New Zealand Food Safety
Haumaru Kai Aotearoa

ACVM 101

An Introduction to Agricultural Compound Regulation and Registration in New Zealand

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Te Kāwanatanga o Aotearoa
New Zealand Government

Ministry for Primary Industries
Manatū Ahu Matua

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This guidebook has been compiled to provide summary guidance on the overall processes and requirements associated with product registration and registration maintenance. For more detail on each topic, and for all the most up to date information, guidance material, and forms, please visit https://www.mpi.govt.nz/processing/agricultural-compounds-and-vet-medicines/.

1 Agricultural Compounds and Veterinary Medicines: An Overview

1.1 The ACVM Act

1.1.1 Agricultural Compounds

The term ‘agricultural compounds’ refers to substances intended for use on or in plants and animals, and includes veterinary medicines, agricultural chemicals, and vertebrate toxic agents (VTAs). These compounds require authorisation under the Agricultural Compounds and Veterinary Medicines Act 1997 (the Act) before they can be imported, manufactured, sold, or used in New Zealand. This authorisation can take the form of either registration under the ACVM Act, authorisation by exemption conditional on compliance with the ACVM (Exemptions and Prohibited Substances) Regulations 2011 (the Regulations), or authorisation by exemption by approval in special circumstances (section 8C of the Act). The Act and Regulations are administered by the ACVM team of the Ministry for Primary Industries (MPI).

The ACVM Act defines an agricultural compound as:

> (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).

Agricultural compounds used for the purposes of mitigating the adverse impacts of agricultural activity on the environment or climate change are collectively known as inhibitors. A list of inhibitor substances currently captured as agricultural compounds has been notified in an Order in Council under the Act, which requires the registration of these specified substances before they can make claims for inhibitor activity. Inhibitor compounds already in the market with such claims at the time the Order was put in place are permitted to remain on the market for a period of two years while seeking registration. Going forward, there is work underway on the Act to capture all inhibitors as agricultural compounds, with the authorisation pathway (registration vs. exemption) to be dictated by compound-related risks.

Agricultural Compounds and Veterinary Medicines (Inhibitor Substances) Order 2022

1.1.2 Managing risks under the ACVM Act

Section 4 of the Act specifies that its purpose is to prevent or manage risk associated with the use of agricultural compounds. The risks to be considered under the Act are the:

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

This section also requires that the use of agricultural compounds will not result in breaches of domestic food residue standards, and that there is sufficient consumer information provided to users about agricultural compounds.

The rest of the Act specifies the details on how agricultural compound trade name products are to be regulated, including the requirements around public notification, assessment, registration, and protection of confidential information (data protection). The Act also outlines requirements around other regulatory functions to manage agricultural compounds such as reassessments, product cancellations, offences, and compliance actions, as well as enabling persons, classes of persons, and agencies to be recognised to carry out certain functions and activities such as veterinarians being recognised to authorise the use of restricted veterinary medicines.

Under the Act, agricultural compounds requiring registration under the ACVM Act must be evaluated to determine the risks and benefits based on all relevant scientific and technical information available for review, the impact the agricultural compound's availability may have on New Zealand's international obligations, assurances, and reputation, and any submissions received from other authorities or the public during the notification process. Registration can then be granted if it is determined that the risk associated with the compound can be managed through imposing conditions of registration and other regulatory controls on its import, manufacture, sale, and use.

Agricultural Compounds and Veterinary Medicines Act 1997

Risk management under the ACVM Act overview

1.1.3 Managing risks under the ACVM (Exemptions and Prohibited Substances) Regulations 2011

The ACVM (Exemptions and Prohibited Substances) Regulations establish the requirements that must be complied with for a product to be considered exempt from registration under the Act. The agricultural compounds eligible for exemption from registration are specific types or groups of products listed in Schedule 2 of the Regulations that have been determined to have similar risk profiles that can be managed by compliance with the general and group-specific conditions of exemption.

To be eligible for exemption from registration, a substance must:

1. Be classed as an agricultural compound according to definition specified in the Act, and used for a listed purpose, and
2. Fit one or more exemption entries for agricultural compounds described in Column 1 of Schedule 2, and
3. Comply with all Column 2 conditions applicable to the relevant exemption entry or entries, and
4. Comply with all relevant requirements in Regulations 4 through 15.

Regulations 4 through 15 detail the requirements for the agricultural compound to be fit for purpose, establish expectations on manufacturing quality controls, specify documentation and record-keeping requirements, specify the information required on product labels, and prohibit the advertisement of misleading statements. The conditions of exemption in Schedule 2 are compound- or group-specific risk mitigation requirements and will include certain substances not permitted in exempt substances, additional required approvals such as operating plans, labelling and user information requirements, and other requirements that must be met to enable exemption from registration. Companies seeking assistance in determining whether their product is eligible for exemption from registration can request

advice through a class determination. Class determinations are also helpful to facilitate the import of products exempt from registration into New Zealand (see section 1.4.4.2).

Compliance with the ACVM (Exemptions and Prohibited Substances) Regulations is largely self-directed, with companies expected to be aware of and comply with all requirements. If ACVM become aware of a non-compliance, the ACVM team will contact the company to identify the breach and help bring them back into compliance; more information on compliance actions can be found in Section 4.6.

Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011

1.1.4 ACVM Notices

The ACVM Act also allows for tertiary-level notices to give effect to and manage specific regulatory controls under the Act and Regulations. There are currently four notices in effect:

1) **ACVM Notice: Imported Feed Commodities (2014):** outlines the general requirements for the importation of feed commodities, and specific requirements regarding the importation of palm kernel expeller (PKE) for use as animal feed;
2) **ACVM Notice: Requirements for Authorising Veterinarians (2015):** specifies the requirements for veterinarians authorising restricted veterinary medicines (RVMs);
3) **ACVM Notice: Agricultural Compounds Exempt from Registration (2020**): provides more detailed information on the requirements for products to be and remain exempt from registration, including obligations around fitness for purpose, manufacturing, information that should be provided to the end user, and record-keeping; and
4) **ACVM Notice: Fertilisers, Plant Biostimulants and Soil Conditioners (2024):** specifies the additional requirements for fertilisers, plant biostimulants and soil conditioners.

1.1.5 Updates to Legislation and Regulatory Instruments

The Act and Regulations are primary and secondary legislation requiring Parliamentary approval to consult on and action amendments. As a result, these kinds of changes tend to happen much less frequently than tertiary instruments (e.g. Notices) and operational documents such as guidance and forms. Proposed changes to the Act and Regulations are usually batched and actioned through a process of public consultation and amendment run by MPI's Food Policy team rather than by the ACVM team.

The ACVM Notices under the ACVM Act and the Food Notice: Maximum Residue Levels for Agricultural Compounds enacted under the Food Act 2014 are directly managed by the ACVM team. The ACVM notices are reviewed periodically to both update content and add new information as needed, while the Food Notice being updated four times a year as new and amended content is required.

Legal framework for food safety in New Zealand

Food Notice: Maximum Residue Levels for Agricultural Compounds 2025

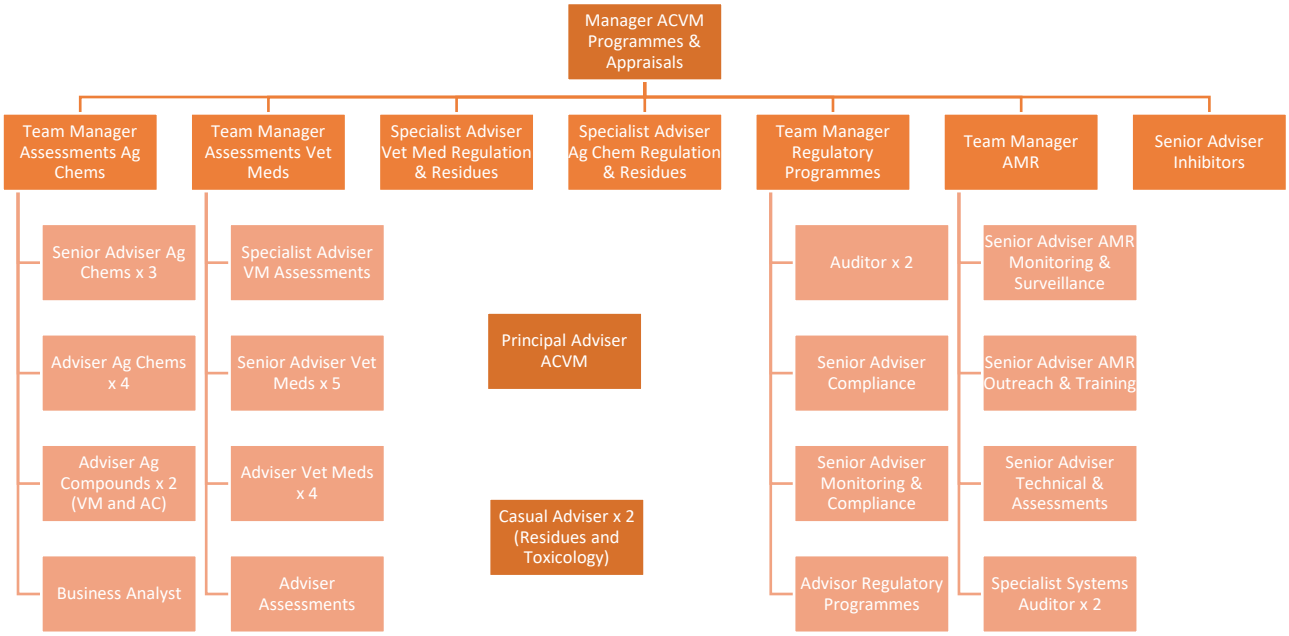
1.2 The ACVM team

The ACVM team are part of the Assurance directorate in the New Zealand Food Safety business unit of MPI. The team's primary responsibility is the administration of the ACVM Act and ACVM Regulations, and therefore managing the regulation of all agricultural and horticultural inputs into the primary industries as well as products for companion animals and home garden use. This is done by conducting independent assessment and review of all products requiring registration to ensure the associated risks for product manufacture through to market release are effectively managed. The team is also responsible for monitoring compliance with the Act and Regulations for both registered and exempt products post-authorisation, evaluating and approving variations to existing registrations, and periodic review and reassessment of products as new information becomes available.

In addition to work regulating agricultural compounds, the team are also responsible for:

- Good Manufacturing Practice (GMP) audits to verify compliance with GMP, and issuing GMP Certification to support both New Zealand product registration and market authorisation internationally;
- Administering the Adverse Event system which monitors adverse events associated with use of agricultural compounds and veterinary medicines;
- Monitoring compliance with ACVM requirements throughout the lifecycle of a product (manufacturing, importation, sale and use);
- Assessment and approval of the use of experimental agricultural compound formulations through trial approvals (research approvals and provisional registrations);
- Assessment and setting of agricultural compound maximum residue levels (MRLs), and the listing of compounds for with no MRL applies, under the Food Act 2014;
- Drafting and maintaining ACVM guidance documents, forms, and website content related to the management of agricultural compounds; and
- Drafting and maintaining ACVM operational policy, tertiary instruments like Notices, and work on primary and secondary legislation with the MPI Policy team.

Figure 1: ACVM Team Structure as of June 2025



Because agricultural compounds include veterinary medicines, agricultural chemicals, vertebrate toxic agents as well as other agricultural, veterinary, and plant management inputs, it is essential that the team consider potential impacts of their use on all areas managed by wider MPI to ensure all risk areas are effectively managed. To accomplish this, the team have close working relationships with the following key teams:

- **Chemical and Microbiological Assurance team, Assurance Directorate, NZFS.** Responsible for managing and maintaining the National Chemical Residues Programme (meat, fish, and honey), National Chemical Contaminants Programme (milk and dairy products), and the Food Residue Survey Programme (retail-level horticultural commodities). These programmes function to verify that the controls in place on agricultural compounds remain fit for purpose and support Good Agricultural Practice with respect to residues in food, so a close working relationship with the ACVM team is an important feedback loop. Work with the CMA team also includes a relationship with MPI's Verification Services Directorate, responsible for field assessments on-farm and at meat processing facilities to oversee and verify day-to-day primary industry practices.
- **Food Risk Management Directorate, NZFS**. The Food Risk Management Directorate is responsible for administering the Animal Products Act, which regulates all meat, dairy, and poultry products and their processing. In addition to the activities related to the regulation and

oversight under the Animal Products Act, the Directorate captures other food risk management functions such as Readiness and Response, Food Compliance, and Principal Advisers for Meat, Dairy, Animal Products, Food and Wine Systems, and Food Risk Management. The Food Risk Management teams work with ACVM to ensure that issues in the primary animal industries, particularly those associated with or involving agricultural compounds, are managed as comprehensively and effectively as possible.

- **Food Risk Assessment, Food Science & Risk Assessment Directorate, NZFS**. The Food Risk Assessment team provides the ACVM team with technical expertise in toxicology and risk assessment for food for human consumption when required to inform both trade name product assessments and post-authorisation issues as they arise.
- **Plant Exports, Import & Export Standards Directorate, Biosecurity New Zealand**. The Plant Exports team work closely with the horticultural industries to facilitate trade in horticultural products. The ACVM and Plant Export teams work closely together, particularly with respect to horticultural residues management, to support the horticultural industries and export trade.
- **Implementation and Approvals, Biosecurity Import and Export Standards, Biosecurity New Zealand.** The Implementation and Approvals team, which consists of the Animal Approvals and Advice and Plant Approvals and Advice teams, manage the biosecurity assessments and approvals associated with all agricultural compounds containing ingredients of biological origin. Their work is integral to ACVM work in the management of agricultural compounds and maintenance in product registrations while maintaining biosecurity and agricultural security for New Zealand.
- **Bilateral Relations and Trade, Trade and International Relations, MPI Policy and Trade**. The effective management of agricultural compound residues in export commodities is integral to trade risk management, particularly with respect to export trade in animal commodities subject to official MPI assurances. ACVM work closely with the different regional teams in the Bilateral Relations and Trade (BRT) team to discuss region-specific and general trade issues and provide technical advice on trade risk management. This includes providing ACVM input into market access work such as overseas competent authority audits and reporting functions, as well as receiving advice on trade risk from the BRT teams where needed for agricultural compound assessment and reassessment. ACVM also work closely with BRT on international liaison work with overseas authorities such as Codex Alimentarius Commission responsible for international food standards.

Because agricultural compounds are central to the health and function of the primary industries, other teams and directorates within MPI such as the MPI legal teams, policy teams, communications teams, and others, are important to the legislative and regulatory role the ACVM play in supporting their stakeholders.

External to MPI, the ACVM team have close working relationships with other New Zealand government agencies involved directly and indirectly with agricultural compound regulation. These include the Environmental Protection Authority (EPA), from which approval is required prior to product registration; the Ministry of Health, from which consent is required prior to the registration of agricultural compounds containing prescription medicines as defined in the Medicines Act; and the Ministries involved in supporting export trade such as the Ministry of Business, Innovation and Employment (MBIE) and the Ministry of Foreign Affairs and Trade (MFAT).

In addition to working with other government agencies, the ACVM team engage regularly with agricultural, veterinary, horticultural and vertebrate pest management sector organisations to support these sectors and ensure a clear understanding of and involvement in agricultural compound regulation. The ACVM team hold regular meetings with primary industry stakeholders in both technical and policy forums, and members of the technical team are involved in regular industry-led meetings in the horticultural, dairy and meat sectors.

Finally, the ACVM team regularly engage with international authorities responsible for agricultural compound regulation in regular regulator forums. Attendees at these forums include the Australian Pesticides and Veterinary Medicines Authority (APVMA), the United States Food and Drug Administration (veterinary) and Environmental Protection Agency (agricultural chemicals), the Canadian Veterinary Drugs Directorate and Health Canada, and the UK's Veterinary Medicines Directorate and Health and Safety Executive.

Agricultural Compounds and Veterinary Medicines Section of the MPI Website

New Zealand Food Safety Section of the MPI Website

MPI Overseas Market Access Requirements

New Zealand Environmental Protection Authority

Ministry of Health

1.3 Approvals under the Act

1.3.1 Section 21: Trade Name Product Registrations

The ACVM Act sets out the requirements and processes for the registration of agricultural compound trade name products. Section 21 of the Act details the requirements associated with making a decision to register a trade name product and specifies that the product must only be registered after a full evaluation of the risks and benefits associated with the product's manufacture and use. Section 21(d) specifies that products can be registered with or without conditions being imposed to manage the risks associated with use while imposing the least cost on the public. Because of the inherent risks associated with agricultural compounds and their manufacture and use, all trade name products have conditions applied at the time of registration. See section 4.1, Appendix 1, and Appendix 2 for more information on the conditions of registration.

Section 21 also outlines the reasons the Director-General may refuse to grant registration. These are either that the risks associated with the product's registration are so significant that they cannot be adequately managed by imposing registration conditions (including risks to New Zealand's assurances and reputation), or that there is insufficient information available to assess the risks and potential mitigation options. For most products, the risks associated with products can be managed through conditions of registration and other regulatory controls such as MRL setting.

