Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

Agricultural Chemical Registration

Application information for registration under the Agricultural Compounds and Veterinary Medicines Act 1997

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New Zealand Government

Title

Guidance Document: Agricultural Chemical Registration

About this document

This guidance describes how to meet the requirements specified for registration and variations to registration of Trade Name Products stated in the 'ACVM Requirement: Registration Information Requirements for Agricultural Chemicals'. This guidance applies to all persons (including consultants) applying to register an agricultural chemical or to vary an agricultural chemical registration under Section 9 of the ACVM Act.

This guidance specifies MPI's expectations for information to support the majority of applications but does not include guidance for unanticipated products/circumstances. In such cases, MPI may request additional information in accordance with section 11 of the ACVM Act.

Unless otherwise stated, the information in this guidance document represents the preferred way of meeting the requirements. The term 'should' is used where the advice is MPI's general expectation, but there may be alternative ways of addressing the requirements while still providing the same level of assurance. When the term 'must' is used, this is in the context of quoting a provision from legislation or a related requirement.

Related Requirements

Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act, the Act)
Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011 (ACVM (E&PS) Regs)
ACVM Requirement: Registration Information Requirements for Agricultural Chemicals

Document history

Version	Section Changed	Change(s) Description
	All	Changed from Information Requirement to Information Guidance and rebranding. Clarification of efficacy guidance when no MRL applies.

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Disclaimer

This guidance does not constitute, and should not be regarded as, legal advice. While every effort has been made to ensure the information in this guidance is accurate, the Ministry for Primary Industries does not accept any responsibility or liability whatsoever for any error of fact, omission, interpretation or opinion that may be present, however it may have occurred.

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1 Purpose

(1) This guidance describes how to meet the requirements specified for registration and variations to registration of Trade Name Products stated in the 'ACVM Requirement: Registration Information Requirements for Agricultural Chemicals'. This guidance applies to all persons (including consultants) applying to register an agricultural chemical or to vary an agricultural chemical registration under Section 9 of the ACVM Act.

(2) If your intent is to conduct research or testing of an agricultural chemical, refer to the information requirements for provisional registration (authorised under section 27 of the ACVM Act), research approval (authorised under Section 8C of the ACVM Act), or the guideline for Research, Testing and Teaching Operating Plans (authorised under section 28 of the ACVM Act).

2 Background

(1) Agricultural chemicals require an authorisation under the ACVM Act 1997 before they can be imported, manufactured, sold or used.

(2) Authorisation is required to prevent or manage the following risks, as specified in section 4 of the ACVM Act:

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.

(3) The authorisation should take the form of a registration under section 21 or 27 unless the agricultural chemical in question is: (a) exempt from registration via the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011, or (b) approved under section 8C for use in special circumstances.

(4) For additional information, please visit Agricultural chemicals documents, including agricultural chemical registration | NZ Government (mpi.govt.nz).

3 Definitions

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

ACVM team means the team in MPI that is responsible for the regulatory control, including registration, of agricultural compounds and veterinary medicines under the Agricultural Compounds and Veterinary Medicines Act 1997.

agricultural chemical as defined in the ACVM (E&PS) Regulations 2011: an agricultural compound other than one used or intended to be used in the direct management of animals; and does not include a vertebrate toxic agent. For the purposes of the ACVM Act, agricultural chemicals are a subset of agricultural compounds.

agricultural compound as defined in the ACVM Act 1997:

a) any substance, mixture of substances, or biological compound, used or intended for use in the direct management of plants and animals, or to be applied to the land, place, or water on or in which the plants and animals are managed, for the purposes of—

i) managing or eradicating pests, including vertebrate pests; or
ii) maintaining, promoting, or regulating plant or animal productivity and performance or reproduction; or
iii) fulfilling nutritional requirements; or
iv) the manipulation, capture, or immobilisation of animals; or
v) diagnosing the condition of animals; or
vi) preventing or treating conditions of animals; or
vii) enhancing the effectiveness of an agricultural compound used for the treatment of plants and animals; or
viii) marking animals; and

b) includes—

i) any veterinary medicine, substance, mixture of substances, or biological compound used for post-harvest treatment of raw primary produce; and
ii) anything used or intended to be used as feed for animals; and
iii) any substance, mixture of substances, or biological compound declared to be an agricultural compound for the purposes of this Act by Order in Council made under subsection (2).

application overview is a summary of the submission, provided with the application, which sets out the purpose of the application and outlines the information provided to support it. It must consider additional hazards, risks and benefits not addressed through the standard expectations, and identify any proposed deviations.

confidential information means information provided to support an application which fits the definition in Section 73 of the ACVM Act.

