Ministry for Primary Industries
Manatū Ahu Matua

ACVM Requirement

Registration Information Requirements

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

[Document Date]

Issued under the Agricultural Compounds and Veterinary Medicines Act 1997

New Zealand Government

TITLE

ACVM Requirement: Registration Information Requirements

COMMENCEMENT

This ACVM Requirement comes into force on [Effective Date]

REVOCATION

This ACVM Requirement revokes and replaces:

a) ACVM Registration Information Requirements for Agricultural Chemicals in New Zealand (issued April 2011); and
b) ACVM Registration Information Requirements for Vertebrate Toxic Agents Including Vertebrate Pest Control Products (issued March 2005); and
c) Veterinary Medicine Registration in New Zealand (issued June 2010).

ISSUING AUTHORITY

This ACVM requirement is made 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 ... day of 2017

Allan Kinsella
Director, Systems Audit, Assurance and Monitoring
Ministry for Primary Industries
(acting under delegated authority of the Director-General)

Contact for further information
Ministry for Primary Industries (MPI)
Regulation & Assurance Branch
Systems Audit, Assurance & Monitoring Directorate
PO Box 2526
Wellington 6140
Email: approvals@mpi.govt.nz

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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) a trade name product under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

Background

Applications for registration of an agricultural compound trade name product must include the information specified by the MPI Director-General. The information is, in effect, the documentation of the identity of the trade name product and the analysis of the risks in the areas specified in section 4 of the ACVM Act. These are:

- risks to public health; and
- risks to trade in primary produce; and
- risks to animal welfare; and
- risks to agricultural security.

While managing these risks regulatory decisions must also ensure that:

- the use of agricultural compounds does not result in breaches of domestic food residue limits; and
- sufficient consumer information is provided when agricultural compounds are sold.

Precise specification of the trade name product and the way it is manufactured must be the point of reference for the applicant's required risk analysis. The application must include the risk analysis and all the supporting information and data. The data must also be assessed by an independent data assessor(s), and the assessment report(s) must be included in the application. The risk analysis may be based on information and data already held by MPI. The request to consider such information or data must be clearly stated in the application along with the rationale explaining why that information or data could be considered relevant to the application.

Applicants are responsible for providing all information and data required to allow MPI to appraise the risks, make a decision on the application, and impose conditions that are necessary and sufficient to manage the risks down to an acceptable level. Applications that do not contain the required information will not be assessed. If further advice is required, you are advised to contract the services of an appropriate consultant prior to submitting your application.

Who should read this ACVM Requirement?

This ACVM requirement should be read by:

- a person applying to register an agricultural compound trade name product; and
- a person conducting an independent data assessment on an application made to register an agricultural compound trade name product.

Why is this important?

If a person does not comply with this requirement, his/her application may be rejected as incomplete or, if it is not immediately apparent that the application is incomplete, it may be received and subsequently declined on the grounds that there is insufficient information to assess the risks.

Other information

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

Part 1: Preliminary Provisions

1.1 Application

(1) This requirement applies to a person applying to register (or vary a registration of) an agricultural compound trade name product under section 9 of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

(2) It does not apply to a person applying to provisionally register an agricultural compound 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

active ingredient means the chemical (or biological component) in a formulated product that is principally responsible for the effect(s) being claimed and as distinct from other formulation components such as surfactants, carriers or diluents

cross-reference means referral to a reference product for which MPI holds the information/data

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

data assessment report means a report from an independent data assessor on data sets from clinical/field/laboratory studies that examines conformance to this ACVM Requirement, including the applicant's risk analysis, and identifies all areas of non-conformance

good clinical practice (GCP) or good field practice (GFP) means an international standard for designing, conducting, monitoring, auditing, recording, analysing, and reporting clinical or field studies that provides assurance that the data and reported results are complete, correct and reliable and, as appropriate for the type of clinical/field study, that the welfare of the study animals and the safety of the study personnel involved in the study are ensured, and the environment and the food chain are protected

good laboratory practice (GLP) means an international standard for a quality system concerned with the organisational process and the conditions under which laboratory studies are planned, performed, monitored, recorded, archived and reported