Once a decision has been made to register a product, additional sections of the Act will apply. These include section 22 (terms of registration - registration periods, *Gazette* notification requirements when registration ceases), section 23 (conditions of registration – what kinds of conditions may apply to a registered product), section 24 (register of trade name products – that a register of registered trade name products must be maintained, and what details must be included), and section 25 (certificate of registration – that a registration certificate must be issued). Part 5 of the Act, relating to offences, and Part 6 of the Act, relating to protection of confidential information, will also apply to products in the market and the information held by the ACVM team for that product, respectively.

1.3.2 Sections 27 and 8C: Provisional Registrations and Research Approvals

Section 27 of the Act allows for the provisional registration of a trade name product to allow the registrant to obtain further information through trial work to support registration or conduct research on the trade name product for another purpose. Approvals can only be granted under section 27 where the compound has the characteristics of a trade name product such as having a fixed formulation. Data and information provided to support provisional registration under section 27 also attract protection of confidential information provisions under Part 6, as they are classed as trade name products.

In situations where a substance will be used as an agricultural compound in research but does not have the characteristics of a trade name product, such as active ingredients administered alone or in a simple carrier, it is approved for use in trial work under section 8C of the Act. Section 8C allows for authorisation of any compound that does not otherwise conform to other mechanisms of approval, and typically attracts similar controls as provisional registrations with respect to compound use and disposition of crops and animals.

The section 8C and 27 types of approvals are more commonly used in veterinary medicine research and are collectively known as trial approvals. There is a specific application form and guidance document available for veterinary medicine trial approvals, that covers requirements for simultaneous approvals under the ACVM, Animal Products, and Biosecurity Acts, and provides additional information on requirements under the Animal Welfare and Hazardous Substances and New Organisms (HSNO) Acts.

ACVM Guidance: Veterinary Medicine Trial Approvals

Veterinary Medicine Trial Approval Data Sheet (ACVM 81)

Section 8C and 27 approvals can also be used for research conducted on agricultural chemicals and vertebrate toxic agents (VTAs), though it is noted that it is more common for agricultural chemicals to use the Research, Testing, and Teaching/Training (RTT) operating plan mechanism discussed in the next section.

Provisional registration in New Zealand information requirements

Provisional registration product data sheet template (ACVM 21)

Research approval information requirements

Research approval template (ACVM 22)

1.3.3 Other approvals under Section 8C of the Act

The purpose of section 8C of the Act is to enable the Director-General to allow the importation, manufacture, sale, or use of an agricultural compound without registration even if registration would normally be required. Apart from use to grant approval for research involving compounds that would normally be subject to registration but do not meet the criteria for either trade name product or provisional registration, it is also used to approve the importation of agricultural compounds under special circumstances. The main criteria for this type of approval are that there are no suitable TNPs available in New Zealand for use, and that the identity and quantity of the product being requested can be sufficiently justified.

Most of these requests are from veterinarians seeking to import a veterinary or human medicine from overseas for therapeutic purposes with the expectations that the request is made in accordance with the Veterinary Council of New Zealand's Code of Professional Conduct and its authorisation decision cascade for a patient under the authorising veterinarian's care. Special circumstances approval can also be granted for unregistered agricultural compounds used in border management (import and/or export of live animals and plants), incursion and biosecurity responses, and other management strategies relevant to the ACVM risk areas where there are no suitable New Zealand-registered products available for use. The TNP must still meet all relevant requirements under other legislation (e.g. HSNO Act, Biosecurity Act).

Authorisation of veterinary medicines under special circumstances

1.3.4 Section 28 Approvals: Operating Plans

In certain circumstances, an operating plan may be required to manage specific aspects of an agricultural compound's risk profile, for either individual compounds or a group of compounds. Simply put, an operating plan is a document which outlines the risks associated with the nominated activity, and the steps the plan owner will take to mitigate and manage those risks. An operating plan may be approved under section 28 in the following risk management situations:

- as a condition of registration, where the standard conditions of registrations are considered insufficient to manage the product-specific risks, or
- to enable exemption from registration under section 8A of the Act as part of a condition in the Regulations, in association with the 'own use' exemption category (Schedule 2, Part A, entry 2) or the RTT exemption category (Schedule 2, Part A, entry 3), or
- as part of the recognition of an agency, a person, or a class of persons under Part 3A of the Act.

The most common use of operating plans is the requirement for good manufacturing practice (GMP) approval under condition 62 for veterinary medicines and under condition 2 for VTAs. GMP requirements associated with initial and ongoing trade name product registration are discussed in section 2.2.1.

The second most common application of the operating plan is under section 8A of the Act, through the approval of an operating plan to undertake RTT activities. Generally referred to as RTT OPs, these plans specify the activities to be undertaken and all controls applied to those activities to mitigate risk,

including residue risk, that will manage the activities associated with use of agricultural compounds. For veterinary medicines, these are commonly associated with registrant use of laboratory animals, and with research organisations and universities with permanent trial animal populations. For agricultural chemicals, use of an RTT OP is more common for general trial work in horticultural crops than section 8C or 27 approvals.

Other common applications of an operating plan are:

- **RVM Sellers**. If restricted veterinary medicines (RVMs) are being sold by anyone other than a registered practicing veterinarian issuing an authorisation for an animal under their own care, the entity must hold a RVM seller operating plan approval. More information on drafting such an operating plan and obtaining RVM seller approval can be found in the RVM sellers guideline linked below. Approved RVM Sellers are also listed on our website.
- **Management of a TNP with a significantly high risk profile.** The requirement for an operating plan is mandated through a condition of registration. It will be applied when more specific controls are required that cannot be achieved by standard registration conditions. Product-specific operating plans usually manage the distribution and use of certain products such as hormonal growth promotants (HGPs) or other compounds that can pose significant residue and trade risks (e.g. ractopamine).
- **Third party uses.** Product-specific operating plans may also be used to allow a third party organisation to use a TNP for a specified purpose and will include roles, responsibilities and activities in scope for the plan.
- **Recognition of an agency, person or persons under Part 3A of the Act.** Part 3A of the Act outlines who may be registered to undertake certain activities relating to agricultural compounds, how they are recognised, and other matters relating to maintaining recognition. The recognition provisions in the Act are rarely used, so this use of an operating plan is not commonly applied.

Some of these operating plans have specific templates available (links below). Alternatively, you may design an operating plan that fits your needs provided it adequately identifies and manages all associated risk areas.

Once assessed, the operating plan is approved by ACVM and must be complied with in its entirety. Any proposed amendments to the approved plan, including administrative amendments such as a change in personnel, must be approved before the change can be implemented on site. For most plans, approval is granted for a period of three to five years after which it must be renewed. Renewal typically involves review and updating by the plan owner, followed by submission to ACVM for review and approval of the revised plan. Most renewals will also require documentation to inform a desktop audit of compliance with the plan and to ensure that the operating plan is working as intended.

ACVM Guideline: Operating plans relevant to the ACVM Act 1997

RTT Operating Plans

- **ACVM Guideline: Operating plan for agricultural compounds used under the regulatory exemption for research, testing and teaching/training purposes**
- **ACVM 26A: Application Form for Operating Plans for Agricultural Compound Use under the RTT Exemption**
- **ACVM 26: Operating Plan Template for Agricultural Compound Use under the RTT Exemption**

RVM Seller Operating Plans

- **ACVM Guideline: Operating plans for RVM Sellers**
- **ACVM 28: Operating plan template for RVM sellers**

Restricted veterinary medicine (RVM) sellers list

HGP Operating Plans

- **ACVM Guideline ACVM expectations of HGP sellers with an approved operating plan**
- **ACVM 27: Operating plan template for HGP sellers**

1.4 Other work undertaken by the ACVM team

1.4.1 Reassessments

Sections 29 (trade name product registrations) and section 30 (provisional registrations) allow for the reassessment of a registered product or group of products if there is found to be sufficient new information to draw the original assessment and risk profile into question. The first step in the process is to consult with the affected registrant(s) on a proposal to reassess, including a summary of the new information triggering considerations. Feedback on the proposal is then considered, and a decision is made whether to proceed with reassessment.

If the decision is made to reassess, the Act dictates that the decision must be notified to the affected registrant(s) in accordance with sections 13 and 14 of the Act, with that decision being deemed a new application for the trade name product(s). See section 3.7 for more information on reassessment and section 4.6 on non-compliance matters that may lead to reassessment.

1.4.2 Compliance Activity

The ACVM team, with assistance from other MPI teams where necessary, undertake or direct all non-compliance work related to the importation, manufacture, distribution, sale and use of registered or exempt agricultural compounds in accordance with Part 5 of the Act. This includes formal notification of a suspected or known breach of the Act, and any investigative work and formal action required to rectify any non-compliant activities including managing the associated risks where product recalls, suspensions, or cancellations are necessary. Compliance activity can be driven by legislative breaches with the Act or Regulations, non-compliances with the conditions of registration or exemption, non-compliance with GMP requirements, or any combination of the above. Some aspects of non-compliance can be rectified through ACVM assessment and authorisation, such as case-by-case approval to release non-compliant batches of product (batch specific variations) when they are urgently needed, or case-specific expedited variations to amend regulatory controls. Other instances of non-compliance may require a longer process of investigation and corrective actions. For more information on managing compliance under the ACVM Act, see section 4.6.

Relevant sections of the Act: Section 30A Suspension of registration, Section 31 Prohibition or restriction provisions, Section 32A Cancellation of registration, and Part 5 Offences

1.4.3 Maximum residue level setting and amendments

Maximum residue levels (MRLs) are the legislative basis for residue and trade risk management for agricultural compounds and are the thresholds against which product-specific withholding periods are determined. The primary function of MRLs is to ensure agricultural compounds are being used in accordance with the good agricultural practice (GAP) use established for that compound, while also managing food safety and trade risks presented by the residues they leave behind. Because the ACVM team hold data for, and are experienced in, the assessment of residue data for agricultural compounds, the team is responsible for maintaining the Food Notice: Maximum Residue Levels for Agricultural Compounds. This notice is set under the section 405 of the Food Act 2014, and Part 6 of the Food Regulations 2015, the legislation which establishes the requirements and structure for MRL setting and the Food Notice.

Maximum residue levels (MRLs) for agricultural compounds

MRL assessment and notice amendment processes – infographic

Food Notice: Maximum residue levels for agricultural compounds

1.4.4 Discretionary services offered to support compliance with the Act

On request, the ACVM team will undertake an assessment of information provided from an applicant to provide an opinion on the suitability of that information to meet ACVM requirements and guidelines. The two most common requests for advice are requests to deviate from information requirements for registration, and class determinations.

1.4.4.1 Deviation Advice

Section 10 of the Act states that registration applications must contain specified information that is needed to inform the evaluation of risks and benefits in accordance with section 20. The agricultural chemical, veterinary medicine, and vertebrate toxic agent registration guidance documents describe the preferred way of meeting those specified requirements, though an applicant can choose to present alternative data to that set out in the guidance documents. For veterinary medicines, the Guidance Document: Equivalence of Veterinary Medicine Trade Name Products sets out the expected approach to support bioequivalence, therapeutic equivalence, and pharmaceutical equivalence to support registration, and if the data and information provided conforms to these expectations no additional deviation request is needed. For other deviations from the information requirements for veterinary medicines, or deviations from the information requirements for agricultural chemicals and VTAs, the applicant may request advice as to whether these deviations would be acceptable.

To do this, the applicant will request an opinion on whether the alternative information and/or technical discussion is likely to provide confidence that the risks and benefits can be accurately characterised and evaluated such that the appropriate risk management controls can be applied. This will typically include a technical discussion explaining why less or different information could be considered equally supportive of the proposed registration or variation, along with any supporting information. These requests can be assessed as part of a registration or variation application if they are straightforward or will be evaluated as a stand-alone request for advice for more significant deviations. In cases where the proposed deviation from guidance is substantial, applicants are advised to pursue a stand-alone evaluation of the deviation prior to submitting the registration for application to avoid cost and time delays associated with the need to procure and/or generate additional information. The ACVM team will assess the request and issue a letter with the appropriate opinion.

Advice provided in a deviation opinion does not itself constitute an approval. The advice will often be conditional on provision of additional information, on the expectation that nothing in the full application package will contradict the information already reviewed, or both. When the application is formally received, the assigned assessor will review the application in its entirety to determine if the advice is still valid. If it is, the registration can proceed using the alternative information to inform the risk assessment. If advice is no longer valid, more data and information may be requested from the applicant, or the registration or variation application may be refused.

Agricultural chemical registration information requirements

Veterinary medicine registration information requirements

Vertebrate toxic agent registration information requirements

Deviation from information specified in ACVM registration guidance

1.4.4.2 Class Determinations

Companies wanting to import, manufacture, sell, or use agricultural compounds can request advice on the status of their product under the Act. On review of the label and product information provided with the application, the team will advise whether the compound fits the definition of an agricultural compound, and whether the product's profile i.e., composition, labelling, and advertising fits one or more of the exemption categories listed in Schedule 2 of the Regulations. If it is determined that the product is exempt from registration, the advice is only valid whilst the product, claims, and advertising remains unchanged and the product complies with all ACVM Regulations in their entirety. A class determination does not absolve the company's responsibilities with respect to conforming to other applicable legislation (e.g. HSNO Act, Biosecurity Act) prior to entering the New Zealand market.

Advice on how a company can make a self-determination is also available on the website.

Class determinations and self-determinations under the ACVM Act 1997

1.4.4.3 Data assessment

As discussed in section 3.8.2, data assessment is required for all substantial data dossiers prior to the submission of an application to register a new product or vary the registration of an existing one. The ACVM team prefers that data assessment is conducted using an independent data assessor prior to the submission of an application for appraisal. This is due to the small size of the team and the outsized impact internal data assessment may have on available application appraisal resource. It is recognised however that from time to time it may be necessary for a member of the team to conduct a data assessment for one or more dossiers intended to support an application. In these cases, the applicant can contact the team and request this service on the understanding that regulatory time frames will not apply, and that application submission will be held until data assessment is complete.

2 Compiling Data and Information to support an application

2.1 General considerations

The most important characteristic of a good application is that it comprehensively provides all the necessary data and information to address the product-specific risk profile. This may be done with product-specific information, publicly available information, information that applies to the active ingredient(s) in the product in question and any similar products, or any combination of these. All data and information submitted for assessment must:

1. be relevant to the product as formulated for the New Zealand market,
2. be relevant to the intended New Zealand use pattern(s);
3. contribute to the risk assessment of the product by providing information that characterises its risk profile, and
4. support the understanding of the risks and benefits posed by the product's importation, manufacture, sale, or use as proposed by the applicant.

Guidance documents have been developed which describe the ACVM team's expectations for data and information to support most types of applications, and applicants are expected to comply with these unless there is an acceptable justification to deviate from them. If there is no ACVM guidance that is relevant to the product or use situation, applicants are still expected to ensure that there is sufficient information provided to thoroughly characterise the product and its risks and benefits. This can be done by reference to international guidance where relevant to intended New Zealand use patterns, or by clear technical discussion of the data provided and its suitability to support the application.

Despite the availability of ACVM and international guidance, there will be some cases where the ACVM team may request additional information to be provided to inform assessment or require that additional information is generated after approval is granted. These will be managed on a case by case basis with the applicant/registrant.

2.2 Chemistry and Manufacturing Data

The chemistry and manufacturing information provided for a product establishes the product's identity and quality characteristics. It is important that this information is as complete as possible, and is robust enough to ensure the product's quality, purity, stability, and batch to batch production consistency. All active ingredient and final product manufacturers must be identified, and sufficient information must be provided to ensure that the product will remain consistent and equivalent across multiple manufacturers, if nominated.

The chemistry of a product refers to all active and excipient ingredients used to produce the final formulation. Each ingredient's purpose in the formulation and quality controls must be specified to ensure all relevant risks can be characterised. New veterinary medicine registrations (including generic products) are also expected to provide information on how the final formulation was developed and refined, to comprehensively understand both the composition of the formulation (identity and quantity of the ingredients) and its use in the target species.

Manufacturing data encompasses all stages of production, from the acquisition and/or manufacture of individual ingredients to final packaging and labelling of product for market. All entities involved in any steps of the manufacture of a product must be listed on the Product Data Sheet, with evidence of current GMP compliance provided where required. It is expected that all manufacturing steps are described in detail, and all in-process and final product controls are identified and justified, to ensure both the risks and the effectiveness of risk management can be defined relative to the final product intended for sale and use.

In situations where some or all chemistry and manufacturing information is confidential to a third party, this information can be directly submitted to the ACVM team and held in confidence.

2.2.1 Good Manufacturing Practice (GMP)

For higher risk products including most veterinary medicines and VTAs, independent verification of their manufacturer's quality management and associated systems, including manufacturing processes, is integral to effective risk management. Because of this, the ACVM team require that products are manufactured in a facility that has been independently confirmed to comply with the Good Manufacturing Practice (GMP) standard and guideline. This involves regular GMP audits by the ACVM auditors according to the ACVM standard and guideline for GMP compliance to ensure the facility has the systems in place to manufacture products consistently and of the required quality, and in compliance with the approved manufacturing processes and other product particulars. The ACVM standard and guidelines for GMP have been adapted from the PIC/S Guideline, which is recognised internationally and used by many regulatory bodies.

