

Ministry for Primary Industries

Manatū Ahu Matua



Verification Report¹

Report ID:	PBV/2501/2020/03
Outcome:	Acceptable
<hr/>	
Issued to:	AgResearch - Ruakura Campus
Operator ID(s):	2501
Issued by:	Crystal Lange Phone: s9(2)(a) Email: crystal.lange@mpi.govt.nz
<hr/>	
Verification Period:	2020-09-01 to 2020-11-28
Verification Date:	2020-11-04
Published:	2020-11-04 13:01
Next Due Date:	2021-02-27
Level/Step:	5.2 (started on 5.1 , and ceiling is 6)
Report Type:	Scheduled
<hr/>	
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 s9(2) or notify by email using crystal.lange@mpi.govt.nz and erase the report and attachments. Thank you.

The Ministry for Primary Industries retains the 'original' of this report and accepts no responsibility for changes made to 'copies', including attachments, however they may be distributed.



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 standards identified. Under section 40 of the Biosecurity Act, AgResearch 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

Glossary of terms :

TF	Transitional Facility
ACU	Animal Containment Unit
BACC	Biosecurity Authority Clearance Certificate
CAR	Corrective Action Required
CAR	Corrective Action Request
COVID-19	Coronavirus Disease of 2019
CTO	Chief Technical Officer
DFO	Delegated Facility Operator
GM	Genetically Modified
HSNO	Hazardous Substances and New Organisms
MPI	Ministry for Primary Industries
NC	Non-Compliance
PBV	Performance Based Verification
PC1	Physical Containment Level 1
PC2	Physical Containment Level 2
PP	Plant Protection
PPE	Personal Protective Equipment
R&M	Repairs and Maintenance
VS	Verification Services

2. Executive Summary

This was a scheduled and announced inspection of the AgResearch transitional and containment facility in Hamilton. The objective of this increased frequency 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 at 3 November 2020 had an acceptable outcome with good compliance with the EPA and MPI standards being observed. One minor non-compliance was identified for structural compliance of PC1 laboratories. Security of GMOs and cell lines closed during the verification period were revisited. Rooms approved for inclusion to the site plan were also inspected.

Good operator control is being maintained and excellent progress continues to be made in developing a robust internal audit and proactive compliance from staff. MPI is satisfied that AgResearch (Ruakura) is operating in compliance with the requirements of the standards it is approved to 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 the containment and storage areas, was carried out by Crystal Lange (MPI) with Genevieve Sheriff (DFO). Crystal's authority of appointment under the Biosecurity Act 1993 and Hazardous Substances and New Organisms Act 1996 (warrant) was displayed throughout.

Health and Safety is covered by an electronic visitor log with COVID-19 declaration.

The inspection process included a review of onsite records, where applicable but not limited to; staff training, biological products register, internal audit and physical inspection of the laboratory area and storage areas. A discussion was also held with Dave Wells around register types including future options.



4. Verification Completed (this period)

Biosecurity

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

The facility manual had been updated to include changes made since the last external inspection and the reactivation of the PC2 Goat Shed.

Internal audits of the various research sections overseen by Gen were reviewed. These continue to be modified into a fit for purpose document. Records reviewed noted current training, relevant HSNO approvals and traceability tasks where applicable.

A register of CTO approvals and current applications was available.

The following elements were verified in this PBV period:

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

Documentation and Certification

No imports have been received since the last inspection (August 2020). One AgResearch tenant had failed to notify transfers completed under a multiple transfer approval to the DFO. This had been raised with him directly, via the 2019 report and a site wide email from the DFO. As a result his multiple transfer permit was cancelled. Single movement requests need to be applied for until the DFO and MPI are confident that reporting will be completed in a timely manner.

Clarification on product types revealed other omissions in relation to transfers from 2019. As these were historical issues covered under CARs for both AgResearch and another facility, no additional action is being taken by MPI, apart from the cancellation noted above.

Storage space for liquid nitrogen banks and freezers containing cell lines and GMOs was added to the foot print. One laboratory was added back into the facility (Rm 16).

The following elements were verified in this PBV period:

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



The following elements were verified in this PBV period:

Documentation and Certification: Documentation and Record Keeping	Acceptable
Documentation and Certification: Site Plans, Specification and Modifications	Acceptable

Identification, Traceability & Management

Acceptable traceability was demonstrated during the internal audit. Site registers have been reviewed and reconciled against stored samples. One transfer was confirmed for DZ1240 (now cancelled), five for multiple transfer CM4366. CM448 was completed 21/10/2020.

