Summary of MPI 2018 Audit

Research, Testing and Teaching Organisations (Agricultural Chemicals)

Operating Plans and Activities

December 2019

A 2017-18 audit of research, testing, teaching/training organisations (RTTOs) that use non-registered agricultural compounds under a regulatory exemption provided valuable information for RTTOs and for MPI. Although no non-compliances were found, the audit identified areas for improvement on both sides.

1. Background

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, Schedule 2, lists exempt categories. One of these exemptions allows organisations to conduct research, testing, teaching or training via the use of an 'operating plan'[1] (see definition in appendix) to control agricultural compounds that are not registered under the ACVM Act. Operating plans (OPs) approved by MPI impose conditions on the organisations that must be met.

[1] Research, testing, teaching/training activities do not require an MPI-approved OP if the substance or compound is not considered an agricultural compound (that is, it is not intended for use in the direct management of plants and animals, or it is not to be applied to the land, place, or water on or in which the plants and animals are managed).

Operating plan

The OP, which is specific to each research, testing, teaching/training organisation (RTTO), must be submitted to MPI for approval under section 28 of the ACVM Act. Once the OP is approved, the RTTO 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. Further substances or compounds that are covered by the existing scope can be added to the OP using a notification process. However, for any other change, a new or amended OP must be approved by MPI.

The OP must be current for the activities and substances/compounds that are being used and must be complied with. An RTTO must not carry out activities outside of the scope of the approved OP. Therefore, the owner of the OP should conduct internal verification at regular intervals to ensure that the OP is appropriate, is being followed, and the OP and associated procedures are current.

Treated animals, plants, produce

Using treated animals/plants, or produce from them, for human or animal consumption requires the RTTO 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 RTT OP should clearly specify the management strategy to mitigate this risk, including the destruction and disposal of treated animals, plants and produce from them.

In addition, RTTOs have the responsibility for complying with the current Animal Products Notice: Contaminant Specifications or other relevant Animal Products Notices if trial animals, plants or derived product will be supplied for human consumption and animal consumption.

Research, testing, teaching/training activities may also need other regulatory approvals, such as HSNO approval or biosecurity clearance, if required by other legislation.

Guidance material

All the above information is included in the ACVM guideline: Operating plan for agricultural compounds used under the regulatory exemption for research, testing and teaching/training purposes.

A template, Operating Plan Template for Agricultural Compounds Used under the Regulatory Exemption for Research, Testing and Teaching/Training Purposes, ACVM 26, is available to help operators develop their OP. It includes details on the contents of an OP and information that needs to be provided to ACVM prior to the approval.

2. Objectives and relevant legislation

The first OPs for use of agricultural chemicals under this exemption were approved in 2013. The intention of this audit was to confirm that the RTT OPs developed were fit for purpose and to identify any improvements to MPI systems, guidance material or OPs, as the OPs approached renewal.

Objectives from the audit terms of reference were*:*

- to assess activities conducted under MPI approved RTT OPs to determine the level of compliance with approved requirements, and
- to confirm that the activities and records required under the RTT OPs (and required to be available for verification) are sufficient to give assurance that the risks from an ACVM perspective (particularly those related to residues and trade in primary produce) are adequately managed.

Legislation relevant to the audit included the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997, the ACVM (Exemptions and Prohibited Substances) Regulations 2011, the Food Notice: Maximum Residue Levels for Agricultural Compounds, the Animal Products Notice: Contaminant Specifications.

3. Audit method

Seven RTTOs with OPs that allowed for non-registered agricultural chemicals (pesticides, herbicides, fungicides) to be used on plants were visited.

The audit at each location commenced with an entry meeting with a person responsible for the OP and, in many instances, also with other key personnel. Usually the same persons were present at the exit meeting.

The audits were conducted with the use of a check sheet the auditors prepared for that purpose. The individualised check sheets were based on information from each RTTO's approved OP.

The auditors examined documents, records, equipment, facilities and other activities associated with OPs.

Each visit to an individual location or a field assessment of an OP resulted in a location findings report being created. Draft location finding reports were provided to the auditees and they were asked for comments on technical aspects of the report prior to finalising the location findings.