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.

formal receipt means acceptance of the application at technical pre-screen.

independent means a person who has not been associated with:

a) the applicant (in a personal or business capacity) – i.e. who does not have a conflict of interest; or
b) designing or undertaking trial work; or
c) collating, preparing or writing of reports, data, or information

in relation to the data assessment reports prepared by that person.

label as defined in the ACVM Act 1997: in relation to any agricultural compound or any container used to contain an agricultural compound, means any written, pictorial, or other descriptive matter under which the compound is sold or to be sold and which purports to give some information about the compound.

reference product means an agricultural chemical product nominated by the applicant with which the ‘test’ product (applicant’s trade name product) is compared.

registration means obtaining authorisation under section 21 or 26 of the ACVM Act for an agricultural compound trade name product in New Zealand.

target species means the pest/disease/weed the agricultural chemical is proposed to manage.

trade name product as defined in the ACVM Act 1997: an agricultural compound identified and packaged under a trade name for a specified use or uses.

(2) Any words or expressions used but not defined in this guidance, have the meaning given to them in the ACVM Act, the ACVM Regulations 2011 and registration information requirements.

4 General guidance

4.1 Application process

The applicant should lodge an application for registration, or variation of an existing registration, with the ACVM team of the Ministry for Primary Industries (MPI).

(1) Only one application for each trade name product can be considered at any one time. However, one application can include multiple variations.

(2) The application should include the information specified in this document (or specified by MPI in unusual cases) and should be in the format specified (see section 4.2 of this document).

(3) The applicant should undertake a comprehensive risk analysis of the product with the aim of identifying and assessing additional ACVM risks posed by the product. Where additional hazards, risks and benefits are identified that are not addressed through the standard expectations of the data volumes, these should be noted in the Application Overview and addressed in the information supplied to support the application. (see section 5 of this document).

(4) Once an application has been submitted to the ACVM team to register a product or vary the registration of an existing product, it undergoes an administrative screen and a technical pre-screen. At the technical pre-screen, the technical team reviews the submitted information to determine whether there is enough information for a formal receipt.

(5) After the application has been formally received, the ACVM team assesses the application, within a timeframe specified in the ACVM Act, to prevent or manage the risks outlined in section 2 of this document.

(6) Based on this assessment, registration is granted with conditions or refused.

(7) For the application process, please refer to Agricultural chemicals documents, including agricultural chemical registration for more details.

4.2 Documentation to be provided

The guidance explains how to provide information specified in the “ACVM Requirement: Registration Information Requirements for Agricultural Chemicals”. It includes advice on the best ways to address expectations and on acceptable alternatives. All guidelines, forms and documents mentioned here are available on our website.

All required documentation must be provided (refer to ACVM Requirement: Registration Information Requirements for Agricultural Chemicals’).

(1) Applications for the registration of an agricultural chemical should include all of the information pertaining to the product. This includes all technical data and/or scientific arguments to support:

a) the identity/formulation, quality, purity, stability, and consistent manufacture of the product; and
b) the product’s effectiveness for all use 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.

(2) You must include a completed application form, either:

a) Registration of an ACVM trade name product (ACVM 1); or
b) Variation to registration of an ACVM trade name product (ACVM 1V).

The form provides a summary of the application type, the information supplied, and payment options. Some changes have specific application forms in addition to the ACVM 1V form, which can be found in the "vary an existing registration" section in Agricultural chemicals documents, including agricultural chemical registration.

(3) Every application must include a completed Agricultural Chemical Product Data Sheet (PDS) and a draft label. The PDS and the label content will become the point of reference for identifying and characterising your product when it is registered. The trade name of product proposed should be unique and not shared with another product. Only one trade name is allowed per registration. Refer to ACVM Guideline: Labelling Agricultural-Chemicals.

(4) Every application must include an application overview. For more information, refer to section 5 in this document.

(5) Applications for a new registration should include information that identifies and addresses all of the ACVM risks posed by the product.

(6) For an application to vary a current registration, information should be provided to support the proposed change. For more details, refer to section 11 of this document.

(7) The application must include data assessment reports (prepared by an independent data assessor) for each of the data volumes provided. The data assessor should not have any vested interest in the product or be under any obligation to the applicant other than to prepare the assessment report(s). Refer to section 12 of this document for further details.

(8) Papers, articles, documents or information (including public domain information with raw data) referenced in the application, if applicable.

(9) The original document and an English translation if the reference information in (8) above is in a language other than English.

(10) Failure to include all information specified in the relevant guidance documents may result in rejection of the application at technical pre-screen. If you have questions, contact us (approvals@mpi.govt.nz).

(11) Where you propose to provide alternative information to address the requirements, you can request a deviation. For information on deviation, refer to section 13 of this document.

(12) The guidance details advice for common agricultural chemical 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. It is the applicant's responsibility to identify additional hazards, risks and benefits, and address these in the data volumes and application overview.

(13) If uncertain on what to include, contact a competent consultant for assistance.