Storage in Animal Physiology (AnPhys) Room 18 and the service area was assessed and was acceptable. Signage was not present on the Dairy Science freezer. It was confirmed the inventory (listed on door) did not contain risk goods.

The following elements were verified in this PBV period:

Identification, Traceability & Management: Inventory Control and Accuracy	Acceptable
Identification, Traceability & Management: Storage Areas	Acceptable
Identification, Traceability & Management: Transfer of Goods and Organisms	Acceptable

Hygiene & Sanitation

Spiderwebs and dust were noted in a number of laboratories. PPE was available in all areas.

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

Design and Construction

Security issues with the AnPhys door had been advised to MPI along with interim actions. The problem was resolved within 24 hours.

Only PC1 laboratories were visited. A number have had items removed from the walls during staff/equipment relocations leaving screw holes in the walls. This and cobwebs under sinks contributed to a shabby appearance.

The following elements were verified in this PBV period:

Design and Construction: Access and Security	Acceptable
--	------------



The following elements were verified in this PBV period:

☸ Design and Construction:Laboratories	Acceptable
Design and Construction:Physical Containment Level 1 (PC1)	Acceptable
Design and Construction:Physical Containment Level 2 (PC2)	Acceptable
Design and Construction:Signage	Acceptable

Subject: Laboratories

Note List:

[Crystal Lange]

- ☸ A fire hose reel is built into the wall of AnPhys 16. The top of the frame needs to be sealed and the water pipe hole reduced or the entire frame capped.

The external door (carpark end) of Room 22 (Dairy Science) requires the weather/insect strip to extend the full width of the door base. Two unsealed wooden door stops were sighted (22 and 23) and an unsealed shelf was in contact with the floor in 23.

Paint work along a bench end (window sill) in South Wing Rm 111 needs addressing to remove cracks. A stool in 114 had a hole in the set and the covering was coming loose. An unsealed wooden tray was removed from the floor behind the chemical cupboard in 117.

Styrofoam was in direct contact with the floor in the Endophyte (30) lab in Plant Protection.

Subject: Physical Containment Level 1 (PC1)

Note List:

[Crystal Lange]

Laboratories visited:
 Animal Physiology: 16, 24, 18, 42-52
 Dairy Science: 1-11, 23, 26, Freezer 1
 Insecticide: 10
 Plant Protection: 8, 30, 32, 34,
 South Wing: 101, 111, 112, 114, 116, 117, 119

Hazardous Substances and New Organisms (HSNO) Act

ERMA200223 was in use by AgResearch staff. ManukaMed was using APP203262 and Synthase BioTech APP203417.

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
---	------------



The following elements were verified in this PBV period:

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)

Ministry for Primary Industries

Manatū Ahu Matua



Verification Report¹

Report ID:	PBV/2501/2021/01
Outcome:	Acceptable
<hr/>	
Issued to:	AgResearch - Ruakura Campus
Operator ID(s):	2501
Issued by:	Crystal Lange Phone: s9(2)(a) Email: crystal.lange@mpi.govt.nz
<hr/>	
Verification Period:	2020-11-05 to 2021-02-27
Verification Date:	2021-03-08
Published:	2021-03-08 16:35
Next Due Date:	2021-08-27
Level/Step:	6.1 (started on 5.2 , and ceiling is 6)
Report Type:	Scheduled
<hr/>	
Peer Reviewed By:	Rana Fathizargaran

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 s9(2)(a) or notify by email using **crystal.lange@mpi.govt.nz** and erase the report and attachments. Thank you.

The Ministry for Primary Industries retains the 'original' of this report and accepts no responsibility for changes made to 'copies', including attachments, however they may be distributed.



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, AgResearch 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

Glossary of terms :

TF	Transitional Facility
ACF	Animal Containment Farm
ACU	Animal Containment Unit
BACC	Biosecurity Authority Clearance Certificate
CAR	Corrective Action Required
CAR	Corrective Action Request
COVID-19	Coronavirus Disease of 2019
CTO	Chief Technical Officer
DFO	Delegated Facility Operator
EPA	Environmental Protection Authority
GM	Genetically Modified
HSNO	Hazardous Substances and New Organisms
MPI	Ministry for Primary Industries
NC	Non-Compliance
PBV	Performance Based Verification
PC1	Physical Containment Level 1
PC2	Physical Containment Level 2
PP	Plant Protection
PPE	Personal Protective Equipment
R&M	Repairs and Maintenance
SAC	Small Animal Containment
VS	Verification Services

2. Executive Summary

This was a scheduled and announced inspection of the AgResearch Limited transitional and containment facility at Ruakura. The objective of this visit was



to verify compliance with the facility manual, the Import Health Standard(s), 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 2 March 2020 had an acceptable outcome with good compliance with the MPI standards being observed. Minor issues in the laboratories resulted in one NC being issued.

