OIA20-0420

2 October 2020

Wendy McGuinness
wmcg@mcguinnessinstitute.org

Dear Wendy McGuinness

Thank you for your email, transferred to the Ministry for Primary Industries (MPI) from the Environmental Protection Authority (EPA) on 3 August 2020, requesting information relating to AgResearch's approval for GM animals - *ERMA200223*. Your request has been considered under the Official Information Act 1982 (OIA).

MPI rejects the claims in your letter as to risks arising from AgResearch's approval for GM animals. New Zealand has robust processes and practices in place to prevent issues arising, which reflect international best practice.

Please find a response to each part of the request relevant to MPI below.

Attachment 2 Point 1 - *Poor reporting and verification processes*

In this section, you raise three concerns:

1. Why MPI does not provide the annual report referred to in *ERMA200223 Control 11* to the EPA.
2. EPA expectations on the content of the annual report required by *Control 11*.
3. EPA expectations of *Control 4*.

Control 11 requires the '*Approval Holder*' (AgResearch), not MPI, to provide the annual report to the EPA. As the enforcement agency, MPI is required to ensure that the report is provided by AgResearch and that it addresses the points listed in *Control 11*.

Sections 6.2.93-96 of *ERMA200223* set out the expectations of the annual report and these are clearly reiterated in parts (a) to (c) of *Control 11*.

Control 4 requires AgResearch to ensure that the containment facilities holding the listed respective new organisms are compliant with the standards listed. As the enforcement agency, MPI inspects against the approvals held by AgResearch and reports on whether *Control 4* has been met, through Verification Inspection Reports.

Attachment 2 Point 2 - *AgResearch's failure to deliver the 'ten year report' on time*

In this section, you raise concerns that *Control 12* has not been complied with because *'the ten year report is now over 10 months late.*'

Sections 6.2.97-98 of *ERMA200223* clearly indicate that the expectations of the tenth annual report are to include '*additional requirements*' as detailed in parts (a) to (c) of *Control 12*. This report is to be provided after the tenth year of research. Following the approval of *ERMA200223* on 13 April 2010, AgResearch's first annual report reported on activities to 30 June 2010. The tenth annual report, which covers activities for the year ending 30 June 2020, and addresses the additional requirements of *Control 12*, has been provided to the EPA.

Attachment 2 Point 3 - *Inadequate MPI audit reports (22 August 2017 and 21 February 2018)*

This section notes concerns relating to a lack of verification inspection timeliness; inadequate reporting; the same verifier completing both the 2017 and 2018 verification reports; and failure to implement recommendations.

Verification inspections of AgResearch's facility are carried out in accordance with the minimum frequency set by the EPA. Further details are provided in response to *Attachment 2 Point 4* below.

In relation to the concern that reporting is not thorough. Based on the two to seven day timeframe for completion of reporting, it is MPI's policy that the report provides a concise summary of the verification visit, along with key details to support the overall conclusions made in relation to compliance. It is not MPI's policy to report on all the details investigated and discussed during the verification. This is accepted practice across many verification agencies and disciplines, with in-depth reporting reserved for scenarios like incident investigation.

The Facility Operator is the primary audience for the verification report, as they are the person accountable for meeting the requirements of the facility approval/s and are responsible for complying with *ERMA200223*. The report must retain its effectiveness as a formal and concise communication tool for use between MPI as the regulator, and the Facility Operator. Verification reports provide more detailed information where a compliance issue has been identified. This is to assist the Facility Operator's understanding of expectations and any subsequent consequences. The reporting process also acts as a means of providing assurance of compliance to the EPA.

The use of alternating verifiers for Containment Facility Verification is just one possible approach to providing effective technical review and calibration of verifier competency. MPI Verification Services currently utilises several different approaches to achieve this. Approaches currently in place include: an annual team calibration session; fortnightly technical meetings; and a three-yearly one-on-one review of the verification process. Since 2019, MPI have also introduced peer review of all verification reports by another qualified verifier.