4.3 Application type

The following application types are used to identify information required:

A1: These are products containing an active ingredient(s) that has not been previously registered as an agricultural compound in New Zealand. For a list of registered products by trade name or active ingredient check the ACVM Register.

A2: These are products only containing an active ingredient(s) that has been previously registered as an agricultural compound in New Zealand. The product proposed has a new risk profile compared to previously registered products (e.g., different formulation type, form of the active ingredient, application method, target pest, or host crops that have not been assessed previously).

B1: These are products that are identical to an existing registered trade name product, except for the trade name.

B2: These are products that are similar to an existing registered trade name product. To be 'similar', the product referenced should have the:

a) same active ingredient(s) in the same form (e.g., same salt, ester, or chain length); and
b) same formulation type; and
c) same host crops/use situations and claims (e.g., target pests, crops, diseases, pests, or effects); and
d) same use pattern (including application rate on an active ingredient basis, timing of application, methods of application and withholding period).

C1: These are applications for any change in the formulation, including changes to the excipients or their quantities.

C2: These are applications for:

a) change in active ingredient and/or formulated product specification and/or test method; or
b) change to manufacturing process and/or quality control; or
c) addition of active ingredient or formulated product manufacturer; or
d) removal of the active ingredient or formulated product manufacturer (where this is the only active ingredient or formulated product manufacturing site approved).

C3: These are applications for:

a) change to the shelf life; or
b) change to the storage conditions; or
c) change to product packaging (e.g. pack size, composition of primary packaging, container closures).

C4: These are applications for extension of use to include an additional host crop/use situation.

C5: These are applications for an addition/variation to the claims to add a new effect or target pests (e.g. to control another pathogen, weed or invertebrate pest or add a new inhibitor or plant growth regulator effect) for an existing host crop/use situation.

C6: These are applications for changes in the use pattern (e.g., change of application rate or application timing), other than a change related to application method (C7) or withholding period (C8).

C7: These are applications for a change to, or addition of, a method of application.

C8: These are applications for a change to a withholding period.

C9: These are applications for administrative changes:

a) changes to label text or layout where the revisions do not alter the approved product profile; or
b) change in trade name only; or
c) change in name, phone number, and/or address of the registrant; or
d) change in name of the manufacturer of the formulated product or active ingredient
e) transfer of registration of a trade name product; or
f) removal of the active ingredient or formulated product manufacturer (where there are more than one active ingredient or formulated product manufacturing sites approved); or

g) addition and/or removal of repacker/relabeller.

C10: These are applications for reassessments of registered agricultural chemicals initiated under Section 29 of the ACVM Act.

C12: These are applications for changes in registration conditions.

Post approval assessment: This is where a registrant has provided information to fulfil a condition of registration set in an earlier registration approval.

Self-assessable change: This means a change MPI allows a registrant to make to a registered TNP without prior MPI assessment or approval. Refer to **Guidance Document: Chemistry and Manufacturing Information for Agricultural Chemicals**.

4.4 Data volumes

(1) Data must be provided in the form of data volumes, also known as data packages or dossiers. The table below lists the application types and the data volumes that are often expected to support each application type.

(2) For variation applications, depending on the ACVM risks identified, it may not be necessary to provide every data volume noted below, or the information required in the data volume may be a subset of the complete data volume, if the information provided is sufficient to address the specific risks identified.

Application Type	Data Volume					
	Chemistry & Manufacture	Efficacy	Plant Safety	Residue	Toxicology	Antimicrobial Resistance
A1: New active ingredient	◆	◆	◆	◆	🇬🇧	♣
A2: Known active ingredient with a new risk profile	◆	◆	◆	◆	🇬🇧	♣
B1: Identical to a registered trade name product	◇	◇	◇	◇		◇
B2: Similar to a registered trade name product	◆	◆	◆	◆		♣
C1: Change in formulation	◆	◆	◆	◆		
C2: Manufacturing related change	◆					
C3: Change in shelf life or packaging	◆					
C4: Additional target host/use situation		◆	◆	◆		♣
C5: Additional pest/disease/weed		◆	◆	◆		♣
C6: Other change in use pattern		◆	◆	◆		♣
C7: Change to application method		◆	◆	◆		
C8: Change in withholding period		◆	◆	◆		
C9: Administrative changes	Explain changes in ACVM 1V form					
C10: Reassessment	◆	◆	◆	◆	🇬🇧	♣
C12: Change of registration condition	★	★	★	★	★	★
Post Approval Assessment	★	★	★	★	★	★

Key

◆ Provide the data information as appropriate to the proposed change(s) or submit a request for a deviation (see section 13) from the information guidance

◇ Data volumes not required when identical to registered product.

🇬🇧 See toxicology requirements (section 9)

♣ For formulations that contain antimicrobial ingredients, see section 10.

★ Information required considered on a case-by-case basis.