Operator Control continues to be reviewed and strengthened. MPI is satisfied that AgResearch Limited is operating in compliance with the requirements of the standards it is approved to. As such the facility and operator approvals will be continued. This inspection falls as scheduled for the ACF and SAC. It is the second of an increased frequency for the laboratories.

3. Operator Summary

The entry and exit meetings along with the reality check of the facility was carried out by Crystal Lange (MPI) with Genevieve Sheriff (delegated Operator) and Tim Hale (delegated Operator ACF) of AgResearch. The Inspectors' authority was confirmed under the Biosecurity Act 1993 and Hazardous Substances and New Organisms Act 1996 was confirmed.

Health and Safety is covered by a visitor register. This inspection was undertaken at COVID-19 Level 2 (2021). No additional hazards were notified.

The inspection process included a review of onsite records, where applicable but not limited to, staff training, biological products and animal registers, internal audit and physical inspection of laboratories and the field test.

Three events had occurred that MPI was required to be notified about. An office air-conditioning unit fire 6/01/2021, requiring the external door to be open (under supervision) for smoke dispersal. A basement door (shared space) was found propped open (5/02/2021), and a glass pane was found broken in the glasshouse 1/03/2021.



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

Subject: Containment Standard for Field Testing of Farm Animals

Note List:

[Crystal Lange]

Controls 1-7, 9, 10 of HSNO Approval ERMA200223 were assessed and no non-compliances were noted. A mob of cows were in the yards and good animal handling was observed. Ears tags were selected for a full records check. Two parent and three baby goats were also sighted next to the yards. A mob of sheep and other cattle were seen in separate paddocks during the Northeast perimeter check.

The secondary access gates were well secured and are electronically monitored. Perimeter check and pest control is recorded in the day book.

Pigs, while held under the Vertebrate Laboratory Animals Standard are managed by ACF staff.

Subject: Containment Facilities for Vertebrate Laboratory Animals

Note List:

[Crystal Lange]

Three SAC staff have received refresher training since the last inspection. Areas of the surgery requiring R&M were sighted and discussed.

Quality Assurance

New laboratory managers are in the process of being appointed to cover staff relocations and retirements. The manual will be updated to cover this and other minor changes.

Induction training had been completed for ten science staff since November 2020. Contractor training was completed 25/02/2021 and site wide refresher training has been booked.



The ACF internal audit for December 2020 had been emailed to the Inspector. Internal audits for laboratories were sighted at the last audit.

The following elements were verified in this PBV period:

Quality Assurance:Biosecurity Contingency Plans	Acceptable
Quality Assurance:Operating Procedures	Acceptable
Quality Assurance:Operator Control	Acceptable
Quality Assurance:Operator Internal Verification	Acceptable
Quality Assurance:Training and Competency of Personnel	Acceptable

Documentation and Certification

All imports and transfers for this inspection period were on file. Monitoring of multiple transfers was demonstrated.

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

Gen had been granted access to the Reproduction register but was unable to access this on the day. One tenant register was able to be viewed and records associated with HSNO Approval GMC100216 were confirmed as meeting the requirements of the standard.

Two cows from the standing mob (in yards) were selected for a records check. All animal records were available including those from prior to movement to or purchase by the ACF.

The following elements were verified in this PBV period:

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



The following elements were verified in this PBV period:

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

Hygiene & Sanitation

Laboratories were clean and tidy with appropriate PPE available.

Vermin continues to be actively controlled on the ACF.

iButton print outs for the Plant Protection (PP) and SAC autoclaves were reviewed. PP met the time temperature requirements for 55 minutes where as SAC had a 5 minute difference between buttons. Neither run recorded for iButton D3 met the requirements. Companion iButton 'BC' indicated acceptable treatment of 18 and 15 minutes for disposal cycles.

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:Waste Management	Acceptable

Subject: Waste Management

Note List:


[Crystal Lange]

iButton D3 should be discarded.

Design and Construction

A selection of PC1 and PC2 laboratories were chosen for inspection.

