Ministry for Primary Industries
Manatū Ahu Matua

ACVM Requirement

Registration Information Requirements for Agricultural Chemicals

Information required to register (or vary a registration of) an agricultural chemical trade name product under the Agricultural Compounds and Veterinary Medicines Act 1997

29 February 2024

Issued under the Agricultural Compounds and Veterinary Medicines Act 1997

New Zealand Government

TITLE

ACVM Requirement: Registration Information Requirements for Agricultural Chemicals

COMMENCEMENT

This ACVM Requirement comes into force on 29 February 2024

REVOCATION

This ACVM Requirement revokes and replaces the ACVM Registration Information Requirements for Agricultural Chemicals in New Zealand (issued April 2011).

ISSUING AUTHORITY

This ACVM requirement is issued under section 10 of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

In accordance with section 10 of the ACVM Act, this ACVM requirement hereby specifies the information every application under section 9 of the ACVM Act must contain for any agricultural compound or group of agricultural compounds or trade name product or products.

Dated at Wellington this 29th day of February 2024

Natalie Collins
Acting Director, Assurance
Ministry for Primary Industries
(acting under delegated authority of the Director-General)

Contact for further information
Ministry for Primary Industries (MPI)
Regulation & Assurance Branch
ACVM Programmes and Appraisals
PO Box 2526
Wellington 6140

Email: approvals@mpi.govt.nz

Contents

Introduction

This introduction is not part of the ACVM Requirement, but is intended to indicate its general effect.

Purpose

This document specifies the information required to support an application to register (or vary a registration of) an agricultural chemical trade name product under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

Background

The purpose of the ACVM Act is to:

a) prevent or manage risks associated with the use of agricultural compounds, being—
   i) risks to public health; and
   ii) risks to trade in primary produce; and
   iii) risks to animal welfare; and
   iv) risks to agricultural security:
b) ensure that the use of agricultural compounds does not result in breaches of domestic food residue standards:
c) ensure the provision of sufficient consumer information about agricultural compounds.

The Act provides that any person may apply to the Director General to register agricultural compound as trade named products. Further, registrants may apply to the Director-General to vary conditions on a registered trade named product.

The Act provides that every application for registration of an agricultural compound must be in the form specified by the Director-General and must contain the information specified by the Director-General.

Who should read this ACVM Requirement?

This ACVM requirement should be read by:

a) a person applying to register, or vary a registration, of an agricultural chemical trade name product; and
b) a person conducting an independent data assessment on an application made to register, or vary a registration, of an agricultural chemical trade name product.

Why is this important?

Failure to provide the information specified in this document may result in an application for registration or an application to vary registration being declined.

Other information

The information contained within a border throughout this document is for guidance and is not part of the requirements.

Also refer to the ACVM Guidance Document: Agricultural Chemical Registration

Part 1: Preliminary provisions

1.1 Application

(1) This ACVM Requirement applies to:

a) a person applying for registration of an agricultural chemical trade name product under section 9(1) of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 (the Act); and
b) a registrant applying to vary a registered trade name product.

(2) It does not apply to a person applying to provisionally register an agricultural chemical trade name product under section 26 of the Act.

1.2 Definitions

(1) In this requirement, unless the context otherwise requires:

Act means the Agricultural Compounds and Veterinary Medicines Act 1997

data assessor means a person who completes a data assessment report who is independent from the applicant or any aspect of the data provided (including trial work).

data assessment report means a report completed by an independent data assessor using the appropriate ACVM template, examining the validity, reliability and credibility of data provided in support of a registration (or variation) application of a trade name product. It considers whether the data complies with the ACVM information requirements and guidance, and determines whether the hazards and risks applicable to the ACVM Act have been adequately identified and addressed.

data set means the raw data recorded from a field/laboratory study (i.e., trial observation entries)

(2) Unless the context otherwise requires, terms used in this requirement that are defined in the Act or the ACVM (Exemptions and Prohibited Substances) Regulations 2011 have those meanings.

Part 2: Requirements

2.1 Documentation for an application for registration

(1) A person applying for registration of an agricultural chemical must provide all of the following documentation with their application:

a) an application form; and
b) information that will be provided to the end user of the product (including the label) in accordance with clause 2.3; and
c) the proposed Product Data Sheet (PDS); and
d) an application overview for the specific product and proposed use with regard to ACVM risk areas in accordance with clause 2.5; and
e) all data set(s) and supporting information in accordance with clause 2.6; and
f) all data assessment report(s) in accordance with clause 2.7; and
g) papers, articles, documents or information (including public domain information) referenced in the application, if applicable; and
h) the original document and an English translation if the reference information in (e) and (g) above is in a language other than English.

(2) A registrant (or a person acting under the registrant's authorisation) applying for a variation of an existing registration must provide the documentation listed under 1(a) – (d) with their application. Documentation listed under 1(e) – (h) must be provided relative to the proposed change.

Guidance

- For information on expectations for different types of applications for registration and variations to registration, refer to the ACVM Guidance document: Agricultural Chemical Registration.
- Deviations from the requirements may be considered.