4. Findings

Activities

The majority of these RTTOs had their OPs approved for use of agricultural chemicals in research and testing with one RTTO specifically focusing on biopesticides. Two RTTOs had training and teaching included in their scope, but none of them actively participated in any of these activities. One of them said that training/teaching was in their OP scope because occasionally they deliver educational presentations/talks on their agricultural products to the end users or field distributors.

OP format and approvals

The ACVM template for OP with use of Agricultural Compounds Used under the Regulatory Exemption for Research, Testing and Teaching/Training Purposes was a popular format for the OP. It was used by most of the audited RTTOs.

The use of some agrichemicals, such as hazardous substances or substances that contain a viable new organism, require approval from the Environmental Protection Authority (EPA NZ) under the Hazardous Substances and New Organisms Act 1996 (HSNO Act) and the audited RTTOs demonstrated that they had the appropriate approvals and related procedures.

No non-compliances

The audits of all these RTTOs resulted in acceptable outcomes and the auditors raised no non-compliances (see definition in appendix). No outcome was given for one RTTO because the company decided not to renew its OP after the expiry date in June 2018.

Overall, the auditors found that the auditees demonstrated a good understanding of the related ACVM legislation and requirements and an acceptable level of compliance with their approved OPs. In the auditors' opinion that was likely due to an easy access to ACVM guidelines and template specific for the OP for the use of agricultural compounds under the regulatory exemption.

5. Areas for improvement

RTTOs

The auditors raised no non-compliances with the RTT OPs as approved but identified several deficiencies and areas where improvements[2] could be made for the RTTOs to demonstrate, when required, that relevant risks are appropriately managed. These are largely around documentation, and include: (if multiple RTTOs, the number is indicated in brackets)

- scope of the OP – outdated information on the contact person, type of activities, use situation and list of contractors
- notification to MPI – lack of prompt notifications to MPI about variations to OP

[2] Recommendations are non-binding and do not affect subsequent audits. Their implementation may provide efficiencies for both the auditee and MPI. The presence of recommendations to change existing specifications does not excuse the absolute requirement to conform to the existing specifications. Changes to specifications that may result from these recommendations will be promulgated officially.

- risk assessment – lack of or poorly defined procedures for the risk assessment of individual study plans prior to the implementation phase (2)
- disposal and disposal records – lack of documented procedures for disposal of treated product; lack of records of disposal of the treated products; lack of signatures and dates on disposal records confirming the destruction of relevant in compliance with stated methods (6)
- surplus agrichemicals - lack of records (inventory) of the disposed surplus agrichemical substances
- subcontractors' documentation – lack of procedure/checks for ensuring that required trial documentation is filed by the subcontractors
- training of personnel – lack of specific training programmes, records, competency requirements and competency assessment that relate to legal and operational requirements of the OP (4)
- review of the OP - lack of the annual assessment of the OP so that conclusions can be made regarding the OP's continuing validity, effectiveness and compliance with its requirements; fragmented (i.e. excluding certain parts) internal verification of the OP (4)
- non-compliances – lack of documents on managing non-compliances including recording of identified non-compliances
- amendments to the OP – lack of the list of amendments to the OP
- adverse events – lack of familiarity with the ACVM official Adverse Event Reporting Programme to ensure compliant reporting of any adverse events.

The existing records were generally adequate, but the quality of the records was variable.

ACVM Guideline

The audit identified the following areas that could be clarified or included in the ACVM Guideline.

The most common deficiency identified was a lack of documented procedure for disposal of treated product and lack of verifiable records of disposal of treated products where these products were not intended for human and animal consumption. The ACVM Guideline indicates that using treated plants or produce from them, for human consumption or animal consumption should be clearly specified. However, that guideline does not specify that the same requirements apply to situations where treated product is not intended for human or animal consumption, in order to avoid any inadvertent passageway of such products into the food chains for humans or animals. The interviewed auditees indicated that they had focused on the first category but didn't put so much attention to that risk where the treated products were not intended to be used in the food chain.

Second and third most common deficiencies identified related to training of personnel and internal verification of the OP, respectively. Training of the personnel as such is not specifically mentioned in the ACVM Guideline, but it is the opinion of the auditors that a training programme should consider minimum skills and competencies of the staff involved in order to understand and meet the requirements of the OP.

