

Ministry for Primary Industries

Manatū Ahu Matua



Verification Report¹

Report ID: PBV/2501/2019/03
Outcome: **Acceptable**

Issued to: AgResearch - Ruakura Campus
Operator ID(s): 2501
Issued by: Crystal Lange
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Verification Period: 2019-08-29 to 2019-11-28
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Level/Step: 5.2 (started on 5.1 , and ceiling is 6)
Report Type: Scheduled

Peer Reviewed By: Davide Zazzaro

¹ A Verification Report is a formal report issued when sufficient evidence has been assessed to arrive at an outcome for a verification period. This report may contain Technical Reviews and external audit findings completed during the period. Inadequate and/or untimely responses to deficiencies identified in this report, poor/unacceptable performance, or failure to pass subsequent audits may result in the escalating imposition of sanctions and/or interventions provided by law.

This report, including any attachments, is intended solely for the **Operator** of 'AgResearch - Ruakura Campus'. The information it contains is confidential and may be legally privileged. Unauthorised use of this report, or the information it contains, may be unlawful. If you have received this report by mistake please call **Crystal Lange** immediately on 9(2)(a) or notify by email using crystal.lange@mpi.govt.nz and erase the report and attachments. Thank you.

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1. Premises Profile

AgResearch - Ruakura Campus is, under section 39 of the Biosecurity Act 1993, approved as a Transitional and Containment Facility in accordance with the requirements of the MPI/EPA standard(s) identified. Under section 40 of the Biosecurity Act, 9(2)(a) is approved as an operator of that facility and is primarily responsible for the facility, compliance with facility approvals and all activities involving risk goods.

The standards that the facility is approved to specify the structural and operating requirements for containment and/or transitional facilities holding regulated organisms and risk goods that are, or may contain:

- Agricultural Compounds
- Animals
- Animal Products
- Biologicals
- Miscellaneous
- Non-risk Goods
- Plant Products

Physical Address :

10 Ruakura Campus Bisley Road, Ruakura, Hamilton

2. Executive Summary

This was a scheduled and announced inspection of the AgResearch transitional and containment facility at Ruakura in Hamilton. The objective of this visit was to verify compliance with the facility manual, the standards identified in the "Biosecurity" section of this report, and the facility and operator approvals as held under the Biosecurity Act 1993.

This was a increased frequency visit due to critical non compliance (unapproved transfer of genetically modified organism) at the end of the last reporting period. One major and two minor issues were also note at the time. During the past three months MPI has been advised of incidents that have occurred; spillage of GMO material and failure of one of the air conditioning units in the Small Animal Containment unit. These incidents have been addressed promptly and correctly with no loss of containment.

9(2)(a) has increased her knowledge on containment and the idiosyncrasies of containment standards incrementally over the past few months. 9(2) is undertaking her role of Delegated Facility Manager to a high standard. MPI is satisfied that AgResearch is operating in compliance with the requirements of the standards and the HSNO approvals. As such the facility and operator approvals will be continued.

3. Operator Summary

The entry and exit meeting along with the reality check of selected containment areas were carried out by Crystal Lange (MPI) with 9(2)(a) (Delegated



Facility Manager (DFO), AgResearch). Crystal's authority of appointment under the Biosecurity Act 1993 and Hazardous Substances and New Organisms Act 1996 (warrant) was displayed.

The inspection process included a review of onsite records, where applicable; staff training, biological products register, internal audit and physical inspection of the laboratory areas.

The AgResearch Operator and CEO resigned and left during this reporting period. **9(2)(a)** has been appointed as the Acting Operator while the CEO position is advertised.

Released under the Official Information Act 1982



4. Verification Completed (this period)

Biosecurity

AgResearch demonstrated good compliance with the standards assessed.

The following elements were verified in this PBV period:

Biosecurity:Facilities for Microorganisms and Cell Cultures: 2007a	Acceptable
Biosecurity:Transitional Facilities for Biological Products	Acceptable

Quality Assurance

A section 52/53 permission for Meloidogyne minor has been issued, this is valid until June 30 2021. The DFO had copies of the HSNO Approval and CTO permission.

Internal audits for the buildings comprising the Ruakura facility have been undertaken. The ongoing need for repairs was noted. Sample tracking was undertaken for imports and transfers. GMO registers are planned to be sampled for the next verification. The internal audits noted completion of repairs identified at the last external inspection.

The manual review is underway. Completion has been delayed while the acting Operator is confirmed.

The following elements were verified in this PBV period:

Quality Assurance:Chief Technical Officer (CTO) Permissions and Decisions	Acceptable
Quality Assurance:Operator Control	Acceptable
Quality Assurance:Operator Internal Verification	Acceptable

Documentation and Certification

BACCs, transfers and inwards goods forms are collected and held on file. The register is updated following receipt of the inwards good form.

The following elements were verified in this PBV period:

Documentation and Certification:Biosecurity Authority Clearance Certificates (BACCs)	Acceptable
Documentation and Certification:Documentation and Record Keeping	Acceptable

Identification, Traceability & Management

Inventory was up to date and matched with MPI records. No packaging issues had be raised by staff.

The following elements were verified in this PBV period:

Identification, Traceability & Management:Inventory Control and Accuracy	Acceptable
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The following elements were verified in this PBV period:

Identification, Traceability & Management:Product and Organism Identification	Acceptable
Identification, Traceability & Management:Transfer of Goods and Organisms	Acceptable

Design and Construction

AgResearch demonstrated good compliance with the standards.

The following elements were verified in this PBV period:

Design and Construction:Laboratories	Acceptable
Design and Construction:Physical Containment Level 1 (PC1)	Acceptable

Hazardous Substances and New Organisms (HSNO) Act

EPA Application APP203820 had been approved for Meloidogyne minor (NOC100221), a nematode that is a new organism found in Hagley Oval, Christchurch.

The following elements were verified in this PBV period:

Hazardous Substances and New Organisms (HSNO) Act:HSNO Act Approvals for Development of New Organisms	Acceptable
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Mandatory Tasks

5. Definitions

Acceptable

Where the Animal Products Officer (or Biosecurity Inspector) is satisfied that the operator is substantially complying with requirements; and where there have been any departures from regulatory requirements, that the operator's corrective actions have been, or are being, applied appropriately and effectively.



Departures from regulatory requirements, identified by the Animal Products Officer (or Biosecurity Inspector), are to be transferred to the operator's issue management system for resolution. (Key Topic / Non-compliance)

Unacceptable

Where the Animal Products Officer (or Biosecurity Inspector) has determined that the operator is not in substantial compliance with regulatory requirements; evidenced by inadequate operator controls. (Key Issue / Non-compliance)