good manufacturing practice (GMP) means an internationally accepted standard which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the manufacturing authorisation

hazard means any characteristic of the product, the way it is manufactured, the information provided with the product, or its intended use that may cause harm in any of the risk areas specified in section 4 of the Act

hazard pathway means the path by which a hazard could cause harm

reference means referral to a reference product for which MPI does not hold the information/data

reference product means an agricultural compound product nominated by the applicant with which the 'test' product (applicant's trade name product) is compared

risk means the probability that a hazard will cause a particular harm and the magnitude of that harm

target host means the species of plant to which an agricultural chemical trade name product is applied

target species means the species of animal to which a veterinary medicine or vertebrate toxic agent trade name product is administered.

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

Part 2: Requirements

2.1 Product identity

(1) The applicant must ensure that the registration application includes all the information as specified in this Part.

Guidance for variation to an existing registration

- For a variation:
  - supply complete product data sheet (PDS) with the variation highlighted; and
  - provide a risk analysis (see 2.2) addressing the impact the proposed variation will have on the product's risk profile.

2.1.1 Registrant and trade name specification

(1) The application must include:

a) the name and contact details of the person making the application; and
b) the trade name under which the product will be registered.

(2) The trade name must be unique and compliant with trademarks.

(3) The trade name must not be:

a) misleading (e.g. suggesting the product controls a pest when the label does not mention control of that pest); or
b) solely the name of the product's active ingredient; or
c) the same as a product that is already registered.

2.1.2 Product specification

(1) The formulation for the product must be specified, including:

a) confirmed chemical or biological identity of the active ingredients, concentrations, quality, likely contaminants/impurities; and
b) confirmed chemical identity of any non-active ingredients, concentrations, quality, likely contaminants/impurities.

(2) Methods used to verify the above must be specified.

(3) The packaging for the product must be specified, including detail of type and quality of material used for primary packaging and any outer packaging, and pack sizes.

(4) The intended use of the product and use instructions must be specified.

(5) The content of any other information to be provided with the product must be specified.

2.1.3 Manufacturing specification

(1) Specification governing the way the product is manufactured must be specified, including:

a) control and quality checks on ingredients; and
b) manufacturing steps and in-process quality checks; and
c) manufacturing process validation; and
d) quality checks before product release.

(2) If the trade name product is a veterinary medicine, the application must include evidence of either:

a) MPI good manufacturing practice (GMP) approval; or
b) acceptable overseas GMP approval of the manufacturer if the product is imported.

Guidance

- For guidance on specifying a trade name product and its manufacture, refer to the relevant MPI chemistry and manufacturing guidelines for veterinary medicines, agricultural chemicals or vertebrate toxic agents.
- These guidelines detail specifications for common products, but new kinds of products or unusual variations of common products may require different specifications.
- If uncertain, contact MPI's ACVM Group approvals@mpi.govt.nz.

2.2 Risk analysis

(1) Documenting an adequate risk analysis to support an application to register an agricultural compound trade name product is the intent behind setting these requirements, and precisely identifying that product, as required in clause 2.1, is the point of reference for a risk analysis.

(2) The product that is used in the risk analysis must be either:

a) the same one, with the same product and manufacturing specifications, as the product that is being considered for registration; or
b) there must be scientifically sound justification as to why the use of some other product or formulation would result in an equally relevant and equivalent risk analysis.

(3) The application must include the risk analysis, detailing the requirements listed below.

2.2.1 Identify potential harms in relevant risk areas

(1) The risk analysis must address the potential for harm in each of the areas specified in section 4 of the Act, i.e. the analysis must consider the impact the use of the product is likely to have that would jeopardise:

a) public health; or
b) trade in primary produce; or
c) agricultural security; or
d) the welfare of treated or exposed animal(s); or
e) food for human consumption either directly or via subsequent exposure of animals or plants to residues from the product.

(2) Each potential harm must be characterised in regard to its definition and likely impact.

2.2.2 Hazard and hazard pathway identification

(1) Relative to the potential harms, the characteristics of the product, how it is manufactured, how it is intended to be used, and the information provided with it must be considered to determine if any aspect constitutes a hazard.

(2) The hazard pathway(s) must be identified and described.