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
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



Subject: Laboratories

Note List:

[Crystal Lange]



Animal Physiology

97 - wall surface (paint) was not sealed by the fridge, sealant should be applied around the doorframe to ensure seepage does not occur under the new flooring or existing walls.

Bench top fittings showed water damage. AS these items are built in, they should be added to the laboratory end of life policy.

96 - A fabric topped foot stool was seen. The fabric and underlying adhesive should be removed or the item added to the laboratory end of life policy.

16 - a section of draw front requires sealing.

Plant Protection

The door to the molecular laboratory would not close without assistance. The fume hood fan was noisy.

The above minor NC should be addressed and confirmed to MPI by 1 April 2021.

Subject: Physical Containment Level 2 (PC2)

Note List:

[Crystal Lange]

Notification was received 1/03/2020 of a glass panel found broken on the PC2 Glasshouse. No plants were in the room at the time. Additional containment methods were discussed at the time. Repair was scheduled for 2/03/2020.

Hazardous Substances and New Organisms (HSNO) Act

GMC100216 was confirmed as in use during inventory checking. APP200223 was assessed and the majority of controls are noted in the Biosecurity section for the Field Test Standard. A development application is underway for Ruakura Technologies.

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)

Ministry for Primary Industries

Manatū Ahu Matua



Verification Report¹

Report ID:	PBV/2501/2021/02
Outcome:	Acceptable
<hr/>	
Issued to:	AgResearch - Ruakura Campus
Operator ID(s):	2501
Issued by:	Crystal Lange Phone: s9(2)(a) Email: crystal.lange@mpi.govt.nz
<hr/>	
Verification Period:	2021-03-09 to 2021-08-27
Verification Date:	2021-08-06
Published:	2021-08-25 17:12
Next Due Date:	2022-02-27
Level/Step:	6.2 (started on 6.1 , and ceiling is 6)
Report Type:	Scheduled
<hr/>	
Peer Reviewed By:	Rana Fathizargaran

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 s9(2)(a) or notify by email using **crystal.lange@mpi.govt.nz** and erase the report and attachments. Thank you.

The Ministry for Primary Industries retains the 'original' of this report and accepts no responsibility for changes made to 'copies', including attachments, however they may be distributed.



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, AgResearch 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

Glossary of terms :

TF	Transitional Facility
ACF	Animal Containment Farm
ACU	Animal Containment Unit
BACC	Biosecurity Authority Clearance Certificate
CAR	Corrective Action Required
CAR	Corrective Action Request
COVID-19	Coronavirus Disease of 2019
CTO	Chief Technical Officer
DFO	Delegated Facility Operator
EPA	Environmental Protection Authority
GM	Genetically Modified
HSNO	Hazardous Substances and New Organisms
MPI	Ministry for Primary Industries
NC	Non-Compliance
PBV	Performance Based Verification
PC1	Physical Containment Level 1
PC2	Physical Containment Level 2
PP	Plant Protection
PPE	Personal Protective Equipment
R&M	Repairs and Maintenance
SAC	Small Animal Containment
VS	Verification Services

2. Executive Summary

The objective of this visit was to verify compliance with the facility manual, the Import Health Standard(s), 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 scheduled and announced inspection of the AgResearch Limited TF and CF at Ruakura, Hamilton on 6 August 2021. The outcome of this verification was acceptable with one NC issued for PC1 laboratories.

Registers were reviewed, animals, enclosures and laboratories reviewed. MPI is satisfied that AgResearch is operating in compliance with the requirements of the standards it is approved to. As such the facility and operator approvals will be continued.

3. Operator Summary

The entry and exit meetings along with the reality check of the facility was carried out by Crystal Lange (MPI) with Genevieve Sheriff (delegated Operator) and Tim Hale (delegated Operator ACF) of AgResearch. The reality check included ACF, SAC including the Pig unit (Goat Shed), PC1 laboratories in Dairy Science, South Wing, Plant Protection and the PC1 and PC2 Plant Protection glasshouses.

The Inspectors' authority under the Biosecurity Act 1993 and Hazardous Substances and New Organisms Act 1996 was confirmed. Health and Safety is covered by a visitor register. No additional hazards were notified.

Operator Control continues to be reviewed and strengthened. Staff in the Pig unit demonstrated good understanding of risk assessment although dissemination of knowledge could be improved.



4. Verification Completed (this period)

Biosecurity

No issues were identified. Specifics for each standard are noted below.