International manufacturers of veterinary medicines are also assessed under equivalent GMP standards. MPI have established collaborative agreements of equivalence with other regulatory authorities to provide a high level of assurance that manufacturers around the world are verified as acting in compliance with an equivalent standard of GMP outside national boundaries. Where an international authority is not able to assess GMP compliance for an international manufacturer, the ACVM auditors may conduct audits overseas for manufacturers producing products for the New Zealand market. Many regulatory authorities will recognise evidence of GMP compliance issued by MPI. If no equivalence arrangement exists, depending on the country they are exporting to, New Zealand manufacturers may also be audited by the regulatory authority of the importing country, if they do not recognise MPI-issued certificates of GMP compliance.

If all manufacturers listed on a product's registration Product Data Sheet are confirmed to operate in accordance with GMP, this is considered compliant with the requirements of Condition 62, typically applied to veterinary medicine registrations, and of Condition 2, typically applied to VTA registrations.

Manufacturing includes raw material dispensing, formulating, testing, filling, packing and labelling for release. It also includes product sterilisation activities.

2.2.1.1 Suppling evidence of GMP compliance

For products where registration conditions 2 (VTAs) or 62 (veterinary medicines) have been applied, the ACVM team require a record of current and valid GMP compliance for all entities specified in the product data sheet as manufacturing the formulated product or performing a manufacturing related activity such as relabelling. This means supply of a current GMP certificate or other evidence at the time of a new registration, and provision of an updated certificate or evidence when applying to vary or renew an existing registration if it has lapsed since the last ACVM approval. For evidence of GMP compliance to be recognised by the ACVM team, it must clearly state the manufacturer's name and the physical site address and specify the scope of the approval including the functions that the manufacturer performs, or specify the product group/type, or identify the name of the products included in the approval. The evidence must also:

- be within the validity period specified on the certificate/license, or
- have been issued within the previous 3 years, or
- have an audit date of within the previous 3 years.

If a validity period or audit date is not specified on the certificate or license, supporting evidence such as the last audit report may be required for review. The manufacturer can supply any confidential documents directly to MPI if preferred.

If the manufacturer is audited by an ACVM auditor and has a GMP Certificate of Compliance issued by ACVM, the manufacturer's certificate is not required to be submitted with the application.

2.2.2 Chemistry and Manufacturing for Agricultural Chemicals

Manufacturers of agricultural chemicals are not subject to GMP or an equivalent quality management system. There is however work underway with the OECD to develop Minimum Manufacturing Requirement for Pesticides, which will provide guidance on minimum expectations for manufacturers.

ACVM Guidance: Chemistry and Manufacturing Information for Agricultural Chemicals

ACVM Guidance: Microbial Agricultural Chemicals

2.2.3 Chemistry and Manufacturing for Veterinary Medicines

Domestic manufacturers of veterinary medicines

New Zealand manufacturers of most veterinary medicines are subject to the requirement to manufacture in accordance with GMP, and therefore must be compliant with the ACVM Standard and Guideline for GMP. Companies manufacturing for the New Zealand market (or for export) can apply for a certificate of GMP compliance, and to be added to our GMP Programmes using the following application form:

Application for approval to manufacture veterinary medicines and VTAs

Following receipt of the application form, and relevant required information and documents, an ACVM auditor will organise for a site audit to assess compliance against the standard and guideline for GMP.

ACVM standard for good manufacturing practice

ACVM guideline for good manufacturing practice

International manufacturers of veterinary medicines

International manufacturers of ACVM registered veterinary medicines must be able to supply evidence of current GMP compliance issued by a recognised regulatory authority for each nominated formulated product manufacturer. A recognised regulatory authority is one that is deemed to have an equivalent GMP Programme, and therefore provides confidence that the products manufactured overseas are of the appropriate quality to be imported, sold and used in New Zealand.
Recognised authorities are those that are:

- EU member states
- EU and UK Mutual Recognition Agreement (MRA) Partners
- Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S) Members
- Authorities that have a technical agreement such as a Memorandum of Understanding with MPI (e.g. APVMA)

Situations where GMP compliance may not be required

In certain situations, such as single ingredient veterinary medicines or registered therapeutic feed products, the risks associated with the product's manufacture and use may not require verified GMP compliance. In these cases, other forms of independent evaluation and approval of the manufacturer's quality management system may be accepted such as FAMI-QS (Feed Additives and Premixtures Quality System). Similarly, other forms of independent approval of their quality management system may be accepted for some entities performing testing and analysis, such as ISO-9001. The ACVM Regulatory Programmes team can be approached to enquire whether alternative evidence would be acceptable on a case by case basis.

ACVM Guidance: Chemistry and Manufacturing of Veterinary Medicines (Chemical)

2.2.4 Chemistry and Manufacturing for Vertebrate Toxic Agents

Domestic manufacturers of vertebrate toxic agents

All VTAs intended for the New Zealand market must be manufactured in a facility that has a quality management system appropriate to manage the associated risks. To achieve this, domestic VTA manufacturers are subject to the ACVM GMP Programme and therefore must be compliant with the ACVM Standard and Guideline for GMP.

Application for approval to manufacture veterinary medicines and VTAs

ACVM standard for good manufacturing practice

ACVM guideline for good manufacturing practice

International manufacturers of vertebrate toxic agents

GMP compliance is not a standard international requirement for VTA manufacturers and is therefore not considered mandatory for ACVM approval. However, these manufacturers must have an independent evaluation of their quality management system and processes for a VTA manufacturer to be eligible for supply to the New Zealand market. Evidence of this independent evaluation and quality management system is assessed on a case by case basis. Manufacturers should complete the application for approval and provide the applicable documents such as their site master file and independent accreditation (e.g., ISO accreditation), for ACVM review.

ACVM Guideline: Chemistry and Manufacturing of Vertebrate Toxic Agents

2.3 Efficacy Data

The efficacy of an agricultural compound is its ability to achieve the proposed effect in the treated crop or animal to which it is administered. Efficacy data establishes the appropriate and prudent use of the compound, providing evidence that the use patterns, application/dose rates, and other considerations are supported as effective under New Zealand conditions when used as directed. For food producing crops and animals, efficacy data makes up a large proportion of the overall consideration of good agricultural practice (GAP).

Trials must conform to the ACVM Research Standard for all agricultural compounds and meet the expectations of the relevant efficacy guidance for each product type. Where specific ACVM efficacy guidance does not exist, guidance provided by other competent authorities or relevant bodies (e.g., a pharmacopoeia) may be consulted.

ACVM Research Standard

2.3.1 Efficacy for Agricultural Chemicals

Efficacy data is required to justify and confirm that the use pattern proposed (including application rate, timing, frequency and WHP) will use the least amount of agricultural chemical product to consistently achieve the proposed label claims. These data must either be generated in New Zealand or be demonstrated to be relevant to use in New Zealand conditions.

The efficacy data provided to support an application is used to

- evaluate the risks (e.g., agricultural security) and fundamental benefits of the product's use,
- establish consistency with the principles of GAP to facilitate and support a 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).

All claims should be supported by appropriate trials, with the data generated from these trials conforming to the requirements outlined in the ACVM Research Standard.

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

Efficacy and Plant Safety of Urease/nitrification Inhibitor Products

Microbial Agricultural Chemicals

2.3.2 Efficacy for Veterinary Medicines

For veterinary medicines, efficacy data is required to support the effective use of the medicine in the intended target species with clearly defined therapeutic endpoints, dose rates, dosing intervals, and retreatment periods. For some products such as antibiotics and anthelmintics, this will also include demonstrating that the intended dose rate(s) both effectively treats or controls the intended pathogen with the least amount of medicine administered as possible while minimising the potential for resistance.

Efficacy guidance has been developed by the ACVM team for some of the more common types of veterinary medicines. Where ACVM guidance does not exist, applicants can refer to publicly accessible guidance provided by other competent authorities, such as the European Medicines Authority (EMA), the UK's Veterinary Medicines Directorate (VMD), the US Food and Drug administration (FDA), and the US Department of Agriculture (USDA), and independent internationally recognised agencies such as the Veterinary International Cooperation on Harmonisation of Technical Requirements (VICH) and the World Association for the Advancement of Veterinary Parasitology (WAAVP).

Anthelmintics in cattle, sheep, goats and deer

Antibloat products

Anticoccidials in poultry

Antihistamine products

Antimicrobial agents for teat disinfection 9

Antispasmodic products

Corticosteroids

Emetics

Oral rehydration therapy products

Vaccines

Zinc prophylactic products for facial eczema

The efficacy of veterinary medicines may also be supported by establishing pharmaceutical ± biological equivalence of a new product (typically a generic product) to an already registered New Zealand veterinary medicine. Separate guidance is available on supporting efficacy through equivalence.

Equivalence of veterinary medicine trade name products

2.3.3 Efficacy for Vertebrate Toxic Agents

The most important features of a VTA that contribute to its efficacy and performance are its toxicity and palatability in an appropriate delivery system. Efficacy trial work for VTAs should include cage and/or pen studies, as well as field trials in actual use conditions. Tests should be designed to measure the toxicity and palatability of vertebrate pesticides to indicate what concentrations can be expected to give optimum results in the field. Efficacy studies should be conducted to determine the lowest possible dose to obtain consistently, statistically significant $LD_{90\text{-}100}$ values. OECD, EPPO and US EPA have additional guidance which can be consulted.

Guidance on demonstrating the efficacy of a VTA to ACVM expectations, including efficacy with respect to the humane termination of target pests, is included in the Standard and Guideline.

ACVM Registration Standard and Guideline for the Efficacy of Vertebrate Pesticides

2.4 Target Animal and Crop Safety Data

Target animal and crop safety data is required to manage the risks associated with agricultural compound exposure when the product is used as directed. This helps establish the good agricultural

practice profile for all products, as well as the local, systemic, reproductive, and long-term safety profile for veterinary medicines.

2.4.1 Crop Safety for Agricultural Chemicals

For herbicides, dedicated crop safety trials are required in the absence of weeds and separate from the efficacy studies. Plant safety trials should include a suitable industry standard, examine the effect of both 1x and 2x application rates, and include a suitable assessment of yield/crop quality.

Dedicated plant safety trials are not a default expectation for insecticides or fungicides. In most cases, efficacy and crop safety assessments can be conducted from the same data set for these product types. However, if crop damage is observed in efficacy studies following use of the agricultural chemical according to the proposed use pattern, specific plant safety trials should be undertaken to more closely examine the extent and nature of damage. There may also be specific situations where additional data or information will be required, such as examining the effects of seed treatments on germination. Further information is available in the APVMA Pesticide efficacy and crop-safety general guidance (Part 8) and the European and Mediterranean Plant Protection Organisation (EPPO) guidance on phytotoxicity assessment.

Some consideration may also be given to the safety of agricultural chemicals in food-producing animals when applied to feed crops and pasture. While no specific animal safety trials are expected as part of the standard data package, additional information may be requested where an animal exposure assessment determines it is warranted.

2.4.2 Target Animal Safety for Veterinary Medicines

Target animal safety trial data and/or information is expected for all new veterinary medicine registrations, as well as all variation applications to add new target species or use patterns. Safety data is required to establish the margin of safety relative to the intended use pattern, and to identify any short-term or long-term adverse effects that may require label warnings, contraindications, or restrictions on use. This is typically achieved by evaluating the effects of 1x, 3x, and 5x dose rates at minimum repeat dosing intervals for maximal treatment durations, while considering the impact on different classes in each of the target species (e.g. neonates vs. adults, lactating vs. non-lactating, pregnant vs. non-pregnant). Where a range of doses are intended for use, margin of safety should be established using the highest proposed dose rate as the 1x. Where use is intended in a range of ages and classes, data should be generated in representative age groups, classes, and species as appropriate; some data may be considered for similar target groups with justification (e.g. data generated in adult sheep *may* be applicable to a similar use in adult goats, though data generated in adult dogs will not be applicable to adult cats).

Alternative dosing schedules may be used where the ingredient or ingredients are known to have a narrower (e.g. 1x, 2x, 3x) or wider (e.g. 1x, 5x, 10x) margin of safety in the target species or class. These alternative schedules must still evidence the margin of safety and overall safety expected from the veterinary medicine with respect to the intended use and target species/class.

ACVM Registration Standard and Guideline for Veterinary Medicine Target Animal Safety

Like efficacy, the target animal safety of veterinary medicines may be able to be supported through establishing pharmaceutical and/or biological equivalence to an already registered New Zealand veterinary medicine where use patterns are the same. Where equivalence is demonstrated using bioequivalence studies, additional data may be required if differences in the formulation could impact the safety profile.

Equivalence of veterinary medicine trade name products

2.4.3 Animal Safety for Vertebrate Toxic Agents

For vertebrate toxic agents, target animal safety is managed through the efficacy assessment process to ensure a humane product effect, while non-target animal safety is managed by the EPA.

ACVM Registration Standard and Guideline for the Efficacy of Vertebrate Pesticides

2.5 Residue Data

Many agricultural compounds used in food-producing animals and plants have the potential to result in residues in harvested crops and animal commodities. Residue data is required to characterise and quantify this potential when these compounds are used according to the GAP established for New Zealand in each target crop or food-producing animal species. This includes characterising and quantifying residues in animal commodities when an agricultural chemical is used on an animal feed crop or pasture. These data are used to establish the MRLs to control for use of the compound according to GAP, confirm new uses conform to already established MRLs, and determine the withholding periods required for harvested crops and animal commodities to comply with new or established MRLs. MRLs are in turn used by MPI to monitor compliance with GAP and to ensure risks to food safety and trade are effectively managed.

2.5.1 Residues for Agricultural Chemicals

For agricultural chemicals, New Zealand residue data should be supplied for products used on or around food and/or feed crops. The data should be generated using the proposed use pattern which has been confirmed as GAP through the efficacy information. Where the label includes ranges, the use pattern should be chosen which is likely to result in the highest residues after normal use (the highest application rate, highest number of applications at the shortest interval, and shortest pre-harvest interval or withholding period). Normal practice does not include crop failure or extreme events, so the pre-harvest interval or withholding period which most approximates normal use should be chosen even if you do not expect any residues to arise.

Where agricultural chemicals are used on crops intended for consumption by food-producing animals, animal feeding studies may also be required. There is a list of 'primary feed crops' in the guidance. Trials on animal feed crops should be conducted using established GAP and include residue evaluation in early 'green' crop, as well as the material present at harvest and post-harvest such as straw or stubble. These data will be evaluated in conjunction with metabolism and feeding study data and information in the species to which the crops will be fed to determine the potential for residues to transfer to animal commodities (e.g. meat, fat, offal, milk, eggs, or honey) and establish animal withholding periods or other controls to manage MRL compliance.

Residue Data for Agricultural Chemical Registration

2.5.2 Residues for Veterinary Medicines

Residue data and/or information is required for all veterinary medicines used in the treatment of food-producing species, which includes:

- ruminants (cattle, deer, goats, and sheep)
- poultry (e.g. chickens, turkeys)
- camelids (e.g. llamas, alpacas)
- rabbits and hares
- pigs
- horses
- fish and shellfish

Residue data must be generated using the highest proposed dose rate and longest interval intended for use, and in all relevant animal tissues and commodities (e.g. meat, fat, kidney, liver, milk, and eggs; injection site where applicable). These data are used to evaluate and determine the withholding periods required to manage compliance with established MRLs and thereby manage food safety and trade risk.

ACVM Guidance: Determination of the Residue Withholding Period for Veterinary Medicines

2.5.3 Residues for VTAs

Residues assessments are generally not conducted for VTAs since there is no GAP use of such compounds in food producing animals. There may however be MRLs set for VTA active ingredients to ensure food-producing animal exposure, and through them human exposure, is minimised.

2.5.4 Data and information to support MRL setting

An MRL is the highest level of an agricultural compound residue that is allowed in food. Residue levels in food must not exceed the relevant MRL. New Zealand's MRLs are listed in the Food Notice: Maximum Residue Levels for Agricultural Compounds, with Schedule 1 setting quantifiable limits to compound/food combinations, and Schedules 2 (agricultural chemicals) and 3 (veterinary medicines) establishing the controls on those compounds to which no MRL applies. For compounds not listed in any of the three Schedules in the Notice but used in food-producing crops or animals, the 'default' MRL of 0.1 mg/kg applies to all foods harvested from those crops or animals.

Food Notice: Maximum Residue Levels for Agricultural Compounds

When an application is made for a new or changed use of an agricultural compound on crops or animals intended for human consumption, or on crops intended for consumption by food-producing animals, ACVM will consider whether an MRL is required. MRLs are set, and compounds listed in Schedules 2 and 3, to ensure that the agricultural compound is used according with what has been evidenced to be GAP in New Zealand while taking both the food safety and trade risk into account when determining the applicable controls.

