

# Ministry for Primary Industries

## Manatū Ahu Matua



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

**Report ID:** PBV/2501/2019/02  
**Outcome:** **Unacceptable**

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**Issued to:** AgResearch - Ruakura Campus  
**Operator ID(s):** 2501  
**Issued by:** Crystal Lange  
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**Verification Period:** 2019-02-14 to 2019-09-09  
**Verification Date:** 2019-08-28  
**Published:** 2019-08-28 10:10  
**Next Due Date:** 2019-11-28  
**Level/Step:** 5.1 (started on 6.2 , and ceiling is 6 )  
**Report Type:** Scheduled

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**Peer Reviewed By:** Craig Mason

<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) 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, and the facility and operator approvals as held under the Biosecurity Act 1993.

The inspection undertaken July 30 and August 20 2019 had an UNACCEPTABLE outcome with one critical area of non-compliance being reported (unapproved transfer). A separate Non Compliance Report (NCR) was generated as a result of the critical non-compliance and a Root Cause Analysis (RCA) completed. 2501/2019/01 has been sent as an attachment to this report. This non-compliance has been closed, however due to the unacceptable outcome the external audit frequency has been increased (Step Drop) to three monthly. I believe this will be beneficial to the training of the new Facility Manager as closer monitoring of transfers, registers and structural compliance will catch rising issues early.

In addition to the above, one major (traceability) and two minor non compliances (hygiene and repairs and maintenance) with the MPI standards were noted during the audit. Corrective Action Requests (CAR) were issued and the major non-compliance has since been closed. The non compliance from the previous inspection was confirmed as closed during the inspection of Dairy Science.

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

The entry and exit meeting along with the reality check of the Small Animal Containment (SAC), (July 30 2019) was conducted by Crystal Lange (MPI) with 9(2)(a) (incoming site Facility Manager) and 9(2)(a) (exiting SAC Manager), the Animal Containment Farm (ACF); August 20 with 9(2)(a) (Farm Manager) and Planthouse and laboratories (August 20); with 9(2)(a). Containment areas (animal, plant and laboratory) were inspected, records for inventory, movement authorities and autoclave efficacy validation were reviewed. One significant change to health and Safety is the additional hazard of the access road to the ACF is now shared with the construction zone for the new water reservoir. Hi-viz is required when accessing this area by foot.

Crystal's authority of appointment (warrants) under the Biosecurity and Hazardous Substances and New Organisms (HSNO) Act were presented and displayed.

During this audit period the site Operating Facility Manger resigned and 9(2)(a) was appointed (Delegated Authority) as the Containment Facility Manager for Ruakura. 9(2)(a) has attended audits in Hamilton and Palmerston North as part of her knowledge based training for this role.

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

##### Biosecurity

Good compliance was noted for animal containment (small and large). Structural and hygiene issues were noted for Plants and laboratory based (Biological Products and Microorganisms) standards. A critical issue was reported for the Microorganism and Cell Culture standard.

The following elements were verified in this PBV period:

Biosecurity:Containment Facilities for Plants: 2007	Acceptable
Biosecurity:Containment Facilities for Vertebrate Laboratory Animals	Acceptable
Biosecurity:Containment Standard for Field Testing of Farm Animals	Acceptable
Biosecurity:Facilities for Microorganisms and Cell Cultures: 2007a	Acceptable
Biosecurity:Transitional Facilities for Biological Products	Acceptable
Biosecurity:Transitional and Containment Facilities for Invertebrates	Acceptable

##### Quality Assurance

9(2)(a) has established a support network with staff at Grasslands. The facility manual needs to be updated following the departures of facility managers and authorised signatories: 9(2)(a), so that staff can identify the relevant contact persons.

