

Ministry for Primary Industries

Manatū Ahu Matua



Verification Report¹

Report ID:	PBV/15389/2020/02
Outcome:	Acceptable
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Issued to:	SCION - GMO Field Test
Operator ID(s):	15389
Issued by:	Crystal Lange Phone: 9(2)(a) Email: crystal.lange@mpi.govt.nz
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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
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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.

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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 9(2)
(a)



9(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.

9(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 9(2)(a) and 9(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.

Released Under the Official Information Act 1982



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
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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
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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
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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
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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
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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)

Ministry for Primary Industries

Manatū Ahu Matua



Verification Report¹

Report ID:	PBV/15389/2021/01
Outcome:	Acceptable
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Issued to:	SCION - GMO Field Test
Operator ID(s):	15389
Issued by:	Crystal Lange Phone: 9(2)(a) Email: crystal.lange@mpi.govt.nz
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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
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Peer Reviewed By:	Richard Tukia

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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 :

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Glossary of terms :

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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 ^{9(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
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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
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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
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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
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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
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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)

Released Under the Official Information Act 1982

Ministry for Primary Industries

Manatū Ahu Matua



Verification Report¹

Report ID:	PBV/15389/2021/02
Outcome:	Acceptable
Issued to:	SCION - GMO Field Test
Operator ID(s):	15389
Issued by:	Crystal Lange Phone: 9(2)(a) Email: crystal.lange@mpi.govt.nz
Verification Period:	2021-05-14 to 2021-11-28
Verification Date:	2021-11-16
Published:	2021-11-25 15:21
Next Due Date:	2022-05-28
Level/Step:	6.2 (started on 6.2 , and ceiling is 6)
Report Type:	Scheduled
Peer Reviewed By:	Els Maas

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- Non-risk Goods
- Nursery Stock
- Plants

Physical Address :

49 Sala Street, Whakarewarewa, Rotorua

Glossary of terms :

COVID-19	Coronavirus Disease of 2019
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
VS	Verification Services

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 16 November 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 ^{9(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 hazards were identified. All visitors were now required to sign in and out (July 2021), however the shed and visitors log have been removed and only a bin for PPE remains.

The inspection process included a review of onsite records, where applicable but not limited to; staff training, plant 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 site 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
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Quality Assurance

A hard-copy of version 3.8 of the facility manual was supplied to MPI. It was agreed that future copies would be electronic.

The internal audit was completed in August as scheduled. Three areas for improvement were identified.

Refresher training had been interrupted by COVID-19 (Delta) restrictions and is now back on track. Security staff had received induction or refresher training. Training records for Scion staff were reviewed.

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

Multiple logs are maintained to record activities undertaken by Scion to meet the controls of the HSNO approval. These logs and the register were sampled and confirmed to be up to date.

The following elements were verified in this PBV period:

Documentation and Certification:Documentation and Record Keeping	Acceptable
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Identification, Traceability & Management

The plant register was sighted along with the fortnightly and monthly inspection logs. Selected trees were located on the field test map and located during the reality check.

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: Transfer of Goods and Organisms	Acceptable
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Hygiene & Sanitation

Prunings are disposed of onsite. There is sufficient space to dispose of trees within the current trial areas.

The following elements were verified in this PBV period:

Hygiene & Sanitation: Waste Management	Acceptable
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Design and Construction

The signage and perimeter fence of FT1 was inspected. While there have been no access issues a alarm test indicated that notification of the alarms to Scion staff was not occurring in the manner expected. The Security protocol was reviewed and security staff retrained.

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 and 13. 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 New Organisms for Containment	Acceptable
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Mandatory Tasks



5. Definitions

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Unacceptable

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Ministry for Primary Industries

Manatū Ahu Matua



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Verification Date:	2022-05-10
Published:	2022-05-19 14:08
Next Due Date:	2022-11-28
Level/Step:	6.2 (started on 6.2 , and ceiling is 6)
Report Type:	Scheduled
Peer Reviewed By:	Rana Fathizargaran

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FT	Field Test
HSNO	Hazardous Substances and New Organisms
MPI	Ministry for Primary Industries
NC	Non-Compliance
PBV	Performance Based Verification
RAT	Rapid Antigen Test
VS	Verification Services

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 10/05/2022 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-VS) with ^{9(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, a visitor's log is maintained for entry into the Nursery area. Scion required a negative RAT less than 48 hours prior to entering site.

The inspection process included a review of onsite records, where applicable but not limited to; staff training, plant 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 site 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
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Quality Assurance

One of the management reporting lines has left Scion, staff are acting in that role until a replacement is found.

The first internal audit of 2022 was completed by ^{9(2)(a)}, the Containment Manger of three other CFs on site. One minor fence modification was made as a result of this audit. Nothing was raised of concern to MPI.

Training had been completed ahead of the reproductive structure inspections for all existing staff. A returning staff member was trained 19/01/2022, one new staff member will be trained following return from sick leave. She currently has 'visitor' status and was being supervised when on site.

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

Multiple logs are maintained to record activities undertaken by Scion to meet the controls of the HSNO approval. These logs and the register were sampled and confirmed to be up to date.

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

Tree 1699 was composting in FT2. Trees in both sites had identifying tags, plus additional coloured tapes as required for monitoring. The tree inspection log recorded dates and tree numbers where reproductive structures were removed. Fell dates were recorded.

Controls 10 and 11 of the HNSO approval were confirmed to have been complied with.

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

Sufficient composting space was available.

The following elements were verified in this PBV period:

Hygiene & Sanitation:Waste Management	Acceptable
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Design and Construction

FT2 was inspected in detail, the modification to the fence following the internal audit was sighted. Signage and perimeter fencing is maintained in good condition for both FT1 and FT2. Access by hedgehogs continues to be a problem as they activate security sensors or get stuck on the electric wires. The alarm fault with FT2 has been identified and repairs booked.

The following elements were verified in this PBV period:

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

Hazardous Substances and New Organisms (HSNO) Act

Compliance with ERMA200479 and GMF100001 was assessed for Controls 1-10 and 13. The facility met all control requirements.



This PBV was conducted to meet Control 5 ... at least once during the period when reproductive structures may develop.

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
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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

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Released Under the Official Information Act 1982