4.5 Format of volumes

(1) The data volumes should be provided in full, as an E-file. Details can be found in the ACVM guideline E Files for ACVM Applications. We do not accept data volumes in hard copy.

(2) The data volumes, regardless of size, should include:

a) a contents page; and
b) a summary of the information provided; and
c) an indication of where the referenced information/documents can be found; and
d) an appendix with a full list of studies included in the data volume.

(3) If a deviation assessment has been completed by the ACVM team prior to the submission of a registration application, the letter in support of waiving certain information should be included in the submission.

(4) If a minor deviation is proposed as part of the submission, scientific arguments/justification are expected to be included.

(5) Signed or authenticated copies of documents should be provided. If scanned, documents should be completely legible.

(6) All supporting literature (such as scientific papers) referenced in the application documents should be data assessed and submitted in full.

(7) If documents included public domain information (such as JMPR, APVMA summary), this should be provided with raw data or permission of access to raw data.

(8) If all the technical data is less than 20 pages long, it may be presented as a single dossier with each volume separated by individual identifiers/headings (such as separating the Chemistry and Manufacturing volume from the Efficacy volume). Otherwise, each data volume should be supplied separately.

(9) All files should be named in English and without symbols.

4.6 Reliability of data from research and trials

(1) It is essential that the information you provide is verifiable and reliable. The ACVM team recommends that you emphasise quality control in your design and implementation of research and trials.

(2) The ACVM team expects that the independent data assessor will review:

a) the veracity and reliability of your data; and
b) whether or not the data complies with MPI requirements; and
c) whether or not the data supports your risk analysis conclusions.

Any suspicion of lack of veracity or reliability of data will undermine the credibility of your application and may result in its rejection.

(3) For more information on acceptable research practices, refer to the ACVM Research Standard.

5 Application overview

(1) The application overview must set out the purpose of the application and provide a high level outline of the information submitted to support the application (refer to Section 2.5 of ACVM Requirement: Registration Information Requirements for Agricultural Chemicals').

(2) The application overview should include:

a) a description of what the application is intended to achieve; and
b) the proposed application type(s), including brief description(s); and
c) a brief description of any relevant deviations that have been approved, including the deviation advice application number; and
d) a description of any proposed deviations (including cross-reference requests), referencing where the request and information can be found; and
e) a list of the data volumes and other supporting information submitted; and
f) any other relevant information (e.g., status under other legislation refer to section 15 of this document).

(3) Where additional hazards, risks or benefits, have been identified which are not addressed through the standard expectations of the data volumes, then the Application Overview must explain these, referencing any additional data or information used to support the conclusions.

(4) A registrant applying for a variation of registration must provide an application overview in terms of the change that is proposed.

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

6 Chemistry and manufacturing

6.1 Introduction

(1) The information provided in this volume should define the identity of the trade name product and should follow **Guidance Document: Chemistry and Manufacturing Information for Agricultural Chemicals**. It should also establish the consistency and quality of the product as a basis for consideration of other data sets and wider risk assessment in order to address the ACVM risk areas.

(2) For new registrations (type A and type B applications), all information listed in "**Guidance Document: Chemistry and Manufacturing Information for Agricultural Chemicals**" should be supplied.

(3) For microbial active ingredients, refer to Microbial Agricultural Chemicals.

(4) For variation (type C) applications that include multiple changes, a chemistry and manufacturing data volume should be provided specifically addressing the changes proposed. If the variation information is complicated and/or includes a large amount of data, the ACVM team may ask the applicant to include a data assessment report.

6.2 Alternative formulations under one registration

(1) Based on their risk, an alternative formulation for a trade name product can be registered when the proposed changes do not alter the following properties of the registered trade name product:

a) identity and concentration(s) of the active ingredient(s); or
b) formulation type; or
c) physical and chemical characteristics of the formulated product to the extent that the risk profile under the ACVM Act changes and cannot be adequately managed.

(2) Each alternative formulation should be uniquely identified (e.g., Formulation A, Formulation B; name of manufacturer; etc). All information must be provided for each formulation (manufacturer(s), manufacturing process, specifications).

(3) Where the manufacturing process, analytical methods, specifications etc may be different, these should be provided and clearly marked as to which alternative formulation they are associated with, or it should be clearly stated that the information provided applies to all formulations.

(4) If alternative formulations are requested, the submitted documentation should clearly state which manufacturer manufactures which formulation(s).

6.3 Changes that prompt a new registration

(1) Any of the following changes to a trade name product or its formulation will prompt a new registration:

a) addition, substitution, or deletion of an active ingredient; or
b) change in formulation type; or
c) the change in formulation/alternative formulation proposed alters the risk profile of the trade name product.

(2) There could be other factors that prompt a new registration. These will be assessed on a case-by-case basis.