2.2 Registrant and trade name

(1) A person applying for registration or a registrant applying for a variation of registration must include the following name and contact information in their application:

a) the name and contact details of the person making the application; and
b) the name and contact details of the New Zealand agent (if any).

(2) A person applying for registration or registrant applying for a variation of registration must only submit one trade name per registration.

(3) The trade name must be a clear, unique trade name under which the product will be registered.

2.3 Provision of sufficient consumer information (label)

(1) A person applying for registration or a registrant applying for a variation of registration must include the information that will accompany the product and be provided to the user.

(2) The information provided in subclause (1) above must be sufficient to enable the user to identify and use the agricultural chemical for the intended purpose, and to manage the risks associated with the product and the intended use.

Guidance

- The information provided to the user is typically the label.
- For more information see the ACVM guidance document Labelling Agricultural Chemicals.

2.4 Product datasheet (PDS)

(1) A person applying for registration or a registrant applying for a variation of registration must supply a completed PDS.

Guidance

- For more information on the PDS, see the ACVM guidance document Agricultural Chemical Product Data Sheet guideline.

2.5 Application overview

(1) A person applying for registration must provide an application overview with the application. This must set out the purpose of the application and provide an outline of the information submitted to support the application.

(2) In addition to subclause (1), the application overview must include consideration of additional hazards, risks or benefits, not addressed through the standard expectations of the data volumes in section 2.6, associated with the following:

a) the identity/formulation, quality, purity, stability, and consistent manufacture of the product; and
b) agricultural security including the product's effectiveness for pest control claims; and
c) the potential harmful effects on treated plants when used as directed; and
d) any possible impact on public health resulting from the use of the product not addressed by the Environmental Protection Authority (EPA) approval (e.g., antibiotic resistance); and
e) any possible impact on trade in primary produce resulting from the use of the product; and
f) compliance with domestic food residue standards; and
g) animal welfare relative to animals that will be intentionally exposed; and
h) efficacy and crop-safety as fundamental benefits.

(3) A registrant applying for a variation of registration must provide an application overview as in subclauses (1) and (2), in terms of the change that is proposed.

(4) The application overview must identify any proposed deviations from the requirements.

(5) The application overview must be supported by the data and information provided in the application.

Guidance for consideration of hazards, risks and benefits

- For more information on risk management under the ACVM Act, refer to Risk Management under the Agricultural Compounds and Veterinary Medicines Act 1997: Overview. This gives more detail on the risk areas specified in the ACVM Act.
- In most cases, provision of data as set out in the ACVM Guidance Document: Agricultural Chemical Registration and associated guidance documents will be sufficient to identify the hazards, risks and benefits and will be able to support the risk analysis. However, the guidance cannot address all risks,

especially for innovative products, and it is the applicant's responsibility to address additional risks comprehensively in the data volumes and application overview.

2.6 Provision of data and supporting information

2.6.1 General requirements for data volumes

(1) A person applying for registration or a registrant applying for a variation of registration must:

a) arrange data and supporting information in data volumes; and
b) ensure that the product formulation used in the studies provided with the application is identical to that being proposed for registration; and
c) ensure that studies provided are robust, reliable, and relevant.

Guidance

- Refer to the ACVM Guidance Document: Agricultural Chemical Registration for further information on data volumes. This guidance includes what MPI considers to be the most appropriate ways to address residues, efficacy, plant safety and animal welfare to support an application for registration.
- If uncertain as to what to include in the data volumes, contact a competent consultant for assistance.

2.6.2 Chemistry and manufacturing data volume

(1) A person applying for registration or registrant applying for a variation of registration must provide chemistry and manufacturing information with the application which:

a) identifies the product; and
b) provides confidence that the product can be consistently manufactured to an appropriate quality; and
c) provides confidence that quality will be maintained throughout the expected shelf life of the product.

Guidance

- For more information on provision on chemistry and manufacturing information, see the ACVM guidance documents Chemistry and Manufacture of Agricultural Chemicals and Microbial Agricultural Chemicals.

2.6.3 Efficacy and plant safety data volume

(1) A person applying for registration or registrant applying for a variation of registration must provide efficacy and plant safety data with an application.

Guidance

- Data generated should follow the ACVM Guidance Document: Agricultural Chemical Registration and the ACVM Research Standard for agricultural chemicals.
- For more information on data generation for microbial agricultural chemicals, see Microbial Agricultural Chemicals.

2.6.4 Residues data volume

(1) A person applying for registration or registrant applying for a variation of registration must provide residue data for products used on/around food and/or feed crops in order to determine the level of residues in plant and animal commodities.

Guidance

- For more information on provision of residue information, refer to the ACVM guidance document Residue Data for Agricultural Chemicals.

2.7 Data assessment

(1) A person applying for registration or a registrant applying for a variation of registration must provide data assessment reports for each volume with their application, including an Overall Data Assessment Report.

(2) The data assessment in subclause (1) must be undertaken by an independent data assessor(s).

(3) The appropriate templates must be used.

Guidance

- For more information on data assessment, refer to the ACVM Guidance Document: Agricultural Chemical Registration. This includes guidance to determine when data volume assessment is not necessary.