Operating plan for agricultural compounds used under the regulatory exemption for research, testing and teaching/training purposes

ACVM guideline (May 2018)

Introduction

Under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997, all substances that are agricultural compounds must be registered unless exempted. The Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011 lists a number of exempt categories. Under Schedule 2, the ACVM (E&PS) Regulations 2011 allows organisations to conduct research, testing, teaching or training with agricultural compounds under an 'operating plan', provided a number of conditions are met.

1. What is an operating plan?

An operating plan (OP) is a document created and used by the organisation that describes the types of activities that the organisation can foresee carrying out, and explains how the organisation will control those activities. This includes:

- the process involved in planning each individual activity
- how the organisation plans to assess risk, and
- how the organisation will record and internally audit the activities carried out under the OP.

The OP, which is specific to an organisation or person, must be submitted to MPI for approval under section 28 of the ACVM Act. Once approved, the organisation can conduct the activities

described in the scope, using the substances or compounds that have been notified to MPI, in compliance with the approved OP. OPs will be approved for up to 5 years.

2. Activities covered under this exemption

The relevant activities covered under this Schedule 2 regulatory exemption are:

Research	Any investigative, analytical, experimental, or diagnostic work or toxicity or potency testing work that involves any agricultural compounds.
Testing	Any work that is carried out for the purpose of testing the safety or efficacy of any agricultural compound.
Teaching/Training	Any training or teaching of persons, of a kind specified in the approved OP, involving agricultural compounds, within the scope of the substances or compounds specified in the plan.

Please note that residue trial work, while not explicitly stated, is considered to be covered under these activities. Not all research, testing, teaching/training activities will require an OP, as the substance or compound may not be considered an agricultural compound if it is not 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 example, if you are carrying out chemical analysis in a laboratory, comparison testing, or training people to do chemical analysis etc, and there are no animals or plants involved, then the substance or compound does not fit the definition of an agricultural compound. Therefore, you do not have to seek MPI approval for the activity.

However, you may have to seek other regulatory approvals (such as HSNO approval, biosecurity clearance, animal ethics committee approval) if required by other legislation. Contact links are provided in Appendix 1 of this document.

3. Conditions that must be met

Two conditions that must be complied with are stated in Schedule 2 of the Regulations:

- An OP covering the type or class of agricultural compounds the person or organisation wishes to use for research, testing, or training, and the nature of the activities contemplated must have been approved and must be complied with.

- The person or organisation subject to the OP must, on an ongoing basis, notify the Director-General of MPI if a substance or compound is to be used that was not notified to the Director-General as being used or contemplated for use at the time the OP was approved, even if the substance or compound to be used is within the scope of agricultural compounds approved for use under that OP.

In practical terms, this means that the OP must be current for the activities and substances/compounds that are being carried out, and must be complied with. A person or organisation cannot carry out any activities that would require approval outside of the scope of the approved OP.

Further substances or compounds that are covered by the existing scope can be added to the OP using a simple notification process. However, for any other change, a new or amended OP must be approved. See section 11-: 'Variations to operating plans' below.

4. Confidentiality of information under this exemption

Any information provided to MPI that the applicant considers to be commercially sensitive should be clearly marked as "commercial in confidence".

5. Confidential supporting information (CSI) (also called data protection)

The specific CSI provisions of the ACVM Act do not apply to innovative agricultural compounds imported, manufactured or used under this regulatory exemption. This means any such innovative agricultural compounds will remain eligible for CSI protection in the event of provisional or full registration involving it. See section 10: 'Alternative approval options' below.

6. Using treated animals/plants, or produce from them, for human or animal consumption

The regulatory exemption does not specifically exclude supplying treated animals, plants or their produce for human or animal consumption. It will be the organisation's responsibility to ensure the treated animals, treated plants or derived produce do not contain residues that would breach the current Food Notice: Maximum Residue Levels for Agricultural Compounds, or any other applicable regulatory standard.

This is considered to be a special risk area, and the management strategy to mitigate this risk should be clearly specified. To avoid non-compliant residues, disposal of treated animals, plants or any produce from them must be addressed. The surest way to manage this issue is to specify destruction and disposal as wastes.