7 Efficacy and plant safety

7.1 Introduction

(1) Efficacy and plant safety data are required to:

a) be specific to New Zealand, and
b) justify and confirm label uses/claims as appropriate, and
c) facilitate consideration of risks (e.g., agricultural security) and fundamental benefits, and
d) establish consistency with Good Agricultural Practice to facilitate/support residue assessment and promote sustainable use (i.e., reducing the probability of issues like resistance which may impact on agricultural security or other risk areas over time).

(2) Claims should be supported by appropriate trials. Data generated should follow the requirements outlined in the ACVM Research Standard for agricultural chemicals.

(3) For urease/nitrification inhibitor products refer to Efficacy and Plant Safety of Urease/nitrification Inhibitor Products.

(4) For products containing a microbial active ingredient(s), refer to Microbial Agricultural Chemicals.

(5) Specific NZ efficacy guidance has not yet been developed by the ACVM team for other types of agricultural chemicals. For general principles, applicants can refer to publicly accessible Australian Pesticides and Veterinary Medicines Authority (APVMA) or European and Mediterranean Plant Protection Organization (EPPO) documents.

7.2 Overseas data

(1) In most cases, local data are expected, and overseas data are not considered sufficient to stand alone. Overseas data may be submitted in support of local data if appropriate technical arguments are provided. Considerations for extrapolation may include (but are not necessarily limited to) the following:

a) the pest/weed/disease/desired effect is the same as in New Zealand; and
b) the epidemiology/life cycle/behaviour of the pest/weed/disease is similar; and
c) the climate and environmental conditions are similar to New Zealand (this may include soil conditions where applicable); and
d) the grower's cultural practices and crop structure/training are similar; and
e) the use pattern, including application rates, timing, and methods of application, is the same as that proposed in New Zealand; and
f) the target crops/cultivars are similar to those in New Zealand, including susceptibility/sensitivity to the pest/weed/disease/desired effect and sensitivity to phytotoxicity; and
g) susceptibility of the pest/weed/disease (e.g., resistance) is expected to be similar; and
h) consideration of the mode of action relative to the above points; and
i) consideration of any other factors that may have aided control - such as significant levels of natural enemies (not present in New Zealand), or other factors that may have reduced pest/weed/disease fitness/susceptibility.

7.3 Resistance management

(1) Resistance refers to loss of performance of agricultural chemicals due to changes in the overall susceptibility of the target pest in response to exposure to the chemical or class of chemical.

(2) The risk of resistance can be reduced by suitable resistance management. Please refer to the New Zealand Plant Protection Society (NZPPS) website for relevant information.

(3) For specific requirements relating to antibiotic resistance to humans and animals, please refer to section 10 of this document.

8 Residues

8.1 Residues in crops

(1) Residue data must be supplied for products used on/around food and/or feed crops. This is in order to determine the level of certain residues in produce or plants used as animal forage/feed.

(2) The data provided in this volume should comply with the MPI residue guidance document for agricultural chemicals: Residue Data for Agricultural Chemicals.

(3) For products containing a microbial active ingredient(s), refer to Microbial Agricultural Chemicals.

8.2 Animal transfer residues

(1) The use of agricultural chemicals on crops intended for consumption by food-producing animals may necessitate animal transfer residue data for edible tissues of animals (e.g., muscle, fat and offal) or other specified primary produce obtained from an animal (e.g., eggs, milk, and honey).

(2) For more information, refer to section 6.7 of Residue Data for Agricultural Chemicals.

8.3 Maximum residue level (MRL)

(1) If a maximum residue level (MRL) for the active ingredient is required to be established for a food commodity under the Food Act 2014, this should be made clear in the application. Applicants are expected to propose MRLs or an exemption for any novel compound or novel use of an existing compound. For more information, refer to MRL Assessment Process.

(2) If an MRL is required, registration will not be granted until the specific MRL has been set. However, if the MRL meets the current MRL (which is the default of 0.1 mg/kg for food crops if not otherwise specified), the ACVM team may agree to finalise the registration before the specific MRL is set.

(3) To check the current MRL of an active ingredient in a commodity, refer to Maximum residue levels (MRLs) for agricultural compounds (ACVM).

(4) The Health Based Guidance Value (HBGV) for an active ingredient from the Environmental Protection Authority (EPA) is required for dietary intake assessment before an MRL can be set. If EPA has not established an HBGV (known as the Potential Daily Exposure (food) (PDE (food))) for the active ingredient, please contact the ACVM team for advice.

(1) For microbial active ingredients, data may be needed to confirm that the active fits the 'Microbial Active Ingredients" listing in Schedule 2 for agricultural chemicals to which an MRL does not apply. This should be done before a product containing the new microbe(s) can be registered for use on a crop that would enter the food chain.

