



# ACVM Registration Information Requirements for Agricultural Chemicals in New Zealand

ACVM Information Requirements 2

Prepared for Approvals and ACVM Group

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<b>Contents</b>		<b>Page</b>
<b>1</b>	<b>Purpose</b>	<b>1</b>
<b>2</b>	<b>Requirement for registration</b>	<b>1</b>
<b>3</b>	<b>Shared agreement</b>	<b>1</b>
<b>4</b>	<b>Types of registration</b>	<b>2</b>
4.1	Registration	2
4.2	Provisional registration	2
<b>5</b>	<b>Information required for registration</b>	<b>3</b>
5.1	Overall application summary	3
5.2	Data volumes	3
5.3	Information required for each application type	6
5.4	Data assessment	6
5.5	Format	7
5.6	International data volumes	7
5.7	Electronic submission	7
<b>6</b>	<b>Deviations from the information requirements</b>	<b>8</b>
<b>7</b>	<b>Data protection</b>	<b>8</b>
<b>8</b>	<b>Other requirements</b>	<b>9</b>
8.1	ERMA NZ approval	9
8.2	MAF Biosecurity New Zealand clearance	9



## 1 Purpose

This document provides guidance on the information that **must** be provided to support applications for registration of a new agricultural chemical trade name product or for variations to existing registrations of agricultural chemical trade name products.

## 2 Requirement for registration

Under section 21 of the Agricultural Compounds and Veterinary Medicines Act 1997 (the Act), agricultural compounds must be registered before importation, manufacture, sale or use is permitted unless exempted via the Agricultural Compounds and Veterinary Medicine Regulations 2001. An agricultural chemical is any substance, mixture of substances or biological compound used or intended for use in the management of plants. Agricultural chemicals are a subset of agricultural compounds.

The Approvals and ACVM Group of the Ministry of Agriculture and Forestry (MAF) is responsible for registration of agricultural compounds in New Zealand. See the website for more background.

[FAQ - regulation under the ACVM Act 1997](#)

If you have questions, contact us ([acvm@maf.govt.nz](mailto:acvm@maf.govt.nz)).

## 3 Shared agreement

The Approvals and ACVM Group undertakes to process applications for agricultural compounds, including agricultural chemicals, in an effective and efficient way in order to prevent or manage the following risks relevant to the Act (section 4):

- risks to trade in primary produce;
- risks to agricultural security;
- risks to animal welfare;
- risks to public health;
- risks to domestic food residue standards.

The applicant undertakes to provide all the information, as detailed in this document, required to enable the application to be processed. Additionally, the applicant undertakes to analyse the hazard profile of their products, providing any additional information (not specified in this document) that the applicant considers would be useful in appraising the risks posed by the product.

See the website for more information on risk assessment and hazard analysis.

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

## 4 Types of registration

Applications can be made for two types of registration:

- registration (including variations to a currently registered trade name product);
- provisional registration.

### 4.1 REGISTRATION

Registration means obtaining authorisation under section 21 of the Act for importing, manufacturing, selling and using an agricultural chemical trade name product in New Zealand.

### 4.2 PROVISIONAL REGISTRATION

Provisional registration means obtaining authorisation under section 27 of the Act to allow an applicant to carry out product development or trial work with a trade name product in order to obtain further information (for example, efficacy, crop safety, or residues data). Obtaining provisional registration of a trade name product is not a prerequisite for subsequent registration under section 21 of the Act.

Data requirements for provisional registration are not the same as requirements for registration and are **not** covered in this document.

**Note:** Where trials are to be conducted on plants using an agricultural compound that does not have the characteristics of a trade name product under the Act, a research approval may be required.

See the website for more information on provisional registration and/or research approvals

[Provisional Registration in New Zealand](#) (91 KB PDF)

[Research Approval in New Zealand](#) (91 KB PDF)

## 5 Information required for registration

Applications for registration of an agricultural chemical must include, among other information (such as a complete covering letter), technical data and/or scientific arguments to support:

- the quality, purity and stability of the product;
- the product's efficacy for all label claims that relate to the risk areas managed under the ACVM Act. Efficacy of a trade name product is only assessed where residue data is needed to establish good agricultural practice. In other words, we only require efficacy data where residue data is required;
- crop safety;
- the establishment of an MRL (or argument/ data to gain an exemption) resulting from trial work that adheres to the residue guidelines (see the website);
- any possible impact on trade resulting from the use of the agricultural chemical in crops, and/or carry over residues as a result of feed crops in food-producing animals;
- compliance with domestic food residue standards.

### 5.1 OVERALL APPLICATION SUMMARY

Registration applications should include a document that summarises the main aspects of the complete application. In particular, the summary should include the following:

- a list of data that is included and how it supports the product registration, such as label efficacy claims, plant safety, shelf life, withholding periods etc;
- scientific arguments (deviations from the information required in this document) in lieu of data not included in the data volumes;
- references to relevant documents;
- clarification of non-conformances identified in the independent data assessment reports.