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

Subject: Transitional Facilities for Biological Products

Note List:

[Crystal Lange]

Only two imports had occurred under this standard during the past six months. Research work is winding down in general with a number of laboratories having little or no recent use.

Subject: Facilities for Microorganisms and Cell Cultures: 2007a

Note List:

[Crystal Lange]

Registers were reviewed, recent transfers and training events were confirmed. PC1 laboratories excluding those in the APC were visited. The PC2 laboratories in Plant Protection was also excluded at the last minute.

Notification of transactions to the delegated Operator are continuing.

Subject: Containment Facilities for Plants: 2007

Note List:

[Crystal Lange]

Controls were reviewed for CTO permissions for velvet leaf, M.minor and black-grass. AgResearch was found to be compliant with the conditions of the relevant approvals. HSNO Approval GMD02023 was in use.

Labelling of pots and seed storage was acceptable. The glasshouse manger was knowledgeable of all work under way.

A replacement autoclave was due to be installed that week.



Subject: Transitional and Containment Facilities for Invertebrates

Note List:

[Crystal Lange]

The PC2 glasshouse was confirmed to comply with PC2 holding requirements. Appropriate signage was present.

Subject: Containment Standard for Field Testing of Farm Animals

Note List:

[Crystal Lange]

The register was supplied and animal transactions discussed. Deaths and animal removals were explained. There were no health issues that required notification to MPI. Training was up to date for all staff and the facility manual (V4) was issued in June 2021. Selected animals from the register were confirmed as present in containment. Sections of the perimeter fence were viewed when entering and leaving site and while travelling to the Pig unit.

Compliance with the 154.03.06 Standard and HSNO Approval ERMA200223 was assessed and confirmed as being compliant.

Subject: Containment Facilities for Vertebrate Laboratory Animals

Note List:

[Crystal Lange]

Quarantine of 46 animals had occurred with only one death. Completion of quarantine was notified to MPI and approval given to transfer the animals to another Containment Facility. Recording of daily quarantine checks was identified as deficient by the facility.

Animal rooms were well maintained. The animal register was checked against cage cards for HD K/O and JMJ3.

The Pig unit is approved under this standard, daily management is by trained members of the science team overseen by the Animal Containment Facility manager. The facility was clean, tidy and secure. Pigs were alert and active. Work was underway for HSNO Approval GMD102650.

Quality Assurance

A number of CTO permissions are held. It was confirmed the PTA approval was not renewed after expiry in 2018. Copies of Velvet Leaf, M.minor and black-grass had been



supplied to MPI. A copy of the Chilean mayten permission was requested. Compliance with controls for black-grass and velvet leaf were discussed and confirmed as being compliant.

Internal audits for the site were completed 27/05-23/6 2021. Key points were the continued failure of the Plant Protection autoclave and a number of hygiene and structural issues for laboratories.

Training had been completed for staff and cleaners. Training for Laboratory Managers was underway.

Excellent (and timely) notification has been received for incidents that have occurred during the past six months (security events and broken panel in the PC2 glasshouse)

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
Quality Assurance:Training and Competency of Personnel	Acceptable

Subject: Operating Procedures

Note List:

[Crystal Lange]

During the Piggery visit the delegated Operator was advised that anyone accessing the Pig unit does not access the PC2 laboratory without showering first.

It was agreed clarity needs to be gained to cover visitors not working with the pigs and access to other laboratories in the Animal Physiology building (e.g. PC1) as these rooms/equipment/laboratory gowns are used by staff accessing PC2 laboratories as well.

A written protocol should then be supplied to relevant staff and placed on the Pig unit door.

Documentation and Certification

All imports were recorded. Records maintained during vertebrate quarantine (C2021/505534) were discussed. The facility was aware of a deviation in recording of daily checks from historic to present imports with the change in supervisory staff. This will be redressed at the earliest opportunity.



Registers for the three animal facilities were maintained and supplied in hard copy, internal audit records and the laboratory/small vertebrate/plant house pre-audit report were supplied in time for part of the external audit preparation.

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 control for M.minor was discussed as numbers can not be confirmed pre-trial without destroying the soil structure and pupation burrows. Grass pots were well labelled, animals tagged, clipped or notched as required.

The following elements were verified in this PBV period:

Identification, Traceability & Management:Inventory Control and Accuracy	Acceptable
Identification, Traceability & Management:Product and Organism Identification	Acceptable

Hygiene & Sanitation

Overall the hygiene of working areas was maintained to a good level except for Dairy Science, particularly in the storage areas. PPE was available and appeared clean.