However, if you intend to supply treated animals, plants or produce for human or animal consumption, then you must ensure compliance with any relevant legislation. If expected residues or withholding periods are self-determined, all calculations, extrapolations and assumptions must be justified and recorded for auditing purposes.

In addition to the above, the applicant organisation has the responsibility for complying with the current Animal Products Notice: Contaminant Specifications if trial animals, plants or derived product will be supplied for human consumption. Similarly, the applicant organisation has the responsibility for complying with the relevant Animal Products Notice if trial animals, plants or derived product will be supplied for animal consumption.

To ensure that these instances are appropriately managed, individual cases where treated animals, plants or derived product are intended to enter the food chain may be approved under either a **provisional registration** or an **approval in special circumstances,** such as a Research approval, rather than under this exemption. See section 10: 'Alternative approval options' below.

7. Importing compounds for some trials

The letter of approval of the OP will include the name and identity of the organisation that owns the OP, the scope, and the expiry date of the OP. This letter may be used to facilitate importation of the compounds/substances that will be released to any person operating on behalf of the organisation. Individual compounds are not specified in this letter. A copy of the approval letter must be shown on request.

8. Contents and format of an operating plan

An OP belongs to the owner and can be in any format as long as it identifies and covers all relevant risks to the satisfaction of MPI. We have developed an OP template that can be used as the basis of your OP. (Appendix 2 also gives guidance to help complete the template.)

9. Internal verification of operating plans

MPI expects the owner of the OP to conduct internal verification at regular intervals to ensure that the OP is appropriate, is being followed as approved, and associated procedures are current. Any amendments to the OP must be approved by MPI.

For the restricted veterinary medicines (RVMs) we state: If there are any changes to the details of your operating plan, you must promptly (within 5 working days) inform the MPI of the changes in writing.

MPI intends to carry out a small desktop audit of individual OPs at renewal (see section 12. 'Renewal of operating plans'). In addition, we will also conduct sector analysis (similar to the 'slice of life' audits of the past) from time to time to confirm that the regulatory exemption is working as intended.

In addition to the sector analysis, MPI will investigate every suspicion or allegation of non-compliance by individual OP owners, and may withdraw the approval of the OP or impose a formal audit if non-compliance is confirmed.

10. Alternative approval options

Alternative approval options for agricultural compounds may be more appropriate in some instances.

Provisional registration may be appropriate for innovative agricultural compounds where the CSI (data protection) provisions of the ACVM Act are required. Note that the innovative agricultural compound must have the characteristics of a trade name product[1] for the compound to be considered for provisional registration.

[1]Characteristics of a trade name product:

- It is in the formulation (or not materially different from the formulation) that will be specified in an application to register.
- It is intended to be marketed under a specified trade name.
- It is packaged or has (or will have) packaging specifications for marketing in New Zealand.

If you intend to send treated animals, plants or derived product for human or animal consumption, then **provisional registration** or **approval in special circumstances** may be more appropriate.

Approval in special circumstances can be applied for under section 8C of the ACVM Act. This approval allows importation of a trade name product without the need to register. One type of special circumstance approval applies to trade name products and will only be considered where the product fulfils a need that cannot be met by any other compound currently available in New Zealand. The criteria for granting an approval under 8C are the same as for registration.

Another type of approval in special circumstances approval is a research approval, which is intended to allow research where the product formulation has not been finalised (i.e. it is not considered to be a trade name product).

For more information on provisional registration, and approval in special circumstances, see our website:

Veterinary medicines

Agricultural chemicals

Vertebrate toxic agents

11. Variations to operating plans

There are three types of variations:

1. **Addition of substances/compounds that fall within the scope of the currently approved OP**: This is a specific case covered by the Regulations. Notification of the new substance/compound must be made to MPI before it may be used. A template for making notifications can be found as Appendix 2 in the Operating Plan Template for Agricultural Compounds Used under the Regulatory Exemption for Research, Testing and Teaching/Training Purposes (ACVM 26).
2. **Minor changes:** Any amendments that do not impact the controls (such as administrative changes) can be made by supplying an updated version of the OP to MPI for approval.
3. **Changes that may impact controls:** Changes that may impact the effectiveness of the OP (such as adding substances that are not covered under the scope or additional activities) may require a new or amended OP to be resubmitted to MPI for approval. Depending on the change, a full reassessment may occur.