9 Toxicology and pathogenicity

(1) Submitting toxicological or pathogenicity data is not a standard requirement for most applications. However, occasionally MPI may request these data on a case-by-case basis, where it is deemed relevant to ACVM risk thresholds.

(2) When these occasions arise, it is generally related to the potential for food safety concerns associated with novel compounds where an EPA approval is not required. There could also be rare occasions

where we need to assess these data even if assessed by EPA for different purposes. This may include active ingredients presented as nanoparticles or microbials with potential pathogenicity to humans.

(3) The submission of toxicology data and information under these situations should usually be the same as that submitted to the EPA for assessment.

10 Antibiotic resistance

(1) Applicants of agricultural chemicals containing antibiotics must provide information addressing the potential risk for development of antimicrobial resistance of relevance to humans, animals, plants and the environment and discuss the risk versus benefits of the agricultural chemical use.

(2) This information should discuss:

a) antimicrobial class, including chemical structure and name of active ingredient; and
b) importance of the antimicrobial class, or related classes, to human and veterinary medicine; and
c) whether products of the same class are used in humans, animals or plants; and
d) details of mechanism of action, including if the compound bacteriostatic or bactericidal; and
e) antimicrobial spectrum of activity; and
f) minimum inhibitory concentration data for target pathogens. Strains of pathogens tested should be from target crops and recent isolates; and
g) antimicrobial resistance mechanisms and genetics; and
h) occurrence and rate of transfer of antimicrobial resistance genes; and
i) occurrence of cross resistance; and
j) persistence on plants or in the environment, including measures which can be taken to minimise unnecessary bacterial exposure; and
k) available non-antimicrobial alternatives.

11 Variations to a current registration

11.1 General information

(1) Once a product is registered, registrants are required to ensure the product's registration is maintained and kept up to date. Registrants may also wish to alter the registration to change or upgrade chemistry or manufacturing information, to add or remove claims or target crops or species or make other changes that would alter the information held for that product.

(2) Changes to a product registration is done through a variation application. MPI assesses the change relative to the product's previously assessed risk profile to determine if the change may be granted or refused. For an understanding of the types of variation applications see section 4.3 of this document.

(3) Changes must be approved before they are implemented.

11.2 C1-C8 application

(1) The data and information required to support the proposed variation will depend on what kind of changes are being made, and how significant of an impact the change will have on the previously assessed risk profile. For example, a change in shelf life (C3) may only require the stability section of the chemistry and manufacturing information requirements document to be addressed.

(2) All proposed variations should address the change(s) and resulting impacts (e.g., change of formulation and its impact on product profile). If the change alters the previously assessed risk profile, it should be supported by data and/or information. It is not sufficient to only state that the efficacy, safety, residues, and/or stability profile of the product are not impacted by the change; there should be

a technical argument or other information/data provided to demonstrate why the product's risk file is unaffected. For these changes, refer to section 6 to 8 of this document to consider all risk areas.

11.3 C9 application

(1) If the C9 application is the only one made at the time, the applicant should declare that there are no other changes made.

(2) You may also include self-assessable changes alongside the C9 application.

11.4 C10 application for reassessment

(1) An application for reassessment of a registered trade name product, or a similar group of trade name products are treated in a similar manner to an application for registration. The reassessment process (authorised under Section 29 of the ACVM Act) potentially culminates in one or more C10 application(s) being made for the affected trade name product(s).

11.4.1 Pre-reassessment

(1) This process commences when significant new information is received. This can be from any source, such as the registrant, third parties or the ACVM team. The type of new information could be either from domestic sources such as results of monitoring programmes, or from international sources such as overseas regulatory authorities, or by the registrant as required by the conditions of registration.

(2) This information is reviewed, and affected registrants are consulted. It is then determined whether it is significant enough to warrant a review of the existing risk profile: if it is, a reassessment is proposed for the product or products impacted by the new information; if it is not, the information is recorded, and a watching brief may be instigated to monitor the situation as it progresses.

11.4.2 Proposal and consultation

(1) If the decision is made to propose a reassessment, affected stakeholders are informed of the reassessment proposal, and feedback is requested. Following consideration of feedback, a decision is made on whether to proceed with the formal reassessment. Where reassessment is triggered, the registrant is required to submit a C10 application to action the reassessment and any subsequent changes. The information required to support a reassessment application varies, as it depends on the scope of the reassessment and the impact of the new information on the risk profile. The type of information and data required with the application would be detailed in a letter advising the registrant that a formal reassessment will proceed. Data or information submitted under a C10 reassessment application is eligible for CI protection (data protection).

11.4.3 Reassessment and appraisal

(1) Once the applications for reassessment variations are accepted by the ACVM team, relevant products undergo public notification. The reassessment appraisal will be completed/finalised after the public notification has closed, taking into consideration any submissions received. The reassessment process ends after the delegate decision is made.