Applicants are expected to propose MRLs or a listing in Schedule 2 or 3 for any novel compound or novel use of an existing compound. These should be based first and foremost on what has been evidenced by trial data or other supportive information to be GAP for New Zealand use of that compound. For animal commodities, overseas MRLs set by Codex or other authorities must be considered when proposing MRLs to ensure trade in primary produce is supported. For plant commodities for human consumption, Codex and Australian MRLs are noted for comparison, though export trade considerations are less significant for plant products than animal products due to the lack of MPI official assurances on exported commodities. If a crop is a primary animal feed commodity, then MRLs are not set in the crop but instead appropriate animal commodity MRLs must also be considered to ensure the potential for residue transfer from treated crops to animal products is appropriately managed.

The data required to support a MRL or Schedule listing for New Zealand registered products is usually limited to the residue data provided to support the new registration, provisional registrations, variation application that involves the treated or exposed food commodity (e.g. new registrations, new use in a food-producing animal species, or new use in a previously unapproved crop for human or animal consumption). MRLs or Schedule listings can also be requested as a deviation independent of a registration or variation application, provided the appropriate supporting data is submitted to establish New Zealand GAP and the residue profile for the compound in the target crop or species.

In addition to MRLs related to New Zealand registered agricultural compound use, applicants may request an MRL to support residue management for imported commodities (e.g. import MRLs). The request for an import MRL must be accompanied by sufficient information to support GAP in the origin country, residue data in the target crop or species, and information to ensure that the import MRL will not pose a risk to New Zealanders from a food safety perspective.

For more information on residue management and MRLs, please see the MPI web page on Maximum Residue Levels for Agricultural Compounds.

MRL assessment and notice amendment processes – infographic

2.6 Other Data Volumes

For certain products, additional information may be required to address specific aspects of the risk profile. The two most common "other" data volumes required for ACVM applications are toxicology dossiers for novel compounds or novel uses with food safety implications, and antimicrobial resistance

(AMR) dossiers for agricultural compounds containing antimicrobial active ingredients. Toxicology data and information may be the same as that submitted to the EPA for assessment, and it can be presented in the manner dictated by that authority.

AMR data and information should address both the potential risk for the product to result in resistance relative to human and animal health, as well as the risk/benefit balance associated with the use of that antimicrobial substance as an agricultural compound. For more information on ACVM's and MPI's policies on AMR, please see the AMR page on the MPI website. Please note that any antimicrobial compound classed as a prescription medicine under the Medicines Act 1981 is subject to consent from the Minister of Health as per section 21(4) of the ACVM Act.

2.7 Data expectations per application type

In general, applications for novel registrations (A1 and A2 type applications) require all data volumes to support the establishment of a complete risk profile. This includes all standard data volumes and the additional data volumes noted in section 3.6, as required, to characterise the individual product's risk profile.

B2 applications will require a full chemistry and manufacturing dossier to confirm product identify and quality to characterise product-specific risk, but will often cross-reference efficacy, plant/animal safety, and/or residue data from a similar product. In these cases, technical argument and/or data (*in vitro* and /or clinical e.g. from a bioequivalence or non-inferiority trial) must be included to support cross-reference and the relevance of ACVM-held data to the new product. If more than one cross-reference product is used, then it should be clear in the application which label claim each cross-reference product relates to. For B2 applications that are identical in every way to an already registered product except trade name and registrant, cross-reference of chemistry and manufacturing information can be considered with authorisation from the registrant who owns the reference product.

Variation applications will generally require data to support the risk profile of the product after the change has been implemented. The type of data required will depend on the variation being proposed and the significance of the change relative to its impact on the original risk profile.

Reassessments will often require the provision of data to support the risk profile of the product with consideration to the new information identified. Like variation applications, this will vary depending on the new information and its impact on the risk profile; the ACVM team will advise registrants of the data and information required once a reassessment has been initiated.

A diagram of all dossiers required for each product type can be found in the different product type's respective Information Requirements documents:

Agricultural Chemical Registration in New Zealand - ACVM Information Requirements [section 4.4]

Veterinary Medicine Registration in New Zealand - ACVM Information Requirements [section 5.4]

ACVM Registration Information Requirements for Vertebrate Toxic Agents Including Vertebrate Pest Control Products [section B2.2]

3 The Application Process

The data and information required for an ACVM application will vary depending on the type of agricultural compound – agricultural chemical, veterinary medicine, or vertebrate toxic agent (VTA) – and why the application is being made. Because ACVM assessment is always related to the unique risks and benefits associated with each product or authorisation, new registrations, variations to existing registrations, trial approvals (research approvals or provisional registrations), operating plans, and other types of approvals all have their own submission requirements.

General information on the three different types of agricultural compounds, and how they fit into the registration and approvals processes, can be explored from the following landing pages:

- **Agricultural chemicals – compounds used to directly manage plants, as well as apiculture products**
- **Veterinary medicines – compounds used to directly manage animals**
- **Vertebrate toxic agents – compounds used to kill or control vertebrate pests**

Inhibitor products are classed as either agricultural chemicals or veterinary medicines depending on the intended use of the product. Those products administered directly to animals for the purpose of reducing enteric methane emissions are classed as veterinary medicines, and are assessed by the Veterinary Medicines Assessment team, while products applied to crops or pasture for the purpose of inhibiting nitrogen release are classed as agricultural chemicals and assessed by the Agricultural Chemicals Assessment team. Nitrification inhibitors applied to animal feed crops or pasture will also attract assessment with respect to residue transfer to food-producing animals where required. The process for screening, assessing, and approving inhibitors is the same as other types of registrations.

For more information on applying to register an inhibitor, see **How to register an inhibitor.**

Registrations are typically granted for a period of five years, with the renewal date reset if a variation is granted during this period. For example, a product is registered in December 2020 with a renewal date of December 2025. The registrant applies to vary the registration in June 2025, and the variation is granted in August 2025. The new renewal date for that product will be August 2030 unless another variation is submitted in that time.

Registration renewal applications can be actioned as their own variation if no other variations are submitted within the registration period – see section 3.6 for more information.

3.1 Compiling an application

3.1.1 General application forms

All product applications must be submitted with a general application form providing the following details:

- Product identification;
- Registrant details;
- Consultant or agent details, when applicable;
- The nature of the application being submitted;
- Biosecurity Act approval status; and
- HSNO Act approval status.

The type of form used will depend on whether the application is for registration of a trade name product (ACVM 1), variation to a trade name product (ACVM 1V) and the product type (agricultural chemical, veterinary medicine, or VTA). There is also a separate form for registration renewal (ACVM 1R).

ACVM 1: Registration of an ACVM trade name product

ACVM 1V-AC: Application to vary the registration of an agricultural chemical

ACVM 1V-VM: Application to vary the registration of a veterinary medicine

ACVM 1V-VTA: Application to vary the registration of a Vertebrate Toxic Agent

ACVM 1R: Renewal of registration of ACVM Product

Applications for new registrations, variations to existing registrations other than those for chemistry and manufacturing changes, and provisional registrations can attract Part 6 provisions for protection of confidential information. These applications should also be submitted with an ACVM 1DP form, either identifying the information included in the application that are subject to these provisions or confirming that no such data has been provided. More information on which applications may be subject to protection and the protection periods can be found in the guideline.

ACVM Guideline: Protection of confidential information about ACVM trade name products

ACVM 1DP: Identification of confidential information for data protection

3.1.2 Product Data Sheets

Each product type has its own product data sheet and guidance on how the PDS should be completed. A completed PDS is required at every application, including variations and registration renewals. If part of the information is confidential to another party, a separate PDS should be provided directly to ACVM. The confidential PDS should include the trade name, footnote, and confidential sections completed, and the owner of the confidential information should be clearly identified.

Agricultural Chemical PDS Guideline

Agricultural Chemical Product Data Sheet (ACVM 1-3)

Veterinary medicine PDS Guideline

Veterinary Medicine Product Data Sheet (ACVM 1-2)

Vertebrate Toxic Agent PDS Guideline

Vertebrate Toxic Agent Product Data Sheet (ACVM 1-4)

3.1.3 Labels

Labels must be provided for each product and pack size where labels are different. The product label includes all leaflets or other content included in the primary, secondary, and/or tertiary packaging, including syringe and vial labels where applicable. The product label(s) are required at every application, including variations and registration renewal. The guidance material for label content expectations can be found in the following documents.

- **Labelling Agricultural Chemicals**
- **Labelling Veterinary Medicines**
- **Labelling VTAs**

Please ensure that you check the most up-to-date version of the labelling guidance before you submit the label for any registration renewal and variation applications, in case any changes are required.

3.2 Applying for a new registration with a novel risk profile

3.2.1 Products with novel active ingredients (“A1” type registration)

An “A1” type application is submitted when a product contains active ingredients novel to registration in New Zealand. This may include brand new products developed for the New Zealand market, or the introduction of a product registered overseas with no product containing the same active ingredient registered here. These types of applications have the highest level of data requirements due to the need for a comprehensive risk assessment for both the active ingredient(s) and the product, with all aspects of the standard data package (chemistry and manufacturing, efficacy, and target animal

safety) as well as information to establish a toxicological profile and, if used in a food-producing crop or species, residue data and information to establish MRLs.

Acceptance of deviations from the information requirements is very limited for this type of application due to the novelty of the compounds and the need to establish a brand new risk profile. There are situations however where alternative data could be considered in support of an application, such as novel compounds in a well-known chemical family, or use of public domain information. Applicants should discuss the use of deviations in A1 type applications with the ACVM team prior to submission.

A1 type applications attract the greatest duration of confidential information protection, at 10 years from the point at which registration is granted. This means that any similar products registered within that period would require their own data packages since cross-reference would not be permitted.

3.2.2 Products containing known active ingredients with a novel risk profile ("A2" type registration)

Products with known active ingredients being used in a novel way, such as use in a new target species or crop, or for an entirely different purpose not previously assessed, are classed as "A2" type registrations. These applications generally have similar data requirements as an A1 application due to the novelty of the product, though there may be aspects of the risk profile that can rely on reference to other registrations if they are outside of the protection period for which a risk profile has been established. For example, if an active ingredient is approved for use in cattle in a single active oral drench but is now being presented in multi-active formulation, it may be possible to cross-reference target animal safety data for the active ingredient where it can be evidenced that the combination product provides no greater drug exposure than the drench formulation.

3.3 Applying for a new registration with a known risk profile

3.3.1 Products that are identical in every way to an already registered product including the registrant ("B1" type registration applications)

A "B1" type application is submitted when the product to be registered is identical in every way, except the trade name, to an already registered product. This includes all details in the product data sheet, the registrant and all product label information. Because these products are identical in every way to a registered product, the risk profile is also considered identical. The new registration can therefore be granted with an assessment limited to confirmation that the two products are identical in all respects.

Any deviation from the details on file for the reference product including any differences in PDS and/or product label content other than the trade name will invalidate use of this pathway for registration. This includes products that are identical in every way except trade name and registrant. Registration for such products would require data and information for assessment as per section 3.3.2 (B2 type registration).

3.3.2 Products that are closely similar to an already registered product ("B2" type registration applications)

A "B2" type application can be made for a product that is similar to an already registered product without any novel use patterns, claims, target species/crops, target pathogens, or any other differences that may or will impact the risk profile.

To be considered 'similar', the product referenced should have:

a) the same active ingredient(s) in the same form (e.g., same salt, ester, or chain length); and

b) the same formulation type; and

c) the same target host crops or animals/use situations and claims (e.g., target pests, diseases, pests, or effects); and

d) the same use pattern (including application/dose rate on an active ingredient basis, timing of application, methods of application and withholding period).

“B2” type applications always include product-specific chemistry and manufacturing information, with the rest of the risk profile typically supported by comparative data or information to an already registered product. This comparison may be evidenced by the provision of comparative data or information to support an equivalence argument and enable cross-reference through comparative trial work, more indirect comparison through *in vitro* chemistry and physiochemical property evaluation of the two products without crop or animal trial work, by incorporation of a technical discussion to deviate from the ACVM guidance, or by a combination of any of the three.

Product specific efficacy, safety and/or residue data may be provided to support B2 type applications. Where no data has been presented however, applicants are expected to provide a technical discussion as to why such data is not necessary to characterise the risk profile and support registration. The technical discussion can be supported by publicly held data and information, data held on file by ACVM for other products which is not subject to protection of confidential information, or any other data or information they feel can be considered in lieu of product-specific trial data. A request for an opinion regarding whether a proposed deviation from ACVM information expectations and guidance is acceptable can be submitted in a stand-alone deviation advice request or incorporated into the product’s registration application. See section 1.4.4.1 for more information on deviation advice.

All information supplied to the ACVM team is held in confidence and is not released to any party other than the owner of that information. If an applicant seeks to reference data held by ACVM, the team will review the applicant’s technical discussion and submitted information as well as the information held by ACVM that is being referenced to determine whether the held information is relevant to the new application. If it is determined that either the information is not relevant to the application or cross-reference is not supported, the applicant will be advised that cross-reference is not supported and information to directly support their application will be requested.

Confidential information subject to protection under Part 6 of the Act cannot be used to support any other registration or variation application, including an equivalency argument with or without comparative data, without the authorisation of the owner of that information. This means that a full data package must be provided to directly support the new registration as cross reference of data held is not possible. Note that the data provisions can apply to an entire registration if all information was provided at the point of registration, or for individual use patterns or other eligible variations to the registration separately. This includes data and information provided to support a reassessment, as reassessments are also eligible for Part 6 protections.

Cross-reference to a product which is no longer registered is possible, depending on the reason for cancellation and the quality of the data available for reference. However, more information is likely to be requested on a case-by-case basis where data requirements have changed since the product was first registered or the data cannot be relied on to inform an updated risk assessment (e.g. historic antibiotic efficacy data where there is now known resistance in certain pathogens).

As stated in section 3.3.1, products that are identical to a currently registered product in all respects except the trade name and registrant are considered “B2” type products. For these types of registrations, data on file for the reference product can be used in lieu of new data provided the reference product’s registrant has authorised use of that information. The new product’s registrant must provide a declaration letter from the registrant of the reference product confirming that the new registrant may reference all details on file.

3.4 Applying for a variation

3.4.1 General information for variation applications

Once a product is registered, registrants are required to ensure the product’s registration is maintained and kept up to date. Registrants may, from time to time, need to alter the registration details as dictated by ongoing product stewardship, such as a change or upgrade of chemistry or manufacturing particulars (suppliers, controls, or other details), to add or remove claims, target crops, or species, or make other changes that would alter the information held and approved for that product. This includes the product label, which should be reviewed at regular intervals to ensure that the information provided to users is still accurate and representative of the understanding of the product’s risks.

Changes to existing product registrations are done by submission of a variation application, to allow the assessment of the change relative to the product's previously assessed risk profile to determine if the change may be granted or refused. These changes must be approved for the product's registration before they are implemented by the registrant or manufacturer.

The data and information required to support the proposed variation will depend on what kind of changes are being made, and how significant an impact the change will have on the previously assessed risk profile. Applications to request a change to the approved product particulars must clearly outline the proposed change and characterise its potential impacts on the product and its risk profile. If the proposed change does result in a different risk profile, the change must be supported by data and information to inform a new risk assessment. It is important to note that simply stating that the change does not impact the efficacy, safety, residues, and/or stability profile of the product is not sufficient; there must at least be some discussion and information to evidence the "before" and "after" of the change and how the risk profile is or is not affected.

Often a proposed change will affect multiple aspects of the product's risk profile and therefore require the submission of multiple variations for assessment at one time. Examples of this are changes to the manufacturing process that impact the formulation, the processes, and product stability (e.g. C1/C2/C3 type change); or the addition of a new target crop or species that has unique diseases or conditions to be managed and requires an entirely different application/dose rate (e.g. C4/C5 type change). All supporting data and information provided for combination applications should be relevant to the changes being proposed, with each risk area being addressed for each change. Where the data and information provided to support the proposed change is substantial, data assessment may be required to ensure the data set is compliant to expectations and scientifically robust.

Finally, it is noted that submission of a variation application requires data and information that conforms to the current requirements applicable to that aspect of the risk profile regardless of when the product was originally registered. Historic data may be considered generally supportive of the change but may not be sufficient to support a variation on their own if the expectations regarding trial design and analysis have changed since these data were originally generated. The relevant assessment team will review data provided to support a variation and will be able to advise if further information will be needed.

All agricultural chemical and VTA applications, and all C4-C8 type veterinary medicine applications, undergo a technical prescreen prior to formal receipt of an application for technical appraisal. Significant data gaps are generally identified at this technical screening, while more minor data gaps may not be found until the full appraisal commences for all application types. If the data gaps identified at screening are significant enough that appraisal cannot proceed, the application will not be accepted and will be returned to the applicant to enable data gaps to be addressed before resubmission. Veterinary medicine applications for chemistry and manufacturing related changes (C1-C3 type variations) do not undergo a technical prescreen; applicants will be contacted regarding data gaps during appraisal for these types of applications.