2.2.3 Risk analysis design

(1) For hazard pathways identified, the probability that the hazard will cause the harm must be estimated.

(2) The magnitude of the likely harm must be estimated.

(3) The estimates of probability and magnitude must be used to state the level of the risk in each case.

(4) Estimates must be supported by corroborating information as follows:

a) clinical/field/laboratory study data supporting the estimates of probability and magnitude; or
b) a request to consider clinical/field/laboratory data held by MPI, that is not subject to protection under section 73, regarding an equivalent reference product, with technical justification as to why the data can be considered equally relevant; or

c) a request to consider previous MPI decision(s), with technical justification as to why the decision(s) can be considered relevant and can be applied; or
d) information in the public domain, with technical justification as to why the information can be considered relevant and can be applied; or
e) a combination of the above sources on information.

Guidance
- For additional guidance regarding risk analysis refer to Risk Management under the Agricultural Compounds and Veterinary Medicines Act 1997 Overview and Risk- Benefit Analysis to Support Registration under the ACVM Act **(draft for consultation)**.

2.2.4 Clinical/field studies

(1) If clinical/field studies are provided, the application must contain documentation showing that:

a) the product formulation used in the studies was identical to that being proposed for registration; and
b) clinical/field/laboratory studies were designed to generate robust, reliable and relevant data that qualifies and quantifies the estimates of probability and magnitude of risk.

2.2.5 Laboratory analyses

(1) The application must contain documentation showing that:

a) the choice of analytical tests on study samples was appropriate to generate robust, reliable, and relevant results regarding what was being examined in the study; and
b) for pivotal residue studies for veterinary medicines, all analytical tests must be carried out by a GLP accredited laboratory.

Guidance
- MPI has prepared a series of guidelines on what it considers to be the most appropriate and minimum clinical/field/laboratory studies for each type of agricultural compound in the areas of residues, efficacy, and target animal safety to support an application for registration.
- The guidelines detail advice for common agricultural compound products. New kinds of products or unusual variations of common products may require additional or different risk analysis with attention to the unique characteristic of the product being proposed for registration.
- If uncertain as to what to address in the risk analysis, contact a competent consultant for assistance.

2.2.6 Data assessment

(1) The application must include all data assessment reports from the independent data assessor(s).

Guidance
- It is the applicant's responsibility to choose and contract a data assessor to carry out the assessment(s).
- For information on data assessors who have been listed by MPI in specific areas, refer to Listed Data Assessors.
- Guidance for Data Assessors can be found on our website.

2.3 Documentation of an application for registration

(1) In accordance with clauses 2.1 and 2.2 and as further prescribed by this clause, the following documents are required to be provided by the applicant for registration:

a) an application in the form specified by the Director-General under section 10(1) of the ACVM Act; and
b) equivalency justification in respect to any request to reference or cross-reference data/information on a reference product if applicable to the application; and
    i) identification of previous decision(s) and relevancy justification in respect to any request for previous decision consideration if applicable to the application; and
c) the full risk analysis, including clinical/field/laboratory study design information, laboratory and statistical methods, and all data set(s); and
d) all data assessor(s) report(s); and
e) papers, articles, documents or information (including public domain information) referenced in the application if applicable; and
f) the original document and a verified English translation if the reference information in (e) above is in a language other than English; and
g) the overseas authorisation/licensing status and supply approved product label(s) if the product is to be imported into New Zealand, including if applicable:
    i) any differences in the overseas approval and what is proposed for registration in New Zealand; and
    ii) reasons why the product is not licensed for use in the country of manufacture, if applicable.

Guidance

- The application forms referred to in clause 2.3 (1) can be found on our website.
- Variations in formulation, manufacturing process, intended use, and use instructions can all nullify the relevance of public domain information, data from reference products or previous MPI decisions. The case supporting relevance must be thorough and technically sound.
- Before an application is lodged, a person can request an opinion from MPI about the likely acceptability of a particular deviation. This will be given but circumstances may change, so the opinion cannot be considered a certainty as to the final decision.
- It is the decision of the Director-General, or the person acting under delegated authority, as to whether or not a deviation from these requirements is acceptable. This decision will be made at the time the application is considered.