11.5 Changing registration conditions

(1) A C12 variation is for change of registration conditions. The ACVM team assesses the information submitted to decide if a condition can be changed.

(2) The expectation of a C12 application is for the registrant to submit all relevant information. The most common situation is to remove condition 101 or condition 86 as part of an application where other

changes are being made. If no other changes to the registration are being proposed, fufillment of the requirements of a condition such as 86, 101 or 107 can be done as a post-approval assessment (see below). Condition 86 prohibits the sale of the product from a new manufacturing site before the submission and approval by MPI. Condition 101 is less specific and can be used to require any additional information specified by MPI to be provided at or before the registration expiry. The information required to satisfy these conditions will have been advised in the approval letter at the time the application was granted.

11.6 Post approval assessment

(1) Conditions of registration requiring additional data to be provided may be fulfilled using a post approval assessment. No other changes are made during a post approval assessment. The ACVM team assesses the information submitted (e.g., batch analysis to fulfil condition 86) to decide if a condition has been fulfilled.

(2) You will receive advice on the acceptability of the additional information.

12 Data assessment

(1) For all new registrations or applications with significant data volumes (e.g., C4, C5 application), the ACVM team requires the submission of independent data assessment reports. These data assessment reports serve to ensure that the data submitted to support an application is compliant with ACVM policies and guidance and are sufficient to allow for technical assessment.

(2) The appropriate templates must be used. Template of the DAS can be found on Data assessors for ACVM registration data assessment reports.

(3) It is the applicant's responsibility to choose and contract an appropriate data assessor(s) to carry out the assessment(s). The data assessor(s) should have suitable qualifications and experience in the area they are being asked to assess.

(4) The ACVM team maintain a list of data assessors who can provide this independent assessment service to registrants:

ACVM: Listed Data Assessors

(5) Data assessment may alternatively be undertaken by the ACVM team. This is a discretionary service.

(6) Data assessment must be undertaken by an independent data assessor. Expectation for an independent data assessor is that:

a) they must not be an employee of the applicant (other than receiving payment for the data assessment or expert opinion requested); and
b) they must not otherwise have a vested financial interest in the applicant company, or products or services they provide; and
c) they must not have otherwise been involved with the application in any other capacity, including:
    i) providing advice or consultancy services related to the application, or
    ii) being responsible for designing, undertaking, quality assurance (QA) or oversight of trial work, or
    iii) collating, preparing or writing of reports, data, data volumes or other information supporting the application.

(7) The data assessor will assess the data and supporting information supplied by the applicant in the data volume (including journal papers etc.) to identify any non-conformances to ACVM requirements and make a recommendation with respect to whether the registration or variation is supported by the information available.

(8) You should address all non-conformances prior to submission of the application either by supplementing the original dossier with relevant additional data and information (clearly identified as supplementary information in the dossier), or by requesting a deviation.Where additional data is supplied, it may require assessment by the data assessor. This generally would not be expected for minor deficiencies.

(9) Where additional information is supplied to the data assessor, then you should make sure to include this additional information/correspondence with the submission to ACVM.

(10) Applications submitted with non-conformances identified by the data assessor that have not been addressed by the applicant, will not progress beyond the technical pre-screen.

13 Deviations

13.1 Purpose

(1) If the applicant believes that certain data is not necessary or alternative data/information is appropriate to meet the expectations outlined in ACVM Information Requirements and guidance, an applicant can request a deviation.

13.2 Information required for deviation application

(1) A technical discussion letter and supporting information, explaining why a deviation from the expectations is acceptable, should be provided.

See Deviation from Information Specified in the ACVM Registration Information Requirements for more details.

(2) The deviation request can be made separately and prior to the application. The ACVM team will provide written advice on the outcome of the request (i.e., the deviation advice letter). Alternatively, where the deviation is minor, the request may be made concurrently in the registration application (e.g., straightforward cross-reference to data held for a similar trade name product that is not subject to data protection). However, ACVM reserve the right to require a deviation to be processed separately from an application if they believe this is warranted.

(3) If the deviation argument is based on a combination of specifically generated data and equivalence to an agricultural chemical product already considered by MPI, a science-based rationale for equivalency and relevance should be provided by the registrant. The rationale should show how the combination of sources collectively create a complete and relevant risk analysis, particularly if you have not specifically complied with the information requirements. For products already registered by MPI, data protection may be in place and cross referencing may not be possible (refer to section 14 of this document).

(4) Where the deviation request has been completed prior to submission of the application, the ACVM deviation advice letter should be included with the registration application. Please note that any differences from the original information provided may invalidate the deviation letter.

(5) Failure to include the deviation letter may result in rejection of the application at technical pre-screen.

(6) While every effort is made to ensure that deviation outcome advice is appropriate, MPI will consider the application in its entirety (including the deviation advice and any new or additional information at hand) during regulatory appraisal of the subsequent application.