Autoclave validation records were supplied for Plant Protection and Small Animal Colony. Chemical treatment was not able to be viewed due to hygiene protocols for the Pig unit that had not been formalised. Pig unit waste (non GM) is collected in wheelie bins and disposed of on farm.

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:Quarantine Isolation	Acceptable
Hygiene & Sanitation:Waste Management	Acceptable


Design and Construction

Issues with the electronic security system and extended periods where doors are required to be open for maintenance work have been notified to MPI.



All animal cages, pens enclosures and fencing had been maintained to an acceptable level. Issues with laboratory based facilities are noting in the NC below.

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
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]

-  Cracks and separating joins in the vinyl flooring of the Nematology laboratory (PP 14) need sealing.

Dust, cobwebs and midges were present in Dairy Science. The storage area with the -80 freezer was especially dirty. Wall/bench seals need replacing and a hole on the sink bench (12A) must be sealed. A bench in 26 had a chip and sections needed to be joined together with new impervious sealing.

Silicon sealant was not present around number of door frames which allows spills and cleaning fluids to seep into the joinery. While a number of doors have been done, the initiative has not been taken to roll this out across the site.

A bench in SW114 was sagging.

Collectively these issues form the PC1 NC. Completion of repairs should be confirmed with MPI by 10 September 2021.

Hazardous Substances and New Organisms (HSNO) Act

ERMA200223, GMD02013, GMD02023, APP203820, APP203942 and GMC03001 were among the approvals in use. It was confirmed GMC100216 was not yet in use.

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)

Ministry for Primary Industries

Manatū Ahu Matua



Verification Report¹

Report ID:	PBV/15389/2020/02
Outcome:	Acceptable
<hr/>	
Issued to:	SCION - GMO Field Test
Operator ID(s):	15389
Issued by:	Crystal Lange Phone: s9(2)(a) Email: crystal.lange@mpi.govt.nz
<hr/>	
Verification Period:	2020-05-19 to 2020-11-28
Verification Date:	2020-11-20
Published:	2020-11-27 11:18
Next Due Date:	2021-05-28
Level/Step:	6.2 (started on 6.2 , and ceiling is 6)
Report Type:	Scheduled
<hr/>	
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 ' SCION - GMO Field Test '. 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 s9(2)(a) or notify by email using **crystal.lange@mpi.govt.nz** and erase the report and attachments. Thank you.

The Ministry for Primary Industries retains the 'original' of this report and accepts no responsibility for changes made to 'copies', including attachments, however they may be distributed.



1. Premises Profile

SCION - GMO Field Test is, under section 39 of the Biosecurity Act 1993, approved as a Containment Facility in accordance with the requirements of the MPI/EPA standard identified. Under section 40 of the Biosecurity Act Scion Research 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 standard that the facility is approved to specifies the structural and operating requirements for containment and/or transitional facilities holding regulated organisms and risk goods that are, or may contain:

- Non-risk Goods
- Nursery Stock
- Plants

Physical Address :

49 Sala Street, Whakarewarewa, Rotorua

Glossary of terms :

TF	Transitional Facility
CAR	Corrective Action Request
EPA	Environmental Protection Authority
FT	Field Test
HSNO	Hazardous Substances and New Organisms
MPI	Ministry for Primary Industries
NC	Non-Compliance
PBV	Performance Based Verification
R&M	Repairs and Maintenance

2. Executive Summary

This was a scheduled and announced inspection of the Scion Field Test in Rotorua. 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 at November 20 2020 had an acceptable outcome with substantial compliance with the EPA and MPI standards being observed. No issues were noted and there was nothing requiring follow-up from the previous visit.

Operator Control is being maintained at a high level. MPI is satisfied that Scion is operating in compliance with the requirements of the standard it is approved to and the HSNO approval. As such the facility and operator approvals will be continued.

3. Operator Summary

The entry and exit meeting along with the records check and physical inspection of the Field Test site (TF1 and FT2), was carried out by Crystal Lange (MPI) with s9(



s9(2)(a) (delegated Operator), Scion. Crystal's authority of appointment under the Biosecurity Act 1993 and Hazardous Substances and New Organisms Act 1996 (warrant) was displayed throughout.

Health and Safety is covered by an electronic visitor login which included a mini induction. Additional requirements for access through the Nursery (Hi-Vis) was notified.

s9(2)(a) advised his role had been confirmed for another three years and that Scion management are aware that the delegation letter will need to be reissued next year after the departure of both s9(2)(a) and s9(2)(a).