The general expectations for each application type, and the specific associated variation forms, are detailed in the following sections. Note that each variation also requires the submission of the relevant overall variation application form:

- **Agricultural Chemicals:** **Application to vary the registration of an agricultural chemical trade name product (ACVM 1V-AC)**
- **Veterinary Medicines:** **Application to Vary the Registration of a Veterinary Medicine Trade Name Product (ACVM 1V-VM)**
- **VTAs:** **Variation to registration of ACVM trade name product form (ACVM 1V)**

3.4.2 Change in formulation or manufacturing process ("C1" or "C2" type change)

To support a change in the formulation or manufacturing process, data must be provided to demonstrate the ability of the altered product to meet the currently approved product specifications and may include a requirement for manufacturing process validation data for veterinary medicines depending on the significance of the change. Where analytical test methods have changed test method validation data may also be required. Applicants should provide a technical discussion and/or

data to demonstrate the impact of the change on product stability. There should also be a technical discussion of the impact on product efficacy, safety, and residue profiles

In cases where the change necessitates a consequential change to the formulated product specifications, a comparison of current and proposed specifications, and data and/or information to support the change, should be included in the application (see section 3.4.3).

Agricultural Chemicals	Veterinary Medicines	Vertebrate Toxic Agents
C1-C3 Change in chemistry and manufacturing information (ACVM 84)	Application to Vary the Chemistry and or Manufacturing Information for a Veterinary Medicine Trade Name Product (ACVM 79)	C1 Change formulation form (ACVM 6) C2 Change manufacturing form (ACVM 9)

3.4.3 Change in the active ingredient or formulated product specifications ("C2" type change)

To support a change in the active ingredient or formulated product specifications, provide data or information to demonstrate that the new specification is appropriate to control active ingredient quality and that amended final product specifications are appropriate (from a stability, manufacturing, and product quality perspective), product type, the target species/crop, and the intended use. Include a technical discussion of the supporting information and the impact of change on the product's risk areas.

Agricultural Chemicals	Veterinary Medicines	Vertebrate Toxic Agents
C1-C3 Change in chemistry and manufacturing information (ACVM 84)	Application to Vary the Chemistry and or Manufacturing Information for a Veterinary Medicine Trade Name Product (ACVM 79)	C2 Change manufacturing form (ACVM 9)

3.4.4 Change in active ingredient manufacturer ("C2" type change)

To support this kind of change, provide batch data from the new active ingredient manufacturing site, a technical discussion of the impact of the change on product quality and stability, and a technical discussion of the impact of the change on efficacy, safety, and residue profiles. For veterinary medicine active ingredients, a drug master file/active substance master file may be required, particularly if manufacture of the active ingredient is not controlled in accordance with a recognised pharmacopeial monograph i.e. USP, BP, Ph. Eur, JP.

Agricultural Chemicals	Veterinary Medicines	Vertebrate Toxic Agents
C1-C3 Change in chemistry and manufacturing information (ACVM 84)	Application to Vary the Chemistry and or Manufacturing Information for a Veterinary Medicine Trade Name Product (ACVM 79)	C2 Change or add manufacturer active form (ACVM7)

3.4.5 Change in formulated product manufacturer ("C2" type change)

For **agricultural chemicals**, provide evidence to establish that the new manufacturer will manufacture an equivalent product to that previously assessed, including production scale batch data or equivalent to demonstrate conformance to the approved specifications, and a technical discussion of the impact of the change on product stability. A technical discussion of the impact of the change on efficacy, safety, and residue profiles the product is also required.

For **veterinary medicines**, provide evidence to establish that the new manufacturer will manufacture an equivalent product to that previously assessed, including production scale batch data or equivalent to demonstrate conformance to the approved specifications, and a technical discussion of the impact of the change on product stability. A technical discussion of the impact of the change on efficacy, safety, and residue profiles the product, evidence of a current GMP approval with all steps of manufacture within the approved scope, and process validation data from the new manufacturing site will also be required in the submission. In some situations, a process validation protocol and a commitment to complete process validation and submit the process validation report may be acceptable to grant the approval, with a condition of registration applied to require submission of the process validation data when it is complete. If a consequential change in test methods is required due to engaging a new formulated product manufacturer, or if test methods are being transferred to a new site, evidence of suitable method transfer or validation as applicable at the new site will also be required.

For **VTAs**, provide evidence to establish that the new manufacturer will manufacture an equivalent product to that previously assessed, including production scale batch data or equivalent to demonstrate conformance to the approved specifications, and a technical discussion of the impact of the change on product stability. Evidence of a current GMP approval for domestic manufacturers, or evidence of current GMP approval or independent assessment of their quality management system for international manufacturers, must be included in the submission. A technical discussion of the impact of the change on efficacy, safety, and residue profiles the product will also be required.

Agricultural Chemicals	Veterinary Medicines	Vertebrate Toxic Agents
C1-C3 Change in chemistry and manufacturing information (ACVM 84)	Application to Vary the Chemistry and or Manufacturing Information for a Veterinary Medicine Trade Name Product (ACVM 79)	C2 Change or add manufacturer formulated product form (ACVM 8)

3.4.6 Change in the shelf life or packaging of the product (“C3” type application)

Provide data or information to demonstrate the product can meet the approved specifications at the new nominated shelf life, including a technical discussion of results and whether the product would still conform to specifications at the end of the shelf life if released at the low end of the release specification. If the packaging is changing, provide data or information to demonstrate the product can meet the approved specifications in the new packaging material. In both cases, provide a technical discussion of the impact of the change on product stability, and a technical discussion of the impact of the change on efficacy, safety, and residue profiles the product.

Agricultural Chemicals	Veterinary Medicines	Vertebrate Toxic Agents
C1-C3 Change in chemistry and manufacturing information (ACVM 84)	Application to Vary the Chemistry and or Manufacturing Information for a Veterinary Medicine Trade Name Product (ACVM 79)	Change in packaging form (ACVM 10) Change in shelf life form (ACVM 11)

3.4.7 Change in the use profile of the product (“C4” to “C8” type applications)

Changes included in this group are those proposed to gain approval for an additional target species (“C4” type application), an additional disease or condition to be treated (“C5” type application), a change in the dose regime or application rate (“C6” type application), a change in the method of administration (“C7” type application), or change in withholding period (“C8” type application). These types of changes most often require product-specific data from trial work as evidence, though reference to public information and/or cross-reference to data held by ACVM for another product can be considered if equivalence and relevance to the existing data or information can be established. The

supporting information must be accompanied by a technical discussion of the impact of the change on the overall efficacy, safety, and residue profiles of the product, and all supporting data and information must be supplied.

Agricultural Chemicals, Veterinary Medicines, and Vertebrate Toxic Agents
C4/C5 Change in crops, species, diseases, conditions form (ACVM 12)
C6/C7 Change in dose regime, application rate, timing, method form (ACVM 13)
C8 Change in Withholding Period form (ACVM 14)

3.4.8 Documentation Variations ("C9" Type Applications)

Changes to a product's label or product data sheet are often processed as C9 applications, as either administrative changes or technical changes. Administrative changes to a product's registration are those changes to information on the product data sheet or product label that do not have any impact on the ACVM risk profile, such as changes in the registrant's address or contact details, correction of typographical errors in non-technical portions of the document, or wording changes to areas of the label related to information transfer or EPA controls. Administrative C9s can also action approval of changes to product labels relating to graphics or content placement provided none of the technical information is altered.

If an application is received as an administrative change but on initial review it is considered that the change may have an impact on the interpretation of technical information in the product data sheet or label, the application may be referred to the relevant assessment team as a technical C9. Examples of changes considered a technical C9 include the addition of a new contraindication or warning to a veterinary medicine product label after resolution of an adverse event, or a change to the application or target pest tables in an agricultural chemical label that may alter end user interpretation of such information. Once referred to the assessments team, they will review the proposed change to determine whether it can be accepted as an administrative change as presented or requires amendment to avoid changing the technical interpretation of the information before acceptance.

If it's determined however, that the proposed change will alter some aspect of the risk profile, or that the registrant still wishes to proceed with the proposed change as presented after confirmation it is not solely administrative, the application may be converted to a technical variation. If this occurs, the registrant will be asked to provide additional data or information to support the change before approval can be granted.

There is no separate form for a C9 type change. If the C9 is the only variation being proposed, the applicant should submit the relevant 1V form and declare that there are no other changes made. Confirmation of self-assessable changes may also be included along with a the C9 application with the details of the change noted in the 1V form.

3.4.9 Change in registration conditions ("C12" type application)

Applications to change the registration conditions are generally submitted to remove the application of a temporary registration condition requiring additional data or otherwise limiting the product's market distribution (see Appendices 1 and 2). The most common use of this type of application is a variation to submit post-registration data and information and remove its associated condition (e.g. conditions 86, 101, 145, or 146), or the MRL-related conditions (136 and 138) once the associated MRLs have been finalised. The information required to satisfy post-registration data requirement conditions and have them removed, and any applicable time frame or additional requirements associated with it, will be advised at the time the application in which the condition was applied has been granted.

Another use of the change in registration conditions variation is to request a reclassification of a veterinary medicine from a restricted veterinary medicine (RVM) to an unrestricted veterinary medicine, or vice versa. This is a relatively rare use of this variation type, as it would require a significant change to the risk profile and/or field use of a product to justify re-classification.

3.5 Applying for a trial approval

3.5.1 Agricultural Chemicals and VTAs

Applications for approval to conduct trial work on experimental agricultural chemical and VTA formulations are submitted in much the same way as applications for registration, with the relevant documents submitted through the Approval Operations team for administrative screening prior to technical screening and appraisal. Trial work authorised through provisional registration under section 27 of the Act is subject to the same appraisal process and legislative time frames as other approvals, though the applications are not submitted for public notification before appraisal and products are not listed in the public register after approval is granted. Trials authorised through special circumstances approval under section 8C of the Act (research approvals) also undergo the same screening and appraisal process but are not subject to the legislative time frame.

For imported experimental formulations containing ingredients of biological origin, approval under the Biosecurity Act may also be required before trial work can progress. The information required for Biosecurity Act assessment and approval is incorporated into the application documents and progressed internally once an application is received.

Provisional registration in New Zealand information requirements

Provisional registration product data sheet template (ACVM 21)

Research approval information requirements

Research approval template (ACVM 22)

3.5.2 Veterinary Medicines

Veterinary medicine trial approvals are like agricultural chemical and VTA approvals in that they are granted under sections 8C and 27 of the Act, but the application process differs in how they are applied for, processed, and granted.

Most veterinary medicine trial work conducted in New Zealand involves the use of food producing animals, often requiring the use of large numbers of commercially farmed animals. This means that trial work usually involves the need for both approval under the ACVM Act to allow the use of an experimental formulation in trial animals, and under the Animal Products Act to allow those animals to enter the food chain or resume production (e.g. dairy animals) once the trial is complete. To facilitate a more streamlined approval process under both Acts, the veterinary medicine trial approval application forms and guidance have been consolidated into one process that allows for simultaneous assessment and approvals. In cases where Biosecurity Act approval is also required, the trial approval data sheet captures the information required for that assessment and approval is also progressed simultaneously.

Due to the high application volumes and limited resource in the Veterinary Medicines Assessment team, veterinary medicine trial approval applications are received and assessed outside of the Assessment team. This allows the applications to progress in a timely manner without negatively impacting the standard application time frames.

ACVM Guidance: Veterinary Medicine Trial Approvals

Veterinary Medicine Trial Approval Data Sheet (ACVM 81)

3.6 Applying for a registration renewal

Registration renewals are a specialised type of variation application that exists solely to reset the registration period with no other administrative or technical changes applied to a registration. Renewal applications are typically required within three months of the expiry period to ensure the product registration remains active. If there are updates or changes required for a product when a registration renewal is due, it is advised to renew the registration first and submit a variation application once this is completed to avoid a lapse in registration.

Renewal of registration of ACVM trade name product form (ACVM 1R)

3.7 Reassessments

Reassessments are initiated as the result of new information that may draw the existing risk profile for an active ingredient, product, or group of products into question. This may include a new efficacy or safety risk identified through adverse event monitoring or changes to good agricultural practice in the field, new trade risks due to a change in overseas MRLs or other considerations related to residues management or export, or any other issue that may require a formal review of an established risk profile.

According to the Act, initiation of a reassessment constitutes a new registration application, and thus is processed as a variation to the registration of the affected product(s). The reassessment process starts with the receipt of new information by ACVM, either from domestic sources such as results of monitoring programmes or from international sources such as overseas regulatory authorities, or by submission of new information by the registrant as required by the conditions of registration. This information is reviewed to determine whether it is significant enough to constitute a change in the risk profile: if it is, a reassessment is proposed to the registrant(s) for the product(s) 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.

If the decision is made to propose a reassessment, the registrant is informed of the proposal and asked to provide comment. When these have been received and reviewed, a final decision is made as to whether to progress to formal reassessment or to continue monitoring the situation for further information. If a formal reassessment is triggered, an application will be opened for each affected TNP, and a request for supporting information will be sent to the registrant. While not a standard variation per se, these applications are administratively managed as “C10” type applications to align with the existing application receipt and processing framework. They do not however attract the same statutory time frame applied to other types of applications. Reassessments are also publicly notified in the NZ Gazette to invite public comment on the reassessment and affected products.

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 will be detailed in a letter advising the registrant that a formal reassessment has been initiated, with a request that data and information be submitted by a certain date. All data and information submitted by registrants to inform a reassessment is eligible for Part 6 protection of confidential information.

3.8 Other considerations for compiling an application

3.8.1 ACVM Consultants

If you are new to dealing with government departments, new to ACVM registration in general or to a particular type of product, or just wanting step-by-step guidance, ACVM recommends contracting the services of a consultant. The ACVM team maintains a list of consultants that have expressed an interest in undertaking this work, and the types of products for which they offer their services. Please note that the listing of consultants does not constitute MPI accreditation or endorsement of their services.

List of consultants under the ACVM Act

3.8.2 Data Assessors and Data Assessment

The ACVM team requires data assessment to be completed before an application for registration, or an application for a variation to a registration, is made under the Act. Data assessments are undertaken by an independent person with individual assessment for each of the four dossier types: chemistry and manufacturing, efficacy, safety, and residues. There is also usually a separate overall summary accompanying these assessments. The purpose of data assessment is to confirm that:

1. the data provided for assessment is robust and scientifically sound, and

2. all data conforms to the information requirements and relevant guidance material for that type of product and/or change.

A single independent data assessor may be responsible for one or all dossier assessments depending on their expertise and experience. A completed data assessment report will include a full review of the data and supporting information with respect to robustness and conformance, identification of any non-conformances in the dossier, and a recommendation of whether the registration or variation is supported by the information available.

The ACVM team maintain a list of data assessors that have been confirmed through the submission of a CV, and other information as needed, to have the appropriate expertise to undertake data assessment for registrants. Data assessors are initially listed as provisional based on their expertise and can be updated to "full" data assessors after their initial assessments have been received and reviewed by ACVM as part of submitted applications. A list of these reviewed provisional and full data assessors can be found at the ACVM Registers and Lists web page.

It is not mandatory for persons completing data assessment reports to be listed by ACVM. However, data assessment reports completed by non-listed persons will require the provision of a CV with the application documents, and their reports will be subject to greater scrutiny and may require peer review.

Data assessors for ACVM registration - Data Assessor List and Data Assessment Report Templates

3.8.2.1 Addressing non-conformances in data assessments

If there are any gaps, inconsistencies, or non-conformances with ACVM requirements and guidelines, the data assessor will identify these as application non-conformances. The applicant must address these non-conformances prior to submission of the application to ensure that the risk profile of the product or change can be fully characterised and assessed. They can be addressed either by supplementing the original dossier with additional data and information relevant to the non-conformance (clearly identified as supplementary information in the dossier), or by providing a technical discussion and a request for a deviation from the guidelines (See section 1.4.4.1).

Where additional data is supplied to address major deficiencies, it may require assessment by the data assessor though this is generally not expected for minor deficiencies. If additional information is subsequently provided to, and reviewed by, the data assessor, the original information, supplemental information, and all correspondence with the data assessor should be included in the application documents submitted to ACVM.

If non-conformances are identified, the applicant is expected to provide a supplemental discussion addressing these non-conformances with additional information or technical discussion; this resolution of the non-conformances must not be argued by the data assessor on the applicant's behalf. Applications that are submitted with any non-conformances in the data assessment report(s) without the registrant addressing and resolving these deficiencies will be returned after the technical screen and will not progress to formal receipt until the non-conformances are resolved.

3.8.3 Approvals required under other legislation

Another key to having an application accepted for assessment is to ensure the required approvals under other legislation have either been granted or are in progress. The most common of these concurrent approvals is HSNO Act approval, which must be granted for all products containing a hazardous substance or a new organism before an ACVM registration can be granted. For agricultural chemicals and VTAs, HSNO Act approval must be sought through an application to the EPA for assessment and approval under the HSNO Act. For veterinary medicines, the EPA have group standards that can apply to most veterinary medicines without a product-specific assessment and approval provided certain criteria are met. However, they may require individual assessments for certain substances or organisms that do not otherwise fit an existing group standard. For more information on EPA approval, visit the EPA's website.

For agricultural compounds manufactured overseas and containing ingredients of biological origin, approval under the Biosecurity Act may be required before a product may be registered and imported for sale and use. Biosecurity Act assessment and approval is managed by another team within MPI, but the ACVM and Biosecurity application processes are integrated into one system which can be internally managed after submission of the appropriate documentation.

