

# Ministry for Primary Industries

## Manatū Ahu Matua



## Verification Report<sup>1</sup>

<b>Report ID:</b>	PBV/2501/2020/01
<b>Outcome:</b>	<b>Acceptable</b>
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<b>Issued to:</b>	AgResearch - Ruakura Campus
<b>Operator ID(s):</b>	2501
<b>Issued by:</b>	Crystal Lange Phone: 9(2)(a) [redacted] Email: crystal.lange@mpi.govt.nz
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<b>Level/Step:</b>	6.1 (started on 5.2 , and ceiling is 6 )
<b>Report Type:</b>	Scheduled
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<b>Peer Reviewed By:</b>	Davide Zazzaro

<sup>1</sup> 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) [redacted] or notify by email using [crystal.lange@mpi.govt.nz](mailto: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, the HSNO Act Approval and the facility and operator approvals as held under the Biosecurity Act 1993.

The inspection undertaken 27 February 2020 was limited (snap-shot) as two inspections had occurred in the preceding 6 months. The inspection had been given a marginally acceptable outcome as one of the non-compliances (Access) was out of the Operators control, and potential containment risks were already well managed. Two non-compliances were issued; one, rated minor for hygiene and construction, and the other major for Access Control.

If non-compliance is not addressed in a timely manner or is ongoing, MPI interventions could include infringement notices, compliance orders, increased inspection frequency, facility suspension or cancellation of the Operator approval.

## 3. Operator Summary

One entry meeting was held with 9(2)(a) (Facility Operator, Containment Farm Manager) at the Animal Containment Farm (ACF), the other with 9(2) and 9(2)(a) (Facility Operator, Senior Animal Technician) for Small Animal Containment (SAC) and other standards. 9(2) provided transport to and from the ACF as the roadway crosses and active construction site, 9(2) was present for



part of the laboratory inspections. 9(2) accompanied Crystal Lange (MPI) for all laboratory inspections.

Uninducted visitors are accompanied by AgResearch staff (as demonstrated), no additional hazards were notified. Crystal's authority of appointment (warrants) under the Biosecurity and HSNO Acts was displayed during the visit.

The inspection process included a review of onsite records, which may include: staff training, internal audit, activity logs, and a physical inspection of laboratories, animal identification and physical counts.

9(2)(a) (Research Director) has been appointed as the (Body Corporate) delegate, replacing 9(2)(a). One event had occurred that MPI should have been notified of. This is detailed in the report.

Released under the Official Information Act 1982



#### 4. Verification Completed (this period)

##### Biosecurity

The following elements were verified in this PBV period:

Biosecurity:Containment Facilities for Vertebrate Laboratory Animals	Acceptable
Biosecurity:Containment Standard for Field Testing of Farm Animals	Acceptable
Biosecurity:Transitional Facilities for Biological Products	Acceptable

##### Quality Assurance

Contingency planning for Covid19 is not know at all levels of staffing. Currently staff packs are being prepared containing face masks and hand sanitiser. Animal care would be managed using bulk feeding systems, staff on roster or utilising onsite accommodation facilities. The laboratory relocations are being managed through a reputable carrier. No liquid or opened chemicals are permitted for transport. A risk assessment for the decommissioning of South Wing ground floor laboratoires was reviewed and approved.

Version 3.1 of the facility manual was accepted December 2019, it covered minor changes to improve functionality and the name changes for key contacts. Internal audits were completed in a timely manner for the Field Test (ACF) and Vertebrate (SAC) standards. Micro and Planthouse audits were done in November, the audits due in May should have GMO registers as a key area of assessment.

Three new users had been trained for access to the SAC, site cleaning staff had been undertaken 20/02/2020. No other training had been given, the site training package is being reviewed ready for presentation in March/April.

The following elements were verified in this PBV period:

Quality Assurance:Biosecurity Contingency Plans	Acceptable
Quality Assurance:Chief Technical Officer (CTO) Permissions and Decisions	Acceptable
Quality Assurance:Operating Procedures	Acceptable
Quality Assurance:Operator Control	Acceptable
Quality Assurance:Operator Internal Verification	Acceptable
Quality Assurance:Organizational Structure and Management	Acceptable
Quality Assurance:Risk Assessments	Acceptable
Quality Assurance:Training and Competency of Personnel	Acceptable

##### **Subject:** Notifications to MPI/EPA

##### Note List:

[Crystal Lange]

At the inspection visit MPI was advised of an incident occurring 19 January 2020 where and AgResearch tennant was given unsupervised access to the SAC without the knowledge of the delegated Facility Operator. The tenant had not



undergone the site or SAC specific training, nor was the person training in the use of the equipment accessed (autoclave), instruction was given by a third party.

This has been reported as a Security and Access non-compliance under the heading Design and Construction

### **Documentation and Certification**

All BACC records were available, the retro request was actions and BACC C2020/77999 issued the day of the visit and supplied immediately.

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
Documentation and Certification:Site Plans, Specification and Modifications	Acceptable

### **Identification, Traceability & Management**

Additional authorised signatories were discussed. Restricted products for retention, transfer or disposal have been identified and applied to the appropriate register. Imported and transferred items were recorded in the Operators site register.