Failure to include the overall application summary may result in the application being rejected at pre-screen.

### 5.2 DATA VOLUMES

MAF's information requirements documents specify the information that **must** be supplied to support an application. They also provide guidance advice, which is not mandatory. The data should be provided in the form of data volumes, also known as data packages or dossiers. Data volumes required to support an application depend on the application type. This section provides a brief description of all the data volumes. The table at section 5.3 lists the application types and the data volumes that must be provided to support that application type. (See section 5.7 below for information on electronic submissions.)

## Volume 1: Chemistry and Manufacturing

The information provided in this volume defines the identity of the trade name product and must conform to MAF's information requirements.

[Chemistry and Manufacture of Agricultural Chemicals](#) (211 KB PDF)

For type A and type B applications (see definitions of application types in 5.3 table), all information requested in the chemistry and manufacturing information requirements document must be supplied.

The information to be supplied for type C applications is determined by the changes to formulation or manufacturing that is proposed. For example, a change in shelf life (C3) will require only the stability section of the chemistry and manufacturing information requirements document to be addressed. For an understanding of the types of application see:

[Guideline: Product Data Sheet for Registration \(or Variation of Registration\) of an Agricultural Chemical](#)

[Agricultural Chemical Smart Track Application Guidance and Link to Forms](#)

## Volume 2: Residues

Residue data must be supplied only for products used on food and/or feed crops. This is required to determine the level of certain residues in produce, and animal transfer residues in edible tissues of animals or other specified primary produce obtained from an animal. Based on the residue data, MAF will recommend a withholding period (WHP) for the trade name product. The WHP, which is the time for which a particular agricultural produce must be withheld before entering the food chain, is a regulatory tool used by MAF as a condition of registration to manage compliance with the specified residue limits in the current New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards.

The data provided in this volume must conform to MAF's residue information requirement document for agricultural chemicals.

[ACVM Data Requirements for a Food or Feed Use Clearance Plant Compounds](#) (114 KB PDF)

If a maximum residue limit (MRL) for the active ingredient is required to be established, this must be made clear in the application. To check the current MRL of an active ingredient, refer to the latest version of the following standard.

[New Zealand \(Maximum Residue Limits of Agricultural Compounds\) Food Standards](#) (261 KB PDF)

## Volume 3: Efficacy and crop safety

In cases where efficacy and plant safety data are required to determine good agricultural practice to support a withholding period, the data generated should follow the requirements outlined in the *ACVM Research Standard*.

In cases (for example, a C5 application for an additional disease/pest/weed) where a request for a deviation from registration requirements is made on the basis that the proposed use rate, timing and use pattern are identical to that already approved, efficacy data on the proposed additional use should be supplied to confirm good agricultural practice.



Efficacy information is required to justify label claims and establish good agricultural practice where lack of efficacy will impact on the risk areas outlined in section 3 above. Efficacy must be demonstrated for use according to the label directions under practical conditions within New Zealand. Claims must be soundly supported by trials as per MAF requirements.

Risks to agricultural security may also arise if an agricultural chemical fails to achieve its claims. In this case efficacy and crop safety data must verify the product will achieve the label claims.

Efficacy data that is not generated under New Zealand conditions may be accepted if appropriate argument is supplied that the data is relevant to New Zealand conditions.

Where the requirements for efficacy are not yet documented but it is indicated in table 5.3 that efficacy data are required, applicants must provide supporting data to show that the trade name product, when used according to directions, is efficacious for the purposes claimed in New Zealand under practical conditions. Data generated should follow the requirements outlined in the *ACVM Research Standard* for agricultural chemicals.

#### **Volume 4: Toxicology**

Submitting human toxicological data is not a standard requirement for most applications. However, very occasionally MAF may request these data on a case by case basis where it is deemed relevant to ACVM risk thresholds.

### 5.3 INFORMATION REQUIRED FOR EACH APPLICATION TYPE

The table below lists the application types and the data volumes that must be provided to support that application type. For an understanding of the types of application see Guideline: Product Data Sheet for Registration (or Variation of Registration) of an Agricultural Chemical and Agricultural Chemical Smart Track Application Guidance (see 5.2 above).

NOTE: These requirements are for ‘known’ products. Any ‘new’ products (for example, nano technology or GMOs) must go through the hazard and risk analysis process before information requirements can be determined.

	Application type	Data volumes				
		Chemistry & Manufacturing	Residue	Efficacy	Safety	Toxicology
A1	New active ingredient	◆	◆	◆	◆	☒
A2	Known active ingredient with a new risk profile	◆	◆	◆	◆	
B1	Identical to a registered trade name product	Dev	Dev	Dev	Dev	
B2	Similar to a registered trade name product	◆	◆	◆	◆	
C1	Change in formulation	◆	◆	◆	◆	
C2	Change in manufacturing process	◆				
C3	Change in shelf life or packaging	◆				
C4	Extension of use to include an additional situation or target host		◆	◆	◆	
C5	Addition of another disease, pest or weed			◆		
C6	Change of application rate or timing		◆	◆	◆	
C7	Change or addition of a method of application		◆	◆	◆	
C8	Change in withholding period		◆			
C9	Administrative change	Fully explain change(s) in a letter.				