Any application made to vary an OP must contain the same information as required for renewal (see 12: ‘Renewal of operating plans’).

12. Renewal of operating plans

To renew an OP, you must supply:

- a completed Operating Plan Application Form (ACVM 26A)
- a complete, updated, clean copy of the OP, and a tracked changes copy of the OP with all changes noted and explained, and
- a master list of all trials carried out under the OP since the last registration date. This should include date, trial name or reference, active ingredient, and whether produce

from crops/treated or exposed animals were destroyed or entered the food chain for human or animal consumption.

MPI will request the associated documentation of the internal verification from one randomly chosen trial. If this trial does not reflect the full extent of the scope, more trials may be audited by MPI or more trial audits may be requested. This is in order to check that trial documentation is in compliance with the OP and to ensure that the OP:

- effectively considers and manages all the risks, and
- includes appropriate internal auditing.

As a condition of the RTT OP exemption in the ACVM (E&PS) Regulations 2011, the formulations of new substances must have been notified to MPI before trial work is carried out. MPI will review these notifications as part of a desk top audit conducted during the renewal assessment.

Appendix 1:

Contact points for statutory clearances or approvals

- **Biosecurity:** Any imported product containing an ingredient originating from an organism (such as plant, animal, fungus) must meet a relevant Import Health Standard or alternatively requires a biosecurity approval issued by Biosecurity New Zealand (http://www.mpi.govt.nz/importing/biological-products-and-organisms/)

- **Hazardous Substances and New Organisms:** Products that are hazardous substances or that contain a viable new organism, including genetically modified organisms (GMOs), require approval from EPA NZ under the Hazardous Substances and New Organisms Act 1996 (HSNO Act). For information see http://www.epa.govt.nz.

- **Animal Ethics**: For information on Animal Ethics Committee approvals for research, testing and training/teaching activities, contact the MPI Animal Welfare team. See http://www.mpi.govt.nz/protection-and-response/animal-welfare/

- **Animal Products:** For information on residues in animal products, or transfer of residues to animals from animal feed, see http://www.mpi.govt.nz/processing/meat-and-game/ or e-mail approvals@mpi.govt.nz.

- **Controlled Substances**: For more information on controlled substances, contact Medsafe at www.medsafe.govt.nz.

- **MRLs:** For information on maximum residue levels (MRLs) for agricultural compounds, see http://www.mpi.govt.nz/processing/agricultural-compounds-and-vet-medicines/maximum-residue-levels-for-agricultural-compounds/

Appendix 2:

Guidelines for completing operating plan application form and template

Operating Plan Application Form for Agricultural Compounds Used under the Regulatory Exemption for Research, Testing and Teaching/Training Purposes (ACVM Application Form 26A)

1. Operating Plan Title, Approval Number and Application Type
Please choose a succinct name. For a new OP, an OP number will be assigned on acceptance. For an existing OP, the application type 'Renewal' should only be used if no other changes are proposed. Otherwise, a variation should be requested. Please note that variations must be approved before they can come into effect.

2. Operating Plan Owner Information
Self-explanatory

3. Organisation Address and Contact Details
Self-explanatory

4. Documentation Required
Self-explanatory

5. Statement of Intended Conformity
This should be completed by a person with the authority to ensure that your organisation is carrying out activities in accordance with the approved OP. This may be the same person as below, or it may be the Research Manager.

6. Applicant Statement
This should be completed by the person who made the application.

7. MPI Service Charge
Our standard hourly rate is charged for time taken to complete the assessment of the OP. An upfront charge for one hour should be provided with the application, and any additional time taken to complete the assessment will be invoiced

Operating Plan Template for Agricultural Compounds Used under the Regulatory Exemption for Research, Testing and Teaching/Training Purposes (ACVM 26)

1. Operating Plan Title and Approval Number
Please choose a succinct name. For new OPs, an OP number will be assigned on acceptance.