Internal audits were reviewed for Small Animal Containment ((SAC) 16/7/19), Animal Containment Farm ((ACF) 22/06/2019), Glasshouse and research laboratories (May 2019). The SAC and ACF audits were thorough and included animal inventories and good supporting evidence. The Glasshouse and laboratories audits were superficial and solely focused on physical structures. 9(2)(a) has attended internal audits at Grasslands as part of her training so it is expected that future audits will be appropriately robust. Presentations from the MPI Operator Workshop held March 2019 were also provided post inspection to provide additional guidance for internal audit improvement and as training material for 9(2)(a).

Site training for staff had been conducted across the site in group sessions; March to June 2019.

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



The following elements were verified in this PBV period:

Quality Assurance:Organizational Structure and Management	Acceptable
Quality Assurance:Risk Assessments	Acceptable
Quality Assurance:Training and Competency of Personnel	Acceptable

### **Documentation and Certification**

Animal import, quarantine, breeding and health records were available in either hard or electronic copy. BACCs and copies of transfer forms were held. One copy held of a transfer, was not the MPI approved copy for CL11136. Several transfers while approved, had not been confirmed as completed. 9(2)(a) has followed up and all transfers have been confirmed, the Receipt Checklists completed and the MPI approved from supplied by the recipient. Staff need to be aware that transfer events under a multiple transfer still need to be reported on each occasion for tracking purposes.

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

**Subject:** Documentation and Record Keeping

Note List:

[Crystal Lange]

**This issue is now closed.**

- ✳ A tenant had an approved single movement transfer (EM1216). Multiple transfers took place and more were planed after the noted completion date. There was no traceability for these transfers. This incident is a major non compliance.

A number of transfers in the register (single and multiple) had not been confirmed to the Facility Manager. AgResearch would be prudent to review the services provided to its tenants and its own accountability for the actions of these tenants.

### **NON COMPLIANCE**

Failure to comply with the facility manual (4.2) and MPI Standard for Biological products (4.8). Transfer without current approval and failure to notify of transfer under a multiple transfer.

### **CORRECTIVE ACTION REQUEST**



1. Ensure all transactions are covered by an appropriate transfer request
2. Ensure staff are aware of transfer limitations (e.g single / multiple)
3. Ensure all movements under a multiple transfer are recorded on the site database.

Transfer CM3578 obtained. CLOSED August 22 2019.

Ongoing non compliance will result in the cancellation of multiple transfers, all movements will then require approval prior to each transaction.

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

Biological products registers are maintained centrally, cell culture collections are maintained by Agresearch staff or site tenants. The recently implemented receipt checksheet has assisted traceability of product when key users are absent.

Cage card checks and inventory reconciliation undertaken in the SAC and goat and sheep identification techniques confirmed at the ACF.

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	Unacceptable
Identification, Traceability & Management:Transport of Risk Goods and Organisms	Acceptable

**Subject:** Transfer of Goods and Organisms

Note List:

[Crystal Lange]

**This issue is now closed.**

-  During the process of writing this report a planned transfer of Genetically Modified Organisms (GMO) took place at short notice. A transfer application had not been submitted and it wasn't until the samples were on the courier that the oversight was noted. An unapproved transfer is a critical non compliance.

The MPI supervisor was notified immediately of unapproved transfer. Samples were confirmed as received and held securely by recipient. Shipper also rang MPI to discuss the incident.



## NON COMPLIANCE

Failure to comply with the requirements of section 52d of the Biosecurity Act, control 9 of the HSNO Act Approval (APP201857 and APP201858), section 4.4 of the EPA Standard: Facilities for Microorganism and Cell Cultures (section 8.8) and section 4.2 of the containment manual.

## CORRECTIVE ACTION REQUIRED

7. Obtain retrospective Transfer Approval.
8. Complete Root Cause Analysis (CAR 2501/2019/01).
9. Ensure staff have been retrained in correct transfer procedure.

RCA supplied and training confirmed 23/08/2019. Transfer approved 26/08/2019 (DZ543). CLOSED August 26 2019.