#### Key

◆ Information must be provided or a deviation from the information requirements be submitted

☒ See toxicology data requirements (section 5.2)

Dev Deviation from the Information Requirements (section 6)

### 5.4 DATA ASSESSMENT

Before an application is accepted for registration the supporting data must be summarised and evaluated by an independent data assessor to confirm that they meet the general and specific

information requirements as outlined under section 5.2 above. This process is called data assessment. See the website for more information on data assessment for your product.

## 5.5 FORMAT

The data volumes, including all the raw data, must be provided in full and the front page of each volume labelled with the following minimum information:

- trade name of the product and registration number (if known);
- volume number (for example, Volume IV: Efficacy);
- date;
- name of the applicant/supplier of the information.

Each data volume must have a table of contents, followed by a summary of the data in that particular volume. Different sections within the volume must be separated by tabbed dividers and the tabs marked with identifiers/headings. If a section within the data volume comprises a series of studies, a concise summary (abstract) should be provided at the start of each study. Within each section, studies should be assembled in terms of their logical groupings.

Photocopies must be legible. Photographs should be of a quality suitable for reproduction, and preferably lodged as original prints. Colour copies should be used, for diagrams, graphs, photographs etc where use of black and white copies makes it difficult to interpret the information.

All supporting literature, such as scientific papers, must be submitted in full.

The pages of the data volumes must be numbered systematically. Pages can be sequentially numbered from start to finish or, if an application is in several volumes, sequentially numbered within each volume. Any system for numbering the pages may be used as long as it is consistent throughout the application and is accurately reflected in the table(s) of contents.

If all the technical data is less than twenty pages long, it can be presented as a single dossier with the different volumes separated by tabbed dividers (for example, separating the Chemistry and Manufacturing volume from the Efficacy volume). Otherwise, each data volume must be contained in its own dossier.

## 5.6 INTERNATIONAL DATA VOLUMES

Data volumes will be accepted from any other country provided:

- the information submitted is in English. MAF may request documents in the original language if those submitted are translated copies;
- the data meet the relevant MAF information requirements.

## 5.7 ELECTRONIC SUBMISSION

We are moving towards a paperless registration system. Therefore, if possible, submit data electronically. You may use the OECD templates provided these can be opened using common software packages such as MS Word, Acrobat Reader.

## 6 Deviations from the information requirements

An application that is not in the specified form or does not contain the required information will be rejected as an invalid or incomplete application. However, section 16 of the Act allows an applicant to request the Director-General to waive the information requirements (or some part of the requirements) or to give a direction about the terms on which the information must be supplied. See the website for details on submitting a deviation.

[Deviation from information specified in the ACVM Registration Information Requirements](#) (33 KB PDF)

## 7 Data protection

Confidential supporting information (CSI) submitted with an application (type A1) for the registration of a trade name product that contains an “innovative agricultural compound”, as defined in section 72 of the Act, will be eligible for CSI protection (data protection). The period of protection is 5 years from the date of acceptance of the application for provisional registration and if the trade name product is registered (or declined registration) within this period, for a further 5 years from the date of registration (or decline of registration).

Other applicants wishing to apply for registration of a trade name product containing the same active ingredient within this protected period have to either supply full data according to the information requirements or obtain a letter of support from the organisation holding the data protection. See the website for more information on data protection.

## 8 Other requirements

### 8.1 ERMA NZ APPROVAL

Under section 21(5) of the ACVM Act, MAF is not permitted to register a trade name product that is a hazardous substance or contains a new organism unless an approval for that hazardous substance or the organism has been issued under the Hazardous Substances and New Organisms (HSNO) Act 1996. The HSNO Act is administered by the Environmental Risk Management Authority of New Zealand.

Most agricultural chemicals will be deemed to be hazardous under the HSNO Act. Applicants are advised to contact the Hazardous Substance Group of ERMA NZ for a ‘Status of Substance’ determination of their products. If the product contains a live organism, applicants are advised to contact the New Organisms Group of ERMANZ for a determination under section 26 of the HSNO Act.

We are unable to issue registration without ERMA approval.

[ERMANZ](#) (External website)

### 8.2 MAF BIOSECURITY NEW ZEALAND CLEARANCE

A biosecurity clearance issued under the Biosecurity Act 1993 must be included with the registration application if the product contains an ingredient originating from an organism (plant, animal, fungus etc) and is intended to be imported. If not included, the application will not be processed. This requirement is in place to mitigate the risks associated with bringing risk goods into New Zealand from a biosecurity perspective.

Applicants are advised to contact the Imports Group in the Border Standards Directorate of MAF Biosecurity New Zealand for more information on biosecurity clearances.

[MAF Biosecurity](#) (External website)