The inspection process included a review of onsite records, where applicable but not limited to; staff training, plant register, internal audit and a reality check of the FT area.



4. Verification Completed (this period)

Biosecurity

The Scion FT containment facility was compliant with the requirements of the standard, as stipulated in Control 4 of the HSNO Approval.

The following elements were verified in this PBV period:

Biosecurity:Containment Facilities for Plants: 2007	Acceptable
---	------------

Quality Assurance

Version 3.7 of the facility manual was supplied in hardcopy. It had been reviewed and accepted by MPI 20/07/2020. A comprehensive internal audit is carried out of all required records with the last one completed 3/08/2020. Training events had taken place 19/8/2020 for staff and 26/08/2020 for security personnel.

The following elements were verified in this PBV period:

Quality Assurance:Operating Procedures	Acceptable
Quality Assurance:Operator Control	Acceptable
Quality Assurance:Operator Internal Verification	Acceptable
Quality Assurance:Training and Competency of Personnel	Acceptable

Documentation and Certification

Logs for FT Activities, Fence Inspection, and Visitors reviewed. Records of Internal Audits, Training and Approved Users were sighted. All records were compliant.

The following elements were verified in this PBV period:

Documentation and Certification:Documentation and Record Keeping	Acceptable
--	------------

Identification, Traceability & Management

Trees continue to be identified using RFID and standard tags. Transfer CM4164 occurred 2/6/2020. The Plant register records felling of trees, finding of reproductive structures is recorded in the Inspection log.

The following elements were verified in this PBV period:

Identification, Traceability & Management:Inventory Control and Accuracy	Acceptable
--	------------



The following elements were verified in this PBV period:

Identification, Traceability & Management:Product and Organism Identification	Acceptable
Identification, Traceability & Management:Reception of Consignments	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

Areas of composting material were fenced as described in page 16 of the manual.

The following elements were verified in this PBV period:

Hygiene & Sanitation:Waste Management	Acceptable
---------------------------------------	------------

Design and Construction

The Security Protocol had been reviewed and remains unchanged. Remote sensing has detected fog, birds and hedgehogs.

The following elements were verified in this PBV period:

Design and Construction:Access and Security	Acceptable
Design and Construction:Open Field Testing Facilities	Acceptable
Design and Construction:Signage	Acceptable

Hazardous Substances and New Organisms (HSNO) Act

The Field Test has only one HSNO approval (GMF100001).

Control 1 - Monthly reports continue to be submitted to Scion senior management.

Control 2 - Trees sighted in the FT were identified as Pinus radiata.

Control 3 - Records check and reality check of the FT confirmed compliance with the control.

Control 4 - Compliance with the Plant Standard was confirmed.



Control 5 - This external audit was the second of the year. Historical audit reports are maintained.

Control 7 - Fencing was compliant, required logs were maintained.

Control 8 - Entrance numbers and security of access was confirmed. The approved users list was current.

Control 9 - Signage complied with wording and logo.

Control 10 - Scion complied with tree identification, monitoring frequencies and record keeping.

Control 11 - Reproductive structure removal and killing of relevant trees was documented. No GM trees near the maximum age.

Control 13 - The 9th annual report was confirmed by the EPA 10/07/2020

Controls 6, 12, 14 and 15 were not applicable to this inspection.

The following elements were verified in this PBV period:

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)

Ministry for Primary Industries

Manatū Ahu Matua



Verification Report¹

Report ID:	PBV/15389/2021/01
Outcome:	Acceptable
<hr/>	
Issued to:	SCION - GMO Field Test
Operator ID(s):	15389
Issued by:	Crystal Lange Phone: s9(2)(a) Email: crystal.lange@mpi.govt.nz
<hr/>	
Verification Period:	2020-11-21 to 2021-05-28
Verification Date:	2021-05-13
Published:	2021-05-17 13:05
Next Due Date:	2021-11-28
Level/Step:	6.2 (started on 6.2 , and ceiling is 6)
Report Type:	Scheduled
<hr/>	
Peer Reviewed By:	Richard Tukia

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 ' SCION - GMO Field Test '. 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 s9(2)(a) or notify by email using crystal.lange@mpi.govt.nz and erase the report and attachments. Thank you.

The Ministry for Primary Industries retains the 'original' of this report and accepts no responsibility for changes made to 'copies', including attachments, however they may be distributed.