With respect to your concerns regarding failure to implement recommendations made in the reports. A recommendation is advice given to highlight areas of an operation or system that could be improved even though a non-compliance has not occurred. Failure to implement a recommendation may lead to a non-compliance if not addressed, however it is not a breach of legal requirements. Facility Operators are only obligated to respond to breaches of legal requirements, and breaches of legal requirements are noted as a '*Non-compliance*' in verification reports.

Attachment 2 Point 4 - *Failure to Manage Specific Controls*
Attachment 3 Point 2g - *ERMA200223 approval*
Attachment 3 Point 3k - *Risks*

These sections note concerns relating to verification inspections and *Control 8*.

Verification reports are intended for a technical audience, primarily the Facility Operator and those with delegated responsibility for ensuring compliance with facility approvals and HSNO Act

approvals. As such, verification principles are not explained to the reader before they are discussed.

The scope of each MPI verification inspection includes Facility Operator compliance with all the relevant Containment Facility Standards, as well as any HSNO approvals held. The key emphasis of such inspections is to determine the adequacy of the overall regulatory compliance system. One of the most important aspects of this, is the effectiveness of the internal audits required to be undertaken by the Facility Operator. While each verification inspection may not directly report on compliance with each control, in addition to checking the internal audit reports, a number of controls will be selected for verification in order to gain further assurance that the overall regulatory compliance system is working.

The 2017 and 2018 verification reports mentioned in your correspondence directly relate to compliance with the field trial. Compliance with laboratory aspects were reported on separately, including *Control 8*. Reports on compliance with the facility approvals and HSNO Act approvals are now combined into one report, as there is usually a significant overlap between facility approval requirements and HSNO approval controls.

During the site visits referenced in the reports, the accuracy of the electronically held register was verified using random sampling to identify a number of register entries. The animals described by these entries are then identified in the paddock by their ear tags. The same process is applied in the paddock - animals are randomly selected and the associated register entries are viewed and reconciled with observations.

As noted above, verification processes often involve the use of random sampling to efficiently draw conclusions about the quality system as a whole. Occasionally, the random selection process may not include a particular species held on site, as was the case with the goats in 2017. However, subsequent site visits did include verification of the accuracy of goat register entries, and all visits include a walk around the perimeter to verify fencing integrity.

Legally, '*conventional sheep*' must be documented on the facility register and were therefore included as part of the verification of register accuracy. At both site visits in question, the electronic register was viewed in person by MPI and found to be compliant with *ERMA200223*. This was referenced as '*selected records*' and '*visible identification*'. The ability to print out a copy of the register is not a legal requirement.

MPI's expectation is that the Facility Operator takes ownership of compliance with legal requirements, by regularly and critically examining operating procedures and staff compliance with those procedures. Much of each verification is focussed on assessing whether the operator's internal audit process is being delivered in accordance with their legal obligations.

Attachment 3 Point 5r & 5s - *Costs*

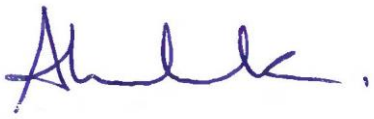
With respect to the costs incurred by MPI. All costs associated with enforcement of containment facility approvals and HSNO Act approvals are cost-recovered by MPI in accordance with the Biosecurity (Costs) Regulations 2010.

As is MPI's normal practice, all costs associated with AgResearch verification inspections are invoiced to AgResearch. The cost to MPI for these verification activities is therefore zero.

Cost regulations are regularly reviewed by the MPI Cost Recovery team to ensure that any changes in the cost of service delivery are accommodated. The last review, and subsequent amendment of these cost regulations, was carried out in 2018.

I trust the information provided is of assistance. Should you have any concerns with this response, I would encourage you to raise these with the Ministry for Primary Industries at Official.InformationAct@mpi.govt.nz. Alternatively, you are advised of your right to also raise any concerns with the Office of the Ombudsman. Contact details are: Office of the Ombudsman, PO Box 10152, Wellington 6143 or at info@ombudsman.parliament.nz.

Yours sincerely



Alan Cook
Director Verification Services