Follow up audit to be conducted in three months time.

## Corrective Action Requests (CARs)

<b>CAR ID:</b>	2501/2019/01	<b>Status:</b>	COMPLETE
<b>Date issued:</b>	23 August 2019	<b>Issued by:</b>	Crystal Lange
<b>Subject:</b>	Identification, Traceability & Management: Transfer of Goods and Organisms		
<b>Date completed:</b>	10 September 2019		
<b>Reason:</b>	Unapproved transfer of GMO material		

## Hygiene & Sanitation

Autoclave records for the SAC ibutton runs were sighted with the shortest run over 121 degrees Celsius was 22 minutes.

Interwaste collections continue without issue. The ibutton results for Plant Protection showed a kill run of 121 degrees Celsius for 51 minutes.

The PC2 Glasshouse corridor was littered with dust and gib powder following the ceiling replacement, the ante room was littered with plant/straw fragments and surfaces were dusty. In Plant Protection cobwebs were noted under the sink (Synthase), hanging from ceiling panels and in corners (Main and Micro) and above lab coats hanging in the hall. A laboratory carry bucket was dirty and biological waste bins were overfill. Cardboard boxes were on the floor in Animal Physiology and cardboard had been used as a door stop, used tips were on a floor. Two small bags (empty) had been placed in a single waste bin, the in-use sharps bin did not have its lid on, the hands-free sanitiser was not working, a yellow damp or mould spot was identified on the ceiling and a multi-board and extension lead were on the floor and potentially an electrical hazard for cleaning or spills. A broom had accumulated dust hanging off the bristles.

The following elements were verified in this PBV period:

	Hygiene & Sanitation: Cleaning and Disinfection	Acceptable
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The following elements were verified in this PBV period:

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]

-  A number of transitional and or containment spaces were not maintained at an acceptable standard.

NON COMPLIANCE Rating Minor

Good Laboratory practices not demonstrated to an acceptable standard

**CORRECTIVE ACTION REQUIRED**

4. Address cleaning of surfaces with particular attention to corners and area where cobwebs were detected.
5. Clean up renovation debris in PC2 Glasshouse
6. Address other items and implement preventative measures in laboratories not inspected this visit.

To be completed by: September 13 2019

## **Design and Construction**

SAC - SPF , Suite 2A, 3A&B were inspected with no issues noted. Containment had been maintained at the ACF during the installation of water pipes outside of and through the perimeter fence.

The walls in Dairy Science (5) had been well finished. Wallpaper continues to peel in other rooms in the building and wooden strip panelling around and above sinks should be sealed. A number of benches need to be sealed to the rear panelling. Unsealed wood was noted in a range or used in Animal Physiology along with cracked paint in ceiling / scotia joins in a PC2 laboratory, a bench edge had not been sealed after is was sectioned, the wall was not stopped and large portion was not sealed.

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
 Design and Construction:Laboratories	Acceptable



The following elements were verified in this PBV period:

Design and Construction:Location	Acceptable
Design and Construction:Open Field Testing Facilities	Acceptable
Design and Construction:Physical Containment Level 1 (PC1)	Acceptable
Design and Construction:Physical Containment Level 2 (PC2)	Acceptable
Design and Construction:Plant Houses and Glasshouses	Acceptable
Design and Construction:Signage	Acceptable

**Subject:** Laboratories

Note List:

[Crystal Lange]



**NON COMPLIANCE** Rating minor

Laboratories at level 1 and 2 physical containment (ASNZS 2243.3) were not maintained at an acceptable level.

**CORRECTIVE ACTION REQUEST**

10. Seal wall and bench edge in Animal Physiology (Rm24)
11. Address wallpaper and sealing issues in Dairy Science

To be completed by: September 13 2019

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

GMC03001, GMD02006, GMC99010, GMD04112.

See unapproved transfer non-compliance in relation to HSNO Act Approval APP201858.

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.



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)

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