The following elements were verified in this PBV period:

Identification, Traceability & Management:Authorised Signatories	Acceptable
Identification, Traceability & Management:Inventory Control and Accuracy	Acceptable
Identification, Traceability & Management:Product and Organism Identification	Acceptable
Identification, Traceability & Management:Segregation	Acceptable
Identification, Traceability & Management:Transfer of Goods and Organisms	Acceptable
Identification, Traceability & Management:Transport of Risk Goods and Organisms	Acceptable

### **Hygiene & Sanitation**

No unexpected pest incidents have been notified. Some accumulation of dust was noted in the South Wing (112), dirty high level cupboard doors (111) and grimy floors and oily bench stains (114). A lab coat draped over a chair (G23) was touching the floor. Floor cleaning in the endophyte laboratory should be revisited as cobwebs were noted on cabinet base boards as well as accumulated dust.



The corridor and anteroom of the PC2 Glasshouse was much improved.

Virkon and ethanol solutions were being used to decontaminate equipment and laboratory spaces as part of the laboratory decommissioning and relocation.

Sufficient room was available post entry quarantine and/or isolation of sick animals.

The following elements were verified in this PBV period:

Hygiene & Sanitation:Cleaning and Disinfection	Acceptable
Hygiene & Sanitation:Personnel Hygiene and Personal Protective Equipment (PPE)	Acceptable
Hygiene & Sanitation:Pest, Vermin and Weed Control	Acceptable
Hygiene & Sanitation:Quarantine Isolation	Acceptable
Hygiene & Sanitation:Waste Management	Acceptable

**Subject:** Cleaning and Disinfection

Note List:

[Crystal Lange]

MINOR NON-COMPLIANCE ( Joint with Design and Construction)

Hygiene not maintained at an acceptable level.

**CORRECTIVE ACTION REQUEST:**

Accumulation of dust, debris and grime needs to be addressed meet the requirements of section 4.7 of AS/NZS 2243.3:2002 as required by the Micro2007a and Biological Products standards.

To Be Completed By: 28 March 2020

## Design and Construction

The sealing of the floor in the Endophyte 2 laboratory is incomplete. Silicon still needs to be applied around the door frames to prevent seepage under cut surfaces. The bench seal has separated at one end and shrinkage or insufficient sealing along the length of the bench mean the silicon is hard to see and the gap difficult to clean. Flooring was damaged in (SW) 144, the coving sealing strip in G22 had become fully detached and an unsealed door stop was noted in G23.

Access was not available for 116, 117, 119 and 101. These doors had physical (key) locks where as the others were unlocked as part of the electronic locking regime. These rooms will be scheduled for the next visit.

The following elements were verified in this PBV period:

Design and Construction:Access and Security	Acceptable
Design and Construction:Animal Enclosures and Facilities (inc. invertebrates)	Acceptable



The following elements were verified in this PBV period:

Design and Construction:Open Field Testing Facilities	Acceptable
 Design and Construction:Physical Containment Level 1 (PC1)	Acceptable
Design and Construction:Signage	Acceptable

**Subject:** Access and Security

Note List:

[Crystal Lange]

 MAJOR NON-COMPLIANCE

Access was granted to a containment facility without appropriate authorisation or training.

As all Genetically Modified Organisms (mice) were appropriately contained in rooms with manual door locks, this has been downgraded from a critical breach.

1.14 Access

Access to the containment rooms is limited to the individual researcher, their associates and their visitors. All visitors to AgResearch have to be 'signed in' to allow them access to all AgR facilities and during any visits to approved CF's they must be accompanied by an appropriately 'trained' AgR staff member. The Small Animal Colony animal maintenance staff has open access to the entire Small Animal Colony.

Access to the Small Animal Colony is controlled by the use of 'swipe' cards and is on a 'need to' basis.

1.19 Training

The Containment Facility Operator is responsible for co-ordinating staff training. All new staff will be expected to read the relevant section of this Containment Manual and to read the AgResearch-Ruakura 'Code of Ethical Conduct'. They will be given a tour of the relevant Containment Suites and be verbally informed as to their responsibilities while working within the containment facility. Staff will acknowledge having received this 'training' by signing a register maintained within the Containment Manual

No new staff will be given any responsibility for any aspect of animal care, animal maintenance or allowed to do any animal manipulations until they have been appropriately trained.

**CORRECTIVE ACTION REQUEST:**

Ensure AgResearch Site Management is made aware of the issue and that approval is granted from one of the delegated Facility Operators prior to authorising access to any transitional or containment area.

To Be Completed By: 13 March 2019

**Subject:** Physical Containment Level 1 (PC1)

Note List:



[Crystal Lange]



**MINOR NON-COMPLIANCE ( Joint with Hygiene and Sanitation)**

Surfaces not maintained to meet the requirements of section 4.7 of AS/NZS 2243.3:2002 as required by the Micro2007a and Biological Products standards.

**CORRECTIVE ACTION REQUEST:**

Complete appropriate repairs

To Be Completed By: 28 March 2020

**Follow-up Note**

South Wing laboratories G22 and G23 were removed from the facility footprint following confirmation of decontamination prior to equipment relocation. Confirmation was emailed 28/02/2020.

**Hazardous Substances and New Organisms (HSNO) Act**

Compliance with the approval (ERMA200223) was verified with animal registers and reality check.

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
Hazardous Substances and New Organisms (HSNO) Act:HSNO Act Approvals for New Organisms for Containment	Acceptable

**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.



**Unacceptable**

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)

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)