14 Protection for confidential information (data protection)

14.1 Eligibility

(1) Confidential information (CI) submitted with an application for the registration of a trade name product that contains an 'innovative agricultural compound' (A1 registration) will be eligible for CI protection (also known as data protection).

(2) Certain other application types may be eligible for CI protection. For instance, a C4 new use application affords CI protection for efficacy and residue data.

(3) To determine whether your application is eligible for CI protection please refer to:

Protection of Confidential Information about Trade Name Products (ACVM guidance)

Identification of Confidential Information for the Purpose of Data Protection (ACVM 1DP form)

(4) For other information on protection of confidential information about trade name products, refer to section 6 of the ACVM Act.

(5) Where information is not eligible for CI protection, or once the period of protection expires, confidential information will be treated as commercially sensitive. This means that while the product can be cross referenced, ACVM will not disclose the information unless required to do so (for example, if the information is requested under the Official Information Act, and the request is upheld).

14.2 Other information

(1) For a new registration that contains a novel active ingredient, to be eligible for CI protection under the HSNO Act, the application has to be submitted and received under the ACVM Act first (Note that 'received' means the application has been formally received into the registration process, i.e., accepted at technical pre-screen).

(2) 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 from the organisation holding the CI protection during the protected period authorising cross-reference to their data.

15 Other legislative requirements

15.1 EPA approval under the HSNO Act

(1) Under section 21(5) of the ACVM Act, MPI 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 organism has been issued under the Hazardous Substances and New Organisms (HSNO) Act 1996. The HSNO Act is administered by the Environmental Protection Authority (EPA).

(2) If your product contains a hazardous substance, or if you are unsure whether it does, contact the Environmental Protection Authority.

(3) HSNO status must be obtained before registration will be issued:

a) section 26 determination or Status of a Substance that the substance is covered by an existing approval issued by the EPA; or HSNO Approval; or
b) self-determination that the product fits an existing HSNO or group standard approval; or
c) self-determination that the trade name product is non-hazardous.

(4) If you have self determined that a product fits an existing HSNO approval or group standard, this should be made clear on your application form.

(5) MPI will accept a declaration if you have self-determined that the agricultural compound you wish to register is not a hazardous substance. The declaration must be in writing on company letterhead. If concerns are identified we may require you to provide a technical argument as to why the ingredients in the product are non-hazardous to support your declaration. If MPI is not certain that the determination is correct, we will advise you to obtain a determination by EPA.

For a product to be considered non-hazardous, it must either contain no hazardous substances as defined under the HSNO Act or contain a hazardous substance at a low enough level that the product as a whole is considered non-hazardous.

(6) If the product contains a live organism, contact the New Organisms Group of EPA for a determination under section 26 of the HSNO Act (neworganisms@epa.govt.nz).

(7) For registrations containing a novel active ingredient, data protection under the HSNO Act will not occur unless the application has already been formally accepted under section 9 of the ACVM Act. It does not apply retrospectively. Please refer to section 14 of this document for more information about confidential Information protection.

15.2 Ministry of Health consent

(1) Under section 21(4) of the ACVM Act, MPI is not permitted to register a trade name product without the consent of the Director-General of Health if that product is a prescription medicine within the meaning of section 3 of the Medicines Act 1981.

(2) The Ministry of Health may also be consulted when public health could be impacted by the registration of a trade name product (e.g., relative to antimicrobial resistance concerns). This situation occurs rarely and other than the requirements relative to antimicrobial resistance discussed in section 10, there are no standing information requirements. If your application does trigger Ministry of Health interest, MPI will advise what additional information you should provide under section 11 of the ACVM Act.

15.3 MPI Biosecurity New Zealand approval

(1) Biosecurity assessment is required for import of products that constitute, or contain, ingredients originating from organisms such as plant, animal, fungus, bacteria, and virus. These assessments aim to confirm that the importation of such products complies with the existing standards outlined in the Biosecurity Act of 1993.

(2) A request for the Biosecurity assessment can be submitted as part of the ACVM application process, and the biosecurity assessment will be conducted by Biosecurity New Zealand in parallel with the ACVM assessment. Relevant guidance can be found in Biosecurity Approval of Imported Agricultural Compounds and Veterinary Medicines.

(3) If an ingredient does not meet the requirements of Biosecurity New Zealand, the ACVM registration will not be granted. The biosecurity requirement is in place to prevent the introduction of unwanted organisms into New Zealand and to mitigate the biosecurity risks associated with the products.

(4) A separate import permit is no longer required for registered product under Requirements documents for importing microorganisms, as this is considered as part of the overall ACVM assessment. However, for products that are exempt from ACVM registration, an import permit is required.

(5) Contact the Plant Product Imports team for more information on the biosecurity approval and import permits (Plantimports@mpi.govt.nz).