2. Operating Plan Owner Information
Self-explanatory

3. Organisation Address and Contact Details
Self-explanatory

4. Scope of the Operating Plan
Ideally the scope will be quite specific in order to be able to identify risks and develop risk management strategies.

Include details to identify the scope of the substances you will be working with (see the Product Types in the Guidelines for Product Data Sheets for Registration of Agricultural Chemicals, Veterinary Medicines or Vertebrate Toxic Agents), or an alternative description that identifies the common features. Indicate those specific exclusions that apply to your OP by checking the appropriate box. We also need to know the nature of the activities (for example, whether it is research, testing, teaching/training). Identify the proposed animal species or use situations. Finally, describe any special risk areas, such as antibiotic use or use of treated produce for human or animal consumption. These will be considered in further detail in Section 8 of the OP. Currently, we require that antibiotics, nanomaterials and genetically modified organisms are specifically excluded from the scope of the RTT OP, unless they are specifically addressed.

5. List of Substances or Compounds
List names and full formulations of substances or compounds intended for use, and/or provide the process that you intend to use to notify MPI. Copies of EPA notifications that include these details are acceptable. Please note that any compounds not included here can NOT be used under the OP until you notify us with the name and full formulation. See Appendix 2 of the form for an example of a notification. If submitted electronically after the OP has been approved, include the OP number and variation in the file name, e.g. OP-002-03-substance name-notification.

6. Individual Study Plan Requirements
For each individual occurrence of a research, testing, training/teaching event, you must complete a study plan and keep it on file, along with documentation to show that the organisation's procedures have been followed in the preparation of the plan.

We do not require all individual study plans. However, provide the template that you will use with this application. The template for the study plans must include all information that could be relevant to the risks associated with the class and type of compound, activities, risks, animal species or use situation named in the scope. See Appendix 1 of the form for a list of information that you should consider. This list is not exhaustive and there may be additional points that you should include in your template.

7. Study Plan Approval Process
This section should include how your organisation will assess and approve each individual study plan. How does the organisation ensure that all risks are identified and managed? How does the organisation ensure that the study plans are followed? If your organisation has standard operating procedures that provide these details, include them with this application.

8. Organisational Strategy for Management of Special Risks
This section relates to the risks identified in Section 4 (Scope). If you have identified any special risks, such as antibiotic use, use of compounds in food or feed crops, use in lactating animals, potential for persistence of compound in soil, or any other risk to areas covered under the ACVM Act, then the way the organisation is planning to identify and manage the risk should be stated here. Please provide the process that the organisation would work through in each instance, in the form of a flow diagram if that is appropriate.

For example:

- For a compound that may be persistent in soil, causing risks with regard to residues found in subsequent crops – you should provide your organisation's management

strategy to identify these compounds and manage the risks. This may be based on calculations or measurement of residues in subsequent crops.

- For a food/feed use – your organisation may choose to manage the risks by applying for a provisional registration for that compound/use situation, to destroy treated plants, animals or derived product, or to use an alternative management strategy.

9. Internal Verification

This is the process that your organisation will use to ensure that the OP and all individual study plans are being followed and that the OP is appropriate.

10. Redirection of Imported Compounds/Substances

If any of the named substances/compounds will be imported, they will be released to the organisation that holds the OP (i.e. an agent who holds a copy of the Letter of Approval). If the substance/compound is to be redirected to another address under control of the OP, the process for redirection should be included here.

Appendix 1: Individual Study Plans

This lists the type of information that may be required in the individual study plans. A template for the study plans should be supplied to us with the OP. We do not require actual study plans, but they should be kept on file for auditing purposes.

Appendix 2: Template for notification of a new substance or compound not previously notified

This template can be used to add new substances/compounds to an existing OP. The substance/compound must fit within the scope of the OP. The name of the substance/compound, and full formulation, must be supplied. Alternatively, we will accept EPA notifications that contain this information.