Biosecurity approval of imported ACVMs guideline

Biosecurity summary of information provided form

3.9 Screening to Finalisation: An Overview

There are two main considerations for making the application process work as efficiently as possible: ensuring that all the right documentation and forms have been submitted and ensuring that all required information is included in the application dossiers. The process starts with an administrative screening by the Approval Operations team on receipt of an application to confirm that all the relevant forms have been completed and submitted correctly, and that all required documentation is included in the submission. If there are any documents missing, or if forms are incorrectly or incompletely filled out, the Approvals Operations advisor will request that the applicant resolve the issues before the application can be lodged.

Once the administrative screening is complete, the application is logged and forwarded to either the Agricultural Chemicals Assessment or the Veterinary Medicines Assessment teams. Agricultural chemical and VTA applications forwarded to the Agricultural Chemical Assessment team are all then subject to a technical application review or "pre-screen", a high-level review of the application documents to confirm that all information necessary to support the registration or proposed change(s) have been provided and appear sufficient for assessment. Prescreen allows the team to determine whether the application can be formally received, and whether it requires public notification; it is not a preliminary assessment of the supporting information or a guarantee that no further data or information will be needed to complete the risk assessment. Most applications that fail to be formally received at the first technical application review (the "technical pre-screen") are returned to the applicant because either the documentation is incomplete or missing, or the supporting information is incomplete or missing.

Veterinary medicine applications are managed slightly differently once the administrative screening is complete. Applications to register new veterinary medicines, or variation applications for new uses, target species, or withholding periods, all undergo technical screening and public notification determination as per the agricultural chemical and VTA applications. Chemistry and manufacturing related variation applications for veterinary medicines however are automatically received into the veterinary medicine application queue without any prior screening and are screened and assessed at the same time once the application reaches the top of the queue. While these applications are automatically received for appraisal, they undergo the same risk assessment as all other applications and can still require additional information from the registrant to inform that assessment.

The time required from submission to formal receipt can vary depending on the quality of the application and whether it was sufficiently complete to pass both administrative screening and technical screening without significant delay. Once received, section 14 of the Act requires public notification of all applications for 30 working days in the New Zealand Gazette to allow members of the public to comment on the proposed registration or variation. Section 18 of the Act requires that all submissions received are forwarded to the applicant for review and comment. The submissions and the applicant responses are considered as part of the technical appraisal.

Under section 15, the Delegate has the power to waive the public notification requirement if either:

a) an application is made to register a new trade name product and there is already a registered product with the same active ingredient(s) and an equivalent formulation, or

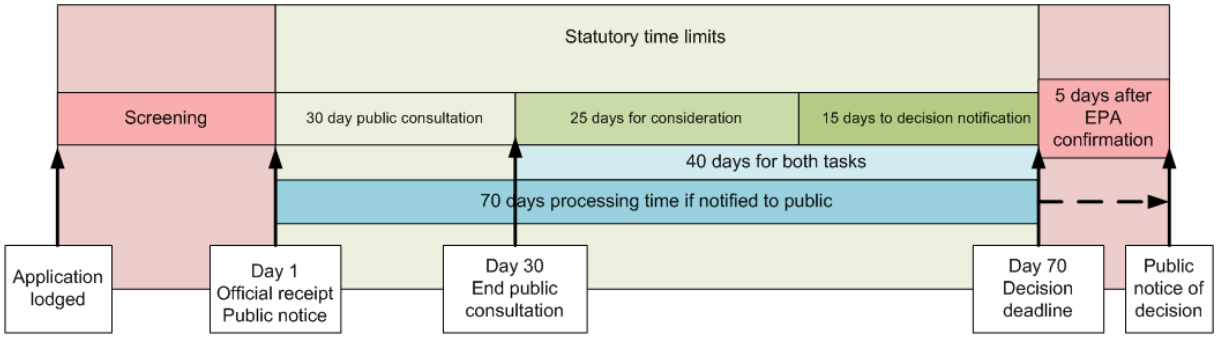
b) an application is made to vary the registration of an existing trade name product, and the variation does not change the risk profile.

If public notification is waived, the application will progress directly from formal receipt to the legislated 40 working day appraisal and decision time frame.

After completion of the public notification period, or at the point of formal receipt if notification if waived, the assessor assigned to the application will then look to complete the technical appraisal within 25 working days from the closing date for submissions. The assessment will review all data packages provided to complete a comprehensive risk assessment, with requests for clarification or further information provided to the applicant for response as it progresses. If the applicant requires

more time to address questions or source and provide the additional information necessary to inform the assessment, the Act provides the ability to apply a time waiver to “stop the clock”. It is noted that the waiver will be applied to include both the time necessary for data and information to be supplied and for the assessor to review the new information to ensure it addresses the gap or to ask for additional information. Most new product registrations will then undergo an internal peer review process to ensure all aspects of the risk profile are addressed and the proposed controls are appropriate prior to submission to the Delegate for a final decision.

The Delegate is the person in the team to which the Director-General’s power to decide on an application under section 21 of the Act has been delegated. This is typically the Team Manager responsible for the relevant Assessment team or the Manager ACVM Programmes and Appraisals, though delegated authority may be granted to another manager or person temporarily as needed. The Delegate is then allowed 15 working days to consider the application and its technical appraisal to make a final decision to either grant or refuse the application.



4 Post-Authorisation Activities

4.1 Compliance with Conditions of Registration

All registered products have conditions applied to their registrations to ensure all risks are being effectively managed. To accomplish this, the ACVM team have a set of standardised conditions that can be used for any product as the product-specific risk profile dictates. The team can also set new conditions as the need arises.

There are two types of standardised registration conditions: permanent conditions and temporary conditions. Permanent conditions are applied to products as dictated by their risk profile and are retained for the life of the registration unless there is a significant change to the risk profile at a later variation. These may include more general conditions like those applied to manage risks related to manufacturing, advertisement, and adverse event management, or product-specific conditions assigned to manage unique risks associated with a particular product or group of products such as conditions 67 (veterinary medicines) and 83 (agricultural chemicals) to mandate MRL compliance, the restricted veterinary medicine (RVM) conditions to mandate veterinarian authorisation, or product-specific reporting, use, and distribution conditions.

Temporary conditions are applied to products where there is an immediate risk to be managed, or a data gap to be addressed after registration has been granted, with or without an altered registration period. These conditions can be removed from the registration once the risk has been determined to have been appropriately managed through either the provision of additional information or the resolution of the finite risk.

A complete list of the permanent and temporary conditions currently used for all agricultural chemical, veterinary medicine, and VTA product registrations is included in the Appendix.

The specific set of conditions applied to each individual product can be found on the **ACVM Registered Product Register**.

It is expected that the conditions of registration are always complied with. However, it is acknowledged that occasionally things can go wrong unintentionally. As a result, conditions of registration may not be complied with. This is considered a non-compliance. See section 4.6 for more information.

4.2 Adverse Event Reporting

An adverse event is defined as any observation in a target crop or animal that is an unfavourable or unintended following any approved or off-label use of an agricultural compound. This can include:

- negative effects on the safety of the animal or crop;
- a lack of efficacy or issues with good agricultural practice (GAP),
- violative residues including inhibitory substance (IS) grades;
- issues with product quality such as unexpected application or distribution on use, sedimentation, or issues with resuspension after stirring or shaking;
- unfavourable interactions or compatibility issues with other registered or exempt agricultural compounds;
- transmission of infectious agents; or
- human adverse symptoms following contact with the compound.

All unfavourable or unintended events that are recognised outcomes of product use and that may or may not be identified on the product label are classified as adverse events.

A serious or significant adverse event is one that results in:

- animal/crop death, or is life threatening to animals;
- persistent or permanent negative impacts on animal/crop health or production;
- a congenital anomaly or birth defect; or
- issues in humans that may extend beyond the affected individual, such as the transfer of human pathogens or antimicrobial resistance; or
- an increased incidence of serious adverse events as described above that exceed the rates normally expected in a particular group of animals.

The investigation and reporting of adverse events to the ACVM team is a mandatory requirement for all registered agricultural compounds through the application of registration conditions 64 (veterinary medicines), 82 (agricultural chemicals), and 37 (VTAs). Registrants are expected to have systems in place to receive, document, and investigate adverse event reports, and to report adverse events to MPI in a timely manner following an investigation and causality determination as per the conditions of registration. Registrants are also expected to consider trends relating to potential batch or product manufacturing issues. In the event a non-compliance or product quality issue is identified, these are also expected to be reported as a non-compliance as well as an adverse event if the implicated batches/product are on the market. See section 4.6.2 for more information on reporting non-compliances.

The time frame expected for adverse event reporting is detailed in the adverse event registration conditions applied to products, but the general expectation is that significant and major events are reported immediately, and less significant or minor events are reported as soon as practicable. Reporting is achieved by completing and submitting an adverse event reporting form and ensuring the registrant investigation is as thorough as possible. For more information on reporting expectations, time frames, reporting forms, please see the adverse event reporting page on the MPI website and the agricultural chemical, veterinary medicine, and VTA adverse event guidance.

ACVM Adverse Events

- **Guideline: Adverse event reporting for agricultural chemicals**
    - **Form: Adverse event report for agricultural chemicals**

- **Guidelines for registrants: Adverse event reporting for veterinary medicines**
    - **Form: Adverse event report for veterinary medicines**
    - **Form: Adverse event report for animal feeds**
- **Guideline: Adverse event reporting for vertebrate toxic agents**
    - **Form: Adverse event report vertebrate toxic agents**

4.3 Significant New Information

Section 32 of the ACVM Act defines new information as any information that "*includes, but is not limited to, information not previously considered by the Director-General during an assessment of the registered trade name product and information indicating that conditions placed on the registered trade name product in accordance with **section 23** or **section 27** do not adequately manage the risks associated with that trade name product.*"

This means that "new information" can be anything that could impact the risk profile as it is currently understood, and includes information obtained for the same product if registered overseas. Registrants must therefore be aware of the risk profile of the product and monitor domestic and international issues to ensure any relevant new information is provided for review.

There are no formal forms or submission criteria for this information, as the type of information and circumstances in which they are discovered and provided can vary significantly from product to product. Contact the ACVM team if there is any information that you feel may be considered significant new information to discuss the issue and what would be expected in a submission.

4.4 Maintaining Manufacturer Approvals

Because the registrants are ultimately responsible for all aspects of their products, it is the registrant's responsibility to ensure that all manufacturers approved for any agricultural compound product (agricultural chemicals, veterinary medicines, and VTAs) have, and are maintaining a robust quality management system suitable for the products they manufacture.

Registrants must also ensure that manufacturers are provided with the applicable product particulars and registration information relevant to their responsibilities (i.e. they know what the approved specifications and manufacturing details are, and are able to follow them and comply), and have a current manufacturing quality agreement with each manufacturer that outlines each parties' responsibilities. This ensures that all products are being manufactured to an acceptable quality every time, that approved manufacturing processes and quality assurance, and control procedures are being followed, and that the final product is consistent from batch to batch and within a batch. A manufacturer should be made aware of and agree to their responsibilities. Making the manufacturer aware of the registration particulars that pertain to the products they manufacture means they can let the registrant know prior to making any changes that may impact a product's registration. Quality agreements and exchange of information should also include details of the active ingredient manufacturers and specifications, and agreement that the active ingredients won't be sourced from other manufacturers without approval and notification to the registration, as this would require a C2 type variation before finished product is released using active ingredients sourced from a new manufacturer.

Registrants of veterinary medicine and VTA products must also ensure that all manufacturers have and maintain current GMP approval (or recognised equivalent), and that the scope of the approval encompasses the activities that manufacturer undertakes for that product. If the scope does not include all activities necessary for the manufacture of the product, the manufacturer cannot be approved to manufacture that product even if their GMP approval is current and valid.

There may be situations where the registrant of a trade name product has decided to cease using the approved formulated product manufacturer(s), and it may be some time before a new manufacturer will be chosen. In these cases, registrants are expected to amend the product data sheet to remove

the manufacturer to ensure the product and manufacturing specifications remain accurate. This may mean that there is no formulated product manufacturer listed on the PDS. For a non-biological trade name product, this is acceptable provided the product is not actively being marketed and a new manufacturer is nominated and approved before product is reintroduced to the market. For a biological trade name product such as a veterinary vaccine, production of the master and working seeds by a new manufacturer presents an entirely new risk profile given the complexities of biological manufacture, and as such would likely constitute a new registration.

4.5 Maintaining product registrations over time

Registrants are expected to:

- **Practice good product stewardship.** Registrants are conditionally required to monitor product use in the field to ensure the determinations about the risk profile of the product and good agricultural practice are still valid and the risks are being adequately managed. This means receiving and investigating adverse event reports, monitoring domestic and international use of the product and/or active ingredient(s) with respect to relevant new information, and monitoring product chemistry and manufacturing details through the life of the product including an ongoing stability and quality control programmes.

- **Keep registrations up to date in a timely manner.** Over time there will likely be changes needed because of information and updates from pharmacovigilance or product management activities. A variation must be submitted prior to implementation of a change to the registration to ensure compliance with the condition requiring conformance to approved product and manufacturing specifications. Product that does not conform to these specifications, including the identity and source of ingredients, batch quality or consistency (even if the quality is uncertain), and labelling information, must not be released for sale.

- **Review product labels regularly**. The label is the main way for ACVM to communicate information to users. At every application and renewal, check the existing label with the relevant labelling guidance for your product

- **Work with MPI to maintain good risk management.** The ACVM team is the regulator for agricultural compounds, and are responsible for all registrations, guidance material, policy management, and other work involved in their regulation. To ensure the best outcome for all stakeholders, the team regularly engage with registrants, veterinarians, and primary industry producers to make sure risk management strategies are as comprehensive and practical as possible. Being active in the regulatory system, by asking questions, providing feedback on consultation documents and other projects, and staying engaged, is the best way to ensure favourable outcomes for everyone.

4.6 Compliance activities

Products authorised under the Act are expected to be manufactured, imported, sold, and/or used in accordance with their registration requirements and controls, or exemption requirements. A non-compliance occurs when an ACVM product or associated activity:

- is not authorised, or
- is in breach of the conditions of registration or exemption.

You may become aware of a non-compliance through:

- a customer complaint regarding a product they've bought and/or used
- unforeseen or unexpected events
- new information
- notification of a non-compliance from MPI
- results from MPI's regulatory monitoring and surveillance
- adverse event reports (both in New Zealand and overseas)

- stability trials and ongoing monitoring
- annual product reviews
- notification from other sources (for example, a non-compliance identified by overseas regulatory authorities that may affect products or batch(es) in New Zealand).

You can find examples of non-compliances and notification forms in section 4.6.2 below.

4.6.1 Compliance outcomes

MPI follows the VADE (Voluntary, Assisted, Directed and Enforced) model to determine the appropriate action to take. Educating and encouraging voluntary compliance is preferred in the first instance. However, directed or enforced compliance action may be taken if:

- a company or person is repeatedly non-compliant or unwilling to co-operate
- MPI has serious concerns regarding the non-compliance.

Once a non-compliance notification has been received, MPI will review the information, risk assessment and actions taken/proposed, and conduct our own risk assessment. Our assessment will ascertain whether the actions taken and/or proposed are appropriate to ensure the potential or confirmed risks are mitigated.

After our review and assessment of the non-compliance, MPI may:

- agree with the actions proposed
- recommend amendments to proposed actions or additional actions
- direct additional actions to be taken such as:
    - issuing a prohibition notice prohibiting the manufacture, sale, import, or use of the product until such time as the contravention of the Act is rectified to the satisfaction of the ACVM officer (refer directly to s65).
    - directing a recall if the compound does not comply with any requirements of the Act or regulations AND the non-compliance could result in serious or significant risk to the matters in section 4 (refer directly to s35G).

Other compliance tools include:

- Suspending the registration for up to 3 months if the Director-General has reasonable grounds to believe that any condition imposed upon registration is not being complied with (refer directly to s30A)
- Cancelling the registration if there are repeated failures, or there is a serious failure, to comply with any conditions imposed on the registration at a time when the registration is suspended under s30A (refer directly to s32A).
- Announced or unannounced site inspections by ACVM officers to determine whether any person is complying with the Act (refer directly to s64).
- Refer for enforcement action (i.e. prosecution) which is done by another MPI team. Every person who commits an offence against section 55 of the ACVM Act and is convicted can be subject to jail for up to 2 years and/or a fine up to $30,000. A corporation can be subject to a fine up to $150,000 (refer directly to s56).

4.6.2 Reporting a potential or confirmed non-compliance (including recall)

It is important to report and investigate a non-compliance as soon as possible as it may be necessary to implement urgent measures to protect animal welfare, public health, trade, domestic food residue standards, and/or agricultural security. Urgent measures may involve a product or batch recall and/or ceasing sale and supply of the product.

To report a potential or confirmed non-compliance (including recall), use the following forms and guidance to assist.

For your registered ACVM product:

- **Notification form**
- **Guideline for Registrants**

For your exempt or unregistered product:

- **Notification form**
- **Guideline for reporting your non-complying exempt or unregistered ACVM product on the market**

If a recall is proposed, also complete the recall form and use the guidance to assist:

- **ACVM product recall notification form**
- **Guideline for conducting recalls of ACVM products**

For more information, please see the **ACVM non-compliance and recalls** webpages.