1. Premises Profile

SCION - GMO Field Test is, under section 39 of the Biosecurity Act 1993, approved as a Containment Facility in accordance with the requirements of the MPI/EPA standard identified. Under section 40 of the Biosecurity Act Scion Research 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 standard that the facility is approved to specifies the structural and operating requirements for containment and/or transitional facilities holding regulated organisms and risk goods that are, or may contain:

- Non-risk Goods
- Nursery Stock
- Plants

Physical Address :

49 Sala Street, Whakarewarewa, Rotorua

Glossary of terms :

TF	Transitional Facility
CAR	Corrective Action Request
EPA	Environmental Protection Authority
FT	Field Test
HSNO	Hazardous Substances and New Organisms
MPI	Ministry for Primary Industries
NC	Non-Compliance
PBV	Performance Based Verification
R&M	Repairs and Maintenance

2. Executive Summary

This was a scheduled inspection of the Scion containment facility holding genetically modified plants, in Rotorua. The objective of this visit was to verify compliance with the facility manual, the HSNO Approval, the standard identified in the "Biosecurity" section of this report and the facility and operator approvals as held under the Biosecurity Act 1993.

The inspection undertaken at 13 May 2021 had an acceptable outcome with substantial compliance with the MPI standard being observed.

MPI is satisfied that Scion is operating in compliance with the requirements of the standard it is approved to. As such the facility and operator approvals will be continued.

3. Operator Summary

The entry and exit meeting along with the records and reality check of the facility was carried out by Crystal Lange (MPI) with s9(2)(a) (delegated Operator) of Scion.



The Inspectors' authority was confirmed under the Biosecurity (1993) and HSNO (1996) Acts. Hi-viz is required to be worn in the nursery area and all visitors are now required to sign in and out. No additional hazards were notified.

The inspection process included a review of onsite records, where applicable but not limited to; staff training, plants register, site activity logs, internal audit and physical inspection of the field test site.

Released under the Official Information Act 1982



4. Verification Completed (this period)

Biosecurity

The Field Test complies with the Plants standard where applicable. Pest control is excluded as per Control 6 of the HSNO Approval.

The following elements were verified in this PBV period:

Biosecurity:Containment Facilities for Plants: 2007	Acceptable
---	------------

Quality Assurance

A new letter of delegation was issued January 2021 which identified two new management reports and a new HSNO advisor. The February internal audit was completed by Scion staff external to the field trail. No non-compliance was identified.

Training was up to date with 11 users and 9 security staff trained. The most recent record was 28/04/2021. Four names have been removed from the approved users group.

The following elements were verified in this PBV period:

Quality Assurance:Operator Control	Acceptable
Quality Assurance:Operator Internal Verification	Acceptable
Quality Assurance:Organizational Structure and Management	Acceptable
Quality Assurance:Training and Competency of Personnel	Acceptable

Documentation and Certification

All record logs are reviewed as part of the internal audit. All records were well maintained.

The following elements were verified in this PBV period:

Documentation and Certification:Documentation and Record Keeping	Acceptable
--	------------

Identification, Traceability & Management

The planting record along with the tree inspection logs were reviewed. Two trees were chosen from the inspection record and located on the planting map. These trees were



successfully located during the reality check. Trees are identified by ear tag and RFID tag.

The following elements were verified in this PBV period:

Identification, Traceability & Management:Inventory Control and Accuracy	Acceptable
Identification, Traceability & Management:Product and Organism Identification	Acceptable

Hygiene & Sanitation

There was no tree felling this report period. Dropped branches from research sampling were seen left under the sampled trees.

The following elements were verified in this PBV period:

Hygiene & Sanitation:Waste Management	Acceptable
---------------------------------------	------------

Design and Construction

There have been no issues with unauthorised access. An UPS has been replaced after failing to reenergize following a power outage. Card access is being transferred to fobs, which allow better utilisation of electronic security and removes the need for multiple cards to be carried to access site areas. Security is monitored remotely. Frequent alarms the night prior to the inspection had resulted in a technician being called to site.

All access gates had visible signage and the Field Test site complied with the physical construction requirements described in the HSNO Approval.

The following elements were verified in this PBV period:

Design and Construction:Access and Security	Acceptable
Design and Construction:Open Field Testing Facilities	Acceptable
Design and Construction:Signage	Acceptable

Hazardous Substances and New Organisms (HSNO) Act

Compliance with ERMA200479 and GMF100001 was assessed for Controls 1-10. The facility met all control requirements.

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
---	------------



The following elements were verified in this PBV period:

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)