website), and
- the appropriate fee (check the website).

6.2 Variation to an existing provisional registration

6.2.1 What may be varied

The following variations to an existing provisional registration are dealt with as variations:

- variation to administration/application method of the product
- variation to the dose/application rate
- variation to species/target host which are the subject of the study
- variation to the number/amount of animals/plants required

- variation to the amount of product required
- extensions to the expiry date provided that the current expiry date has not yet been reached
- variation to the following security arrangements
  - name of the study director
  - criteria for selection of sites
  - measures taken to limit access to the investigational product
  - precautions taken to prevent environmental contamination
  - measures taken to ensure that the study site is left free of residues that might compromise further use of the site
  - method of disposal of any unused investigational product
  - method of disposal of animal or plant wastes
  - method of disposal of treated animals or plants or their produce.

6.2.2 Information to be supplied

The following information must be supplied:

- an application letter detailing the requested variation and reasons for it, and confirming that there have been no variations to other information held in support of the current registration
- an application form (available on the website) with the areas of variation completed
- the appropriate fee (check the website)
- an ERMA NZ approval where appropriate (i.e. significant change in formulation creating a new hazardous substance etc.).
- an AEC approval reconfirmed where appropriate.

Where an import approval has been issued for a provisional type registration and variations are being made to:

- the expiry date, and/or
- the amount of product required,

the original import approval must be enclosed with the application for variation so that it can be reissued with the updated information.

Where the method of disposal of the animals or plants or their produce has changed so that an approval for sale of treated produce is now sought, the information detailed in section 4 must be provided.

Appendix: Default Withholding Periods (Veterinary Medicines only)

An application may be made for one of the following default withholding periods to be assigned to a provisionally registered product. See section 4.1.3 for information required to support such an application.

These withholding periods do not apply to sustained release formulations as the withholding period must apply to the time after the release period, not after administration.

Species	Days for Meat	Days for Eggs	Days for Milk
Avians	63	10	NA
Ruminants (including deer)	91	NA	35
Camelids	63	NA	NA
Lagomorpha (eg rabbits, hares)	63	NA	NA
Monogastrics (eg pigs, horses)	63	NA	NA
Fish, crustaceans, molluscs	35	NA	NA