5 Contacting Us

All operations and technical team members are usually balancing large workloads from multiple registrants and other stakeholders including manufacturers, so knowing who to contact and when to contact them will help ensure your query is answered in the most efficient way possible. Here are some general guidelines for contacting us, at the time of publication. If you are unsure, contact approvals@mpi.govt.nz in the first instance and they will direct your query accordingly.

If you have…		Contact…
General Queries and Issues	A general ACVM query	Your Operations Team Client Manager or the Approvals Inbox: **Approvals@mpi.govt.nz**
	A query for or an issue to raise with a Team manager,	Ag Chem & VTAs (Assessments): **Amanda.McKay@mpi.govt.nz** Vet Meds (Assessments): Currently vacant Regulatory Programmes (GMP, Compliance, RVM Sellers): **Holly.Jeboult-Jones@mpi.govt.nz**
	An urgent query or issue that require escalation to the ACVM Manager,	Karen Booth: **Karen.Booth@mpi.govt.nz**
	A query for or an issue to raise with the Operations Team manager,	Imogen Dear: **Imogen.Dear4@mpi.govt.nz**
Application Management	A general technical query regarding data and/or application requirements,	Your Operations Team Client Manager or the Approvals Inbox: **Approvals@mpi.govt.nz**, who will refer the query to the technical team for a response.
	A product-specific or application-specific query before an application has been submitted,	Your Operations Team Client Manager or the Approvals Inbox: **Approvals@mpi.govt.nz**, who will refer the query to the technical team.
	An application to register a product or vary the approval for a registered product,	Your Operations Team Client Manager or the Approvals Inbox: **Approvals@mpi.govt.nz**, who will complete an administrative check and refer the application for technical screening.
	An application-specific query regarding an application that has been screened but not accepted,	Your Operations Team Client Manager, who will refer the query to the technical assessor who screened the application.
	A response to an application not being accepted at screening,	Your Operations Team Client Manager, who will send the application back through the screening process.
	An application-specific query after an application has been formally received (i.e. the application has passed pre-screen),	Your Operations Team Client Manager, who will refer the query to the technical assessor assigned to the application.
	A response to a query posed by a technical assessor during an application's appraisal,	The technical assessor appraising the application or your Operations Team Client Manager, depending on how you received the query.

If you have…		Contact…
Post-Authorisation Management	A request to remove a temporary special condition,	Your Operations Team Client Manager or the Approvals Inbox: **Approvals@mpi.govt.nz**, who will complete an administrative check and refer the application for technical screening.
	An adverse event report,	**ACVM-AdverseEvents@mpi.govt.nz**
	Identified significant new information that needs to be reported,	Your Operations Team Client Manager or the Approvals Inbox: **Approvals@mpi.govt.nz**, who will redirect the information accordingly.
	A report of non-compliance including recall notification	See the **Non-compliant ACVM products or activities** web page for the online reporting tool or submission forms, or email **ACVM-recallsandcompliance@mpi.govt.nz**
Manufacturing approvals and other regulatory programmes	A request for GMP approval or other GMP/manufacturing-related matters including requests for additional GMP Certificates (there is a form online for this),	**ACVM.manufacturingandassurance@mpi.govt.nz**
	Other manufacturing related queries,	**ACVM.manufacturingandassurance@mpi.govt.nz**
	A request for approval of your RVM Seller Operating Plan, or other RVM seller activity queries,	**ACVM.RVMsellers@mpi.govt.nz**
MRL Setting	Queries associated with MRL setting, or a request to set or change a MRL that is not associated with a product registration application,	Your Operations Team Client Manager or the Approvals Inbox: **Approvals@mpi.govt.nz**, who will redirect the request and supporting information accordingly.

GLOSSARY

GAP means good agricultural practice

GMP means good manufacturing practice

MRL means maximum residue level

OP means operating plan.

PDS means Product Data Sheet

PIC/S means the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme

TNP means trade name product.

RVM means restricted veterinary medicine

RTT OP means Research, Testing, and Teaching/Training operating plan

VTA means vertebrate toxic agent

APPENDIX 1: Permanent and Temporary Standardised Conditions Applied to Agricultural Chemical and Veterinary Medicine Product Registrations

Permanent Conditions Applied to manage product identity, characteristics, and manufacturing

Condition	Assessment	Impact on registrant/user
60. The manufacture of the product must, at all times, conform to the product and manufacturing specifications approved as part of this registration.	Applied to require ongoing conformance to all approved formulation and manufacturing details.	The registrant is required to ensure that any changes to the approved product chemistry and manufacturing information is submitted for assessment and approved before implementing those changes. This includes the addition or removal of any of the active ingredient or formulated product manufacturers, changes to the formulation, changes to active ingredient or formulated product specifications, changes to packaging, changes to the shelf life, or changes to any other technical or administrative details in the product data sheet.
62. The product must be manufactured by a person specified to manufacture it and acting in accordance with an operating plan approved under section 28.	**VETERINARY MEDICINE USE ONLY** Applied to ensure the product is only manufactured by the approved manufacturer(s), in accordance with their approved operating plan, and only perform the steps for which they are approved.	The approval of manufacturing operating plans, and site audits to ensure manufacturers are acting in accordance with those operating plans, are conducted under the GMP programme. All manufacturers must have either current certificate issued by MPI following an inspection by an ACVM auditor or have evidence of GMP compliance issued by a recognised overseas authority. Registrants must ensure that all entities undertaking any step of formulated product manufacturing, in part or for the entire process, have a current GMP approval from a recognised authority. They are also responsible for ensuring that they only use manufacturers approved for the scope of the activity being undertaken, and that manufacture of their products are being done in accordance with the approved product particulars. This condition also manages conformance to other independently assessed quality management system approval for veterinary medicines where it has been determined that an alternative evaluation of product manufacture is acceptable, such as FAMI-QS approval for certain animal feed manufacturers.

Condition	Assessment	Impact on registrant/user
108. The registrant must provide sufficient consumer advice about the on-going stability of the product for use if requested by any purchaser of the product. The registrant must withdraw the product from the marketplace where evidence shows it is no longer capable of meeting its expiry specifications prior to its use, when stored in line with the manufacturer's recommendations.	**AGRICULTURAL CHEMICAL USE ONLY** Specific condition for products with demonstrated stability of 2 years or over.	This condition is applied when the registrant is satisfied they can manage shelf-life through means other than an expiry date printed on the label. It will not be applied to non-standard products such as those that require real-time stability testing, for example microbials, antibiotics, or those containing active ingredients which are known to have toxic degradation products over storage.

Permanent Conditions to manage distribution, sale and use (including labelling and advertising)

Condition	Assessment	Impact on registrant/user
58. Advertising and promotion must only be directed to registered veterinarians or persons with an ACVM approval to trade in this product	**VETERINARY MEDICINE USE ONLY** Applied to products with restrictions on advertising and promotion.	This condition is applied to products where advertising and promotion must not be directed to the end user and is applied to all veterinary medicines containing antibiotics of significance to human health. Registrants must ensure that products are not being advertised directly to anyone other than registered practising veterinarians and approved sellers.
61. The product must be labelled in accordance with the product and manufacturing specifications approved as part of this registration.	Applied to ensure the product label is as approved.	The registrant is required to ensure that any changes to the approved label information is submitted for assessment and approved before implementing those changes. Any product information, use information, warnings, and storage information on the label approved by ACVM is considered be part of the approved product and manufacturing specifications subject to regulatory control.

Condition	Assessment	Impact on registrant/user
63. Persons responsible for the product at each stage throughout its distribution must maintain the product in a manner that ensures it conforms to the approved product and manufacturing specifications through to the product's retail sale.	Applied to manage risks associated with the product's distribution across the supply chain.	The registrant and all persons and entities in the distribution chain must ensure that quality control and risk management procedures are effective throughout all steps in the distribution chain to ensure the product is fit for purpose and compliant with its product and manufacturing specifications at the point of retail sale. This is especially important for products with specialised distribution chain requirements such as cold storage or specific handling conditions.
66. No advertisement for the product may: (a) include content or be presented in a manner that does not conform to the approved product and manufacturing specifications (this includes approved uses); (b) contain false or misleading claims, statements or information in relation to the product; or (c) without limitation to the generality of (b), directly or by implication make false or misleading claims or statements about the regulatory status of the product under the ACVM Act.	Applied to ensure advertising is aligned with the approved claims.	The registrant must ensure that all labelling, advertising, and promotional material complies with the controls and information approved for that product. The product must only be advertised with claims and/or uses for which it is approved (i.e. registrants must not advertise off-label uses). Advertisements must not represent the product in a manner that contradicts the approval, or any controls applied to registration such as product classification and restrictions on distribution and use.
68. Any person using the product on any animal or in any manner other than as specified in the approved product and manufacturing specifications must, before using the product, seek advice from an appropriately qualified source and confirm that the intended use is not likely to cause unnecessary or unreasonable pain or distress in the animal treated.	**VETERINARY MEDICINE USE ONLY** Applied to unrestricted veterinary medicines to ensure that users consult with a source of appropriate expertise to provide guidance on the safety of off-label use.	This condition is applied to unrestricted veterinary medicine products for which off-label use is permitted to manage the potential risks to animal welfare posed by such use. To communicate this requirement to the user, registrants must ensure that the mandatory label statement for this condition is included in the product labelling: **By law the user must take due care, obtaining expert advice when necessary, to avoid unnecessary pain and distress when using the product other than as directed on the label**.

Permanent Conditions to <u>restrict</u> distribution, sale and use

Condition	Assessment	Impact on registrant/user
31. This product must only be used as specified in the label content.	Applied when discretionary off-label use is not appropriate or carries significant risk (e.g., acephate, hormonal growth promotants).	This condition is on the user. To communicate this requirement to the user, registrants must ensure that the mandatory label statement for this condition is included in the product labelling: **It is an offence to use this product off-label** or **By law this product must only be used according to the label**
42. The product must be sold only by an approved trader. The product must be sold only to an approved trader, or to any person with a veterinary prescription or authorisation, or to persons approved under Section 103 of the Biosecurity Act 1993. The product must be administered to an animal only by a veterinarian, or under and in accordance with the authority or prescription of a veterinarian, or by persons approved under Section 103 of the Biosecurity Act 1993 when applying cattle and deer tuberculin tests.	**<u>VETERINARY MEDICINE USE ONLY</u>** Applied to veterinary tuberculin diagnostic products only, to manage the unique risks associated with tuberculosis monitoring and control in New Zealand.	This condition is applied to products that may impact the management of tuberculosis in ruminants with respect to testing. Registrants are required to ensure that the distribution of the product conforms to this control, and to communicate this requirement to the user through the following mandatory label statement: **It is a legal requirement that this product is only used under the authorisation of a veterinarian or by persons approved under section 103 the Biosecurity Act 1993.**
<u>Restricted Veterinary Medicine Conditions</u> 69. The product must be sold only by either: (a) A veterinarian recognised under section 44G to authorise its purchase and use for animals under that veterinarian's care; or (b) A person specified to sell the product or similar products in and acting in accordance with a relevant operating plan approved under section 28. 70. For the purposes of the condition, 'veterinary authorisation' means that a veterinarian recognised under section 44G has issued a valid authorisation for its purchase and use. Any advertisement of this product must contain a statement that the product is available for purchase and use only under and in compliance with a veterinary authorisation.	**<u>VETERINARY MEDICINE USE ONLY</u>** Applied to veterinary medicines which require authorisation by and oversight from a veterinarian to ensure all associated risks are being managed.	These conditions are applied to restrict and manage who is permitted to sell (69), purchase (71), and use (72) restricted veterinary medicines (RVMs). They also define what a veterinary authorisation is (70), and the regulatory requirements applicable to veterinarians regarding their authorisation role (73). Registrants, wholesalers, and other entities approved as RVM sellers must ensure that products classed as RVMs are distributed and sold according to the expectations in the conditions, that all products are appropriately labelled as RVMs, and that the requirements for promoting and advertising RVMs are complied with.

Condition	Assessment	Impact on registrant/user
71. The product must be sold only to: a) A person specified in an approved operating plan; or b) Any person in possession of a valid authorisation issued either, (i) by a veterinarian recognised under section 44G to issue an authorisation for its purchase and use, or (ii) under and in accordance with an approved operating plan. 72. The product must be used under the authority of and in accordance with a valid authorisation issued either: (a) by a veterinarian recognised under section 44G to issue a valid authorisation for its purchase and use; or (b) under and in accordance with an approved operating plan. 73. All veterinarians recognised under section 44G to issue an authorisation to purchase and use a restricted veterinary medicine must comply with 'ACVM Notice Requirements for Authorising Veterinarians' issued by the Director General, and for the time being in place, under section 44ZN of the Act, for authorising this type of product.		
84. The product must not be used on animals unless the use is approved as part of this registration.	**AGRICULTURAL CHEMICAL USE ONLY** Applied to prevent agricultural chemicals being used in or on animals.	This condition is placed on the user, to prevent off-label use of agricultural chemicals in or on animals. This is because these products have not been assessed for animal safety as a veterinary medicine would. To communicate this requirement to the user, registrants must ensure that the mandatory label statement for this condition is included in the product labelling: **It is an offence to use this product on animals.**

Condition	Assessment	Impact on registrant/user
89. The product must be imported, distributed, sold or used only in accordance with the relevant operating plan approved under section 28.	Applied when the risk profile indicates that distribution, sale, and use of the product requires an additional level of product-specific risk management.	This condition is used where controls beyond those imposed by the standard conditions is needed to manage the associated risk. The requirement for product-specific operating plans is usually applied where there is a need to more strictly and specifically manage distribution and/or use of the product. Registrants are required to ensure that the operating plan is followed as approved and maintained over time to ensure continued risk management, and that the mandatory label statement is included in product labelling to relay these restrictions to the user: **By law, the distribution and use of this product must comply with the requirements of the approved operating plan.**
90. This product must not be used on any animal producing, or intended to produce, food for human consumption.	**VETERINARY MEDICINE USE ONLY** Applied to ensure no residue and trade risks are managed where residues from the active ingredient(s) must not occur in food from production animals.	This condition is reserved for application to products requiring a specific prohibition for use in food-producing animals, usually in situations where the risk cannot be otherwise managed with the application of a product-specific withholding period or the default withholding period for the treated species. Because these products are usually RVMs due to the risk profile, responsibility for compliance is shared between the registrant, authorising veterinarian, and user. To communicate this requirement to the user, registrants must ensure that the mandatory label statement for this condition is included in the product labelling: **It is a legal requirement that this product is not used in any animal producing or intended to produce food for human consumption.**
147. The product must not be used for the promoting growth or increased yield in ruminants from which animal material as defined in the Animal Products Act 1999 is likely to be used for human consumption.	**VETERINARY MEDICINE USE ONLY** Applied to manage the specific risks associated with the presence of coccidiostat residues in animal products intended for export.	This condition is applied to specifically manage the trade risk associated with the use of products for the purpose of growth or yield promotion, though its application is limited to coccidiostat-based products used in ruminants. To communicate this requirement to the user, registrants must ensure that the mandatory label statement for this condition is included in the product labelling: **By law, this product must not be used for the purpose of promoting growth or increased yield in ruminants.**

Permanent Conditions to manage reporting requirements (adverse events, new information, sales data)

Condition	Assessment	Impact on registrant/user
34. An annual report of sales by month must be supplied by the registrant to the Ministry for Primary Industries.	Applied to ensure sales reporting for products for which the risk profile indicates monitoring and trending is required.	Registrants are required to provide sales information yearly, stratified by month, for all products for which the risk profile indicates that sales trends must be monitored. The condition is generally applied to all agricultural chemical and veterinary medicine products containing antibiotics of significance to human health, though it can also be applied to other products for which there is a risk-based need to monitor product sales.
64. The registrant must investigate the significance of every adverse event associated with the use of the product; and report to Ministry for Primary Industries within 20 working days the outcome of this investigation. The registrant must notify Ministry for Primary Industries immediately upon becoming aware of an adverse event that seems to have seriously jeopardised the health and welfare of the treated/exposed animal(s); and may require the use of the product to be stopped or restricted to prevent similar adverse events.	**VETERINARY MEDICINE USE ONLY** Applied to ensure all adverse events associated with a product are investigated and reported to ACVM, and to ensure serious adverse events are reported immediately.	The registrant must investigate all adverse events within 20 working days and report their findings and any corrective actions to ACVM. Where an adverse event is found to have seriously jeopardised animal welfare, the event is reported immediately and updates on the registrant's investigation findings are updated as they develop. This is because all adverse events can potential significant and immediate impacts on animal welfare, agricultural security, trade, and/or public health depending on the nature of the event. Events are considered serious where animals are significantly injured or have died, or there are negative impacts on a large number of animals such as an entire herd or region. Each incident, and the determination of what constitutes "serious," should be evaluated on a case by case basis relative to the product's risk profile.
65. The registrant must, as soon as practicable after becoming aware of new information, advise Ministry for Primary Industries of any new information that relates to the relevance, reliability or correctness of information provided at the time of registration and upon which the decision to register the product was made.	Applied to ensure that any new information is provided to ACVM in a timely manner.	The registrant must diligently monitor new information that is relevant to their products, ingredients used to formulate their products, or any other information that may impact the previously assessed risk profile of the product or compound. This includes anything that may impact the product's manufacture and use in New Zealand, or anything occurring overseas related to a product or compound that could impact trade in treated primary produce.