Although internal verification is discussed in the Guideline, that section could be reviewed/revised as most of the RTTOs did not carry out internal verification for the purpose of assessing if the OP was appropriate, current or if unapproved activities were carried out.

MPI

In addition to suggestions regarding the Guideline, the auditors identified opportunities for improvements in the MPI ACVM systems and raised several issues regarding the ACVM appraisal process and communication with the industry.

The auditors recommended:

1. reviewing the ACVM appraisal and approval process to ensure that the following have been addressed:
   - contents of the OP matches the information as provided by the RTTOs in the application form
   - conditions or recommendations resulting from the appraisal process are carried over on to the final Delegate Decision, and that these are effectively passed on to the applicant, where appropriate
   - the accuracy of Delegate Decisions is checked
   - the OP reference number and the version number is included in the approval letter
   - a check sheet for the minimum elements/requirements of the OP is developed, and
   - feedback provided to applicant where incomplete information was supplied

2. reviewing the effectiveness of ACVM's post-approval monitoring system to ensure timely identification of the overdue for renewal OPs and notifications of the affected RTTOs

3. refining the OP Guideline (as discussed above)

4. developing a dedicated post box to help facilitating clarification requests from research institutes.

6. MPI Actions

Several of the audit recommendations have been implemented in the latest application form and Guideline (May 2018), which were reviewed to give greater clarity around the process for renewals of RTT OPs.

- Review and separation of the application form from the OP template, to avoid duplication (and associated potential for error) of information provided. Note that RTTOs can choose to use the templated format, or any other format appropriate to their organisation.
- Inclusion of RTT OPs in ACVM's workflow system, to facilitate tracking of applications.
- Development of a desktop audit process for use with renewal of RTT OPs, to allow for reconciliation of agricultural compound notifications.
- ACVM appraisal specifically includes consideration of how an RTTO intends to confirm and audit destruction of treated plants or animals that are not intended to enter the food chain. Desktop audit of such trials includes verification that this has occurred as specified.
- Appraisal for a new RTT OP or a renewal follow a similar process to ACVM registration of trade name products -- we will contact the applicant directly to request further information if required, and a complete, amended OP must be provided before approval is granted.
- RTT OP approval letters have been revised to include the RTT OP number and version, expiry date, and advice (if any) from the Delegate or from the ACVM reviewer.

Actions at the next review are expected to include:

- amendment of the guidance material to take into account the updated RTT OP exemption in the ACVM Regulations (when promulgated)
- clarification of the expectation of more information in the RTT OP around competency and training of RTTO personnel
- clarification of expectation around disposal and verifiable records of disposal of treated produce that must not enter the food chain
- clarification of expectations around internal verification of the RTT OP, and
- development of a separate checklist of essential elements/requirements.

Other recommendations:

- **Post-approval monitoring of expiry dates**
  We do not currently have the facility to notify upcoming expiry dates to applicants automatically. This has been included in our 'wishlist' for development of ACVM systems.
- **Dedicated post box**
  E-mail correspondence regarding RTT OPs should be directed to approvals@mpi.govt.nz. MPI does not support dedicated e-mail addresses for small volumes of correspondence due to the difficulty in monitoring them in a timely manner.

Appendix: Definitions

audit findings:

critical situation: Any situation which, in the professional judgement of the SAT Auditor or Manager, places market access, official assurances, or MPI's/MPI's Directors' credibility at risk

MPI issue: Audit findings and auditor's interpretations of these findings that have outcomes that key MPI staff need to be aware of and consider for remediation

non-compliance: Deficiency that is expected to be resolved by auditee or the auditee's organisation, whether or not it is described as a serious non-compliance

serious non-compliance: Deficiency that constitutes a system failure. It has a profile such that the effectiveness of the corrective actions will be measured in subsequent SAT audits. Inadequate resolution can lead to failure of the subsequent audit

operating plan (OP): a documented quality system (work instructions, procedures, tasks etc) that describes 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.

approved operating plan: OP approved by MPI under section 28 of the ACVM Act.