

Corrective Action Request
Issued To: AgResearch - Ruakura Campus
Status: CLOSED



CAR Number:	2501/2019/01	Issued by:	Crystal Lange	Date issued:	Fri, Aug 23, 2019
Subject:	Identification, Traceability & Management: Transfer of Goods and Organisms (primary)				

Part 1 - Summary of Issue

- 1.1 **The required outcome not being met:**
Unapproved transfer of GMO material.
- 1.2 **The objective evidence requiring corrective action:**
Email received from Facility Manager advising of transfer of GM embryos and sperm to 9(2)(b)(a)(i) [REDACTED].
- 1.3 **The proposed target date:**
Tue, Sep 10, 2019
- 1.4 **The likely interventions, or sanctions, if not resolved within agreed timeframes:**
Inspection frequency increase, infringement, facility suspension or cancellation.

Note Interventions / sanctions may be imposed by an Animal Products Officer using their powers under section 89 of the Animal Products Act 1999 or by a Biosecurity Inspector under s126 of the Biosecurity Act 1993.
E.g. interrupt operations, direct the operator, or restrict or prohibit the use of any process / animal material or product / equipment

Part 2: Root Cause

Staff negligence – if there was any doubt about the requirement of a transfer approval the shipment should have been held at Ruakura until confirmation was received, and the appropriate authorisation was granted.

Part 3: Corrective actions / Product Disposition

MPI notified within 24hours of the DFO being informed of the non-compliance
A retrospective transfer approval application is currently being completed – awaiting a signature from the receiving facility – and once complete it will be forwarded to MPI for approval.
9(2)(a) [REDACTED] to be reminded in writing of the procedure that must be followed for moving risk items.

Part 4: Preventive Actions

Email to be sent to all science staff reiterating the procedure that must be followed when sending or receiving risk items – if they aren't sure, ASK.
Reminder that DFO must be notified of all movements on current or future transfer approvals

Part 5 - VS Verification Summary and Closure of CAR

Ruakura staff have been proactive with notification of issue, completing the Root Cause Analysis and ensuring the documentation was completed in retrospect. MPI is confident the learning from this experience, plus the increased verification frequency will be sufficient to ensure this does not happen again.

Date Closed: Tue, Aug 27, 2019

The operator has implemented their corrective and preventive actions effectively. Operator and VS verification confirms that the root cause of the CAR has been addressed.