Condition	Assessment	Impact on registrant/user
66. No advertisement for the product may: (a) include content or be presented in a manner that does not conform to the approved product and manufacturing specifications (this includes approved uses); (b) contain false or misleading claims, statements or information in relation to the product; or (c) without limitation to the generality of (b), directly or by implication make false or misleading claims or statements about the regulatory status of the product under the ACVM Act.	Applied to ensure advertising is aligned with the approved claims.	The registrant must ensure that all labelling, advertising, and promotional material complies with the controls and information approved for that product. This includes only advertising the product for claims and/or uses for which it is approved (i.e. registrants must not advertise off-label uses) and advertisements must not represent the product in a manner that contradicts the approval, or any controls applied to registration such as product classification and restrictions on distribution and use.
82. For the purposes of this condition, an adverse event is any event that brings into question the relevance or reliability of information provided at the time of registration and upon which the decision to register the product was made. The registrant must notify Ministry for Primary Industries of an adverse event in relation to the product, immediately upon becoming aware of the event, where the event has or may have significant implications for the continued use of the product.	**AGRICULTURAL CHEMICAL USE ONLY** Applied to define what an adverse event is, and ensure significant events are reported to ACVM.	The registrant is required to evaluate reported adverse events to determine whether it will have significant implications for the ongoing use of the product, and if significant, then report it immediately to MPI for further review and consideration. As well as phytotoxicity, this may also include inefficacy and residue non-compliance when used according to label directions, Adverse events must be managed and reported quickly to implement mitigation strategies at both the registrant and regulatory level and limit the scope and significance of a product- or compound-related event.

Permanent Conditions to manage residue risk via MRL compliance

Condition	Assessment	Impact on registrant/user
67. Any person using the product on any animal from which animal material as defined in the Animal Products Act 1999 is likely to be used for human consumption (whether that use is in accordance with the approved product label or not) must ensure that residues of any substance in the product that may occur in animal material produced from the treated animals, do not exceed the lower of either: (a) the specified residue level in the current Food Notice: Maximum Residue Levels of Agricultural Compounds; or (b) where a maximum residue level for that substance has not been specified, the default maximum residue level in the current Food Notice: Maximum Residue Levels of Agricultural Compounds.	**VETERINARY MEDICINE USE ONLY** Applied to ensure all use of the product complies with applicable MRLs, including off-label use. NOTE: Also applies to apiculture products due to the designation of honeybees as food-producing animals under the Animal Products Act, and honey as food under the Food Act.	This condition applies to the use of the product but is managed at the product registration level to ensure residue risks are appropriately communicated to the user and managed through compliance with MRLs (including the default MRL where no specific MRL is set). To communicate this requirement to the user, registrants must ensure that the mandatory label statement for this condition is included in the product labelling: **It is an offence for users of this product to cause residues exceeding the relevant MRL in the Food Notice: Maximum Residue Levels for Agricultural Compounds.** The tool used to ensure compliance with MRLs when products are used according to label directions are the on-label withholding periods assigned to product registrations. These are applied to all relevant food commodities from treated food-producing animals, e.g. meat, milk, honey, eggs. When products are used ‘off-label’ it is the user’s responsibility to ensure compliance with MRLs is still achieved.

Condition	Assessment	Impact on registrant/user
83. Any person using the product must ensure that residues of any substance in the product that may occur in: (a) Plant material intended for human consumption produced from plants or plant material treated with the product, or (b) Animal material as defined in the Animal Products Act 1999 intended for human consumption produced from grazing or direct feeding plants or plant material treated with the product to food producing animals does not exceed the lower of either: (i) the specified residue level in the current Food Notice: Maximum Residue Levels for Agricultural Compounds; or (ii) the default maximum residue level in the current Food Notice: Maximum Residue Levels for Agricultural Compounds, when a maximum residue level for that substance has not been specified.	**AGRICULTURAL CHEMICAL USE ONLY** Applied to ensure all use of the product complies with applicable MRLs, including off-label use. This is not required on home garden products packed in sizes no greater than 1 kg or 1L.	This condition applies to the use of the product but is managed at the product registration level to ensure residue risks are appropriately communicated to the user and managed through compliance with MRLs (including the default MRL where no specific MRL is set). This condition also manages the risks associated with residue transfer to animals from treated crops, provided animal commodity MRLs are met. To communicate this requirement to the user, registrants must ensure that the mandatory label statement for this condition is included in the product labelling: **It is an offence for users of this product to cause residues exceeding the relevant MRL in the Food Notice: Maximum Residue Levels for Agricultural Compounds.** The tool used to ensure compliance with MRLs when products are used according to label directions are the on-label pre-harvest, pre-grazing, and other withholding period statements assigned to product registrations. These are applied to all relevant food commodities from treated crops as well as animal commodities from food-producing animals when the product is used on crops intended for use as animal feed. When products are used 'off-label' it is the user's responsibility to ensure compliance with MRLs is still achieved.

Temporary conditions to manage risk on a case by case basis

Condition	Assessment	Impact on registrant/user
86. The registrant must provide a batch analysis, which confirms that the product meets the approved release specifications, from the first production batch at the new manufacturing site to Ministry for Primary Industries for approval prior to sale of product from this new site.	Applied when a manufacturer is approved without production data, and evidence is required to demonstrate the site can manufacture to approved specifications before product may enter the market.	This condition (often accompanied by a shortened registration expiry period) is used when batch data is not available, considering some manufacturing sites will not start commercial production until the site is approved. This allows for approval to commence manufacture but restricts release to market until batch data can be provided to and reviewed by ACVM. It can apply to both formulated product and active ingredient manufacture. For veterinary medicines this condition is often applied with Condition 144 The condition is removed when the required data has been supplied.
<u>General post-registration information requirement Conditions</u> 101. The registrant must provide additional information specified by the Ministry for Primary Industries at or before the expiry of the current product registration period. 140. The registrant is responsible for ensuring that the additional information specified by the Ministry for Primary Industries is provided at or before the expiry of the current product registration period. 144. The registrant must provide manufacturing process validation data in the agreed format and within the agreed time frame for the stipulated manufacturer. 145. The registrant must ensure that the additional information specified by the Ministry for Primary Industries is provided and found acceptable before product is sold in New Zealand. 146. The registrant must ensure that the additional information specified by the Ministry for Primary Industries is provided and found acceptable within the stipulated timeframe	Applied where the information provided is considered adequate to confirm that risks can be managed or unlikely to occur (from an ACVM perspective), but additional information is required post-registration to confirm or refine the conclusions and/or controls resulting from the initial risk assessment.	These conditions (often accompanied by a shortened registration expiry period) are used when additional data is required to support or confirm the conclusions of the application assessment. These conditions can be applied to require any data or information related to the risk profile and risk assessment for the product, such as confirmatory process manufacturing validation or stability data after commercial production commences, results from ongoing longer-term studies, or field evaluation of adverse events once a product is in use. Specific advice explaining why the condition was added and the data and information to satisfy and remove the condition is included in the registration letter. The relevant condition is removed when the required data has been supplied.

<u>Post-registration information requirement conditions when reserve manufacturers are approved</u> 141. The registrant must provide a batch analysis, which confirms that the product meets the approved release specifications, from the first production batch from the reserve manufacturing site to Ministry for Primary Industries for approval prior to sale of product from this reserve site. 142. The registrant must provide manufacturing process validation data in the agreed format and within the agreed time frame for the reserve manufacturer. 143. The registrant must provide analytical method validation data in the agreed format and within the agreed time frame for the reserve manufacturer.	Applied where the information provided is considered adequate to confirm that risks can be managed or unlikely to occur (from an ACVM perspective), but additional information is required post-registration to confirm or refine the conclusions and/or controls resulting from the initial risk assessment.	These conditions are used when additional data is required to support or confirm the conclusions of the application assessment but are used in the specific situation of the manufacturer being a 'reserve' manufacturer. These are manufacturers that either may not be used for some time or may never be used in the regular production of the product, and therefore the timeframe to generating the required data is unknown. While data provision expectations and application of these conditions are generally similar to the use of conditions 101, 140, 144, 145, and 146, these conditions may remain on a registration for multiple registration cycles or indefinitely and as such do not usually attract a shortening of the registration period.
136. The product must not be sold until all proposed MRLs specific to the use directions on the product label are promulgated. 138. The product must not be advertised or sold with uses or claims on the label that are subject to proposed MRLs until such MRLs have been promulgated.	Applied when a product's registration can be finalised but the MRL setting process is not yet complete.	These conditions exist as an interim residue and trade risk management option to facilitate product manufacture or marketing during MRL setting. The conditions either allow for registration with authorisation to advertise but not sell (136) or registration with a prohibition on both advertising and sale (138) pending MRLs, instead of holding the entire application for completion. Use of these conditions are considered on a case by case basis following discussion with the registrant and the ACVM delegate. The applicable condition is removed once the associated MRLs have been finalised.

APPENDIX 2: Permanent and Temporary Standardised Conditions Applied to Vertebrate Toxic Agent (VTA) Product Registrations

Note: While the registration conditions below are current at the time of publication, Vertebrate Toxic Agents containing brodifacoum are currently undergoing a reassessment which will result in the development and setting of new registration conditions. For more information on the VTA reassessment, please see Reassessment of Registered Vertebrate Toxic Agents (VTA) Products contain brodifacoum. A reassessment for all other VTAs will follow the work on brodifacoum products.

Permanent Condition Applied to manage product identity, characteristics, and manufacturing

Condition	Assessment	Impact on registrant/user
2. The product must be manufactured in accordance with the Ministry for Primary Industries Standard for Good Manufacturing Practice and to the chemistry and manufacturing specifications provided by the registrant and approved as part of the registration.	Applied to manage product identity, manufacturing and consistency for VTAs, as well as GMP compliance.	The registrant is required to ensure that any changes to the approved information in the product data sheet is submitted for assessment and approved before implementing those changes.

Permanent Conditions to manage distribution, sale and use (including labelling and advertising)

Condition	Assessment	Impact on registrant/user
31. This product must only be used as specified in the label content.	Applied when discretionary off-label use is not appropriate or carries significant risk (e.g., acephate, hormonal growth promotants, VTAs). Application of this condition is common to VTAs as the animal welfare has not been considered for off-label use.	This condition is placed on the user. To communicate this to the user, registrants must ensure that the mandatory label statement for this condition is included in the product labelling: **It is an offence to use this product off-label** or **By law this product must only be used according to the label**

Condition	Assessment	Impact on registrant/user
43. The product must be sold only by a person who has been approved by the Ministry for Primary Industries.	Applied to restrict sales of VTA products to approved persons.	The registrant must ensure that all product sales are conducted by an appropriately approved seller.
44-47. If the label indicates the product can only be sold to and/or used by a person holding a controlled substances licence then: 44. This product must be sold only to a person holding a controlled substances licence issued by a test certifier who has been approved by the Ministry for Primary Industries. 45. Any advertisement or promotion for this product must clearly state that it can only be sold to a person who holds a controlled substances licence. 46. The product must not be displayed for the general public to see. It must be kept secure from unauthorised persons and individual containers marked for trace back purposes. A register of sales must be kept (minimum of 3 years), recording who the product was sold to (controlled substances licence reference) and the container(s) serial identity. 47. The product must be used only by a person either holding a controlled substances licence issued by a test certifier who has been approved by the Ministry for Primary Industries, or by a person under the direct supervision of a person holding a controlled substances licence.	Applied to restrict sales and/or use of VTA products according to product-specific risk in different scenarios.	The registrant must ensure that all product sales and use comply with the restrictions stated in the condition(s).

Condition	Assessment	Impact on registrant/user
48. If the product is to be aerially applied, then the public must be given sufficient notice prior to application informing them of: a) what is being used; b) when it is to be used; c) where it is going to be used; d) the responsible person; and e) appropriate warnings in regard potential harm (dogs should be kept out of the area). The application must not be earlier than the date of application stated in the public notification and, if the product has not been applied within 2 months, the notification is invalid.	Applied to manage product-specific risk where it is applied by aerial release.	The registrant must ensure that the condition is complied with.
49, 50. If the label indicates the product can only be sold to and/or used by a person holding a controlled substances licence then: 49. Signs must be posted in prominent places around the perimeter of the treated area. The signs must remain in place until monitoring confirms that the product is no longer present. Signs must state: a) that it is an offence for any person to remove the sign(s) prior to clearance of the area; b) that it is an offence for any person (other than the applicator) to remove/move baits from the area; c) Warning of potential harm to dogs. 50. Security, identity and application of the product must be under the control of a specified person who also holds a controlled substances licence from a test certifier approved by the Ministry for Primary Industries.	Applied to restrict sales and/or use of VTA products according to product-specific risk in different scenarios.	The registrant must ensure that all product sales and use comply with the restrictions stated in the condition(s).

Condition	Assessment	Impact on registrant/user
51. Vertebrate Toxic Agents: In addition to any labelling, advertising or promotion requirements specified in the current registration, labelling, advertising or promotion of the product must comply with the current Ministry for Primary Industries - New Zealand Labelling and Advertising Guide for Vertebrate Toxic Agents Requiring Registration	Common condition to ensure advertising is aligned with the approved claims.	The registrant must ensure that all labelling, advertising, and promotional material complies with the controls and information approved for that product. This includes only advertising the product for claims and/or uses for which it is approved (i.e. registrants must not advertise off-label uses) and must not represent the product in a manner that contradicts the approval, or any controls applied to registration such as product classification and restrictions on distribution and use.
55. For pack sizes greater than 3kg, the product must be sold only by a person who has been approved by the Ministry for Primary Industries	Applied to manage the risks associated with large-volume VTA sales and use.	The registrant must ensure that sales are limited to authorised persons.
98-100. If the label indicates the product can only be sold to and/or used by a person holding a controlled substances licence then: 98. This product must be sold only to a person holding a controlled substances licence. 99. The product must be used only either by a person holding a controlled substances licence or by a person under the direct supervision of a person holding a controlled substances licence. 100. Security, identity and application of the product must be under the control of a specified person who also holds a controlled substances licence.	Applied to restrict sales and/or use of VTA products according to product-specific risk in different scenarios.	The registrant must ensure that all product sales and use comply with the restrictions stated in the condition(s).

Permanent Conditions to manage reporting requirements (adverse events, new information, sales data)

Condition	Assessment	Impact on registrant/user
37. Ongoing obligations: The registrant must provide an annual summary of adverse events to the Ministry for Primary Industries. Adverse events which have serious implications for the continued use of the product must be notified immediately. The registrant must also advise the Ministry for Primary Industries of any new studies or data that contradict information previously supplied.	Applied to VTAs to ensure use and adverse events are effectively managed, and the product label is as approved.	The registrant is required to investigate and report any adverse events to ensure the risk profile is as previously assessed and all risks are being managed appropriately. The registrant is also required to ensure that any changes to the approved label information are submitted for assessment and approved before implementing those changes. Any product information, use information, warnings, and storage information on the label approved by ACVM is considered be part of the approved product and manufacturing specifications subject to regulatory control.
56. For pack sizes greater than 3kg, a register of sales must be kept (minimum of 3 years), recording who the product was sold to and the quantity sold	Applied to manage the risks associated with large-volume VTA sales and use.	The registrant keeps records of all sales as specified in the condition. Data and information pertaining to VTA sales may be requested by MPI for review.

Temporary conditions to manage risk on a case by case basis

Condition	Assessment	Impact on registrant/user
86. The registrant must provide a batch analysis, which confirms that the product meets the approved release specifications, from the first production batch at the new manufacturing site to Ministry for Primary Industries for approval prior to sale of product from this new site.	Applied when a manufacturer is approved without production data to require evidence the site can produce production-scale product that meets approved specifications before product may enter the market from that site.	This condition (often accompanied by a shortened registration expiry period) is used when data is not available, considering some manufacturing sites will not start commercial production until the site is approved. This allows for approval to commence manufacture but restricts release to market until batch data can be provided to and reviewed by ACVM. It can apply to both formulated product and active ingredient manufacture.

Condition	Assessment	Impact on registrant/user
101. The registrant must provide additional information specified by the Ministry for Primary Industries at or before the expiry of the current product registration period.	Applied where the information provided is considered adequate to confirm that risks can be managed or unlikely to occur (from an ACVM perspective), but additional information is required post-registration to confirm or refine the conclusions and/or controls resulting from the initial risk assessment.	This condition (often accompanied by a shortened registration expiry period) is used when additional data is required to support or confirm the conclusions of the application assessment. This condition can be applied to require any data or information related to the risk profile and risk assessment for the product, such specific data such as confirmatory manufacturing or stability data after commercial production commences, results from ongoing longer-term studies, or field evaluation of adverse events once a product is in use. Specific advice explaining why the condition was added and the data and information to satisfy and remove the condition is included in the registration letter.