Reassessment of ERMA200223

Overview of GE Free New Zealand

concerns with the

GM Animal Experiments

Table of Contents:

1. Background information on ERMA 200223:

The ERMA200223 application generated a new approval to continue the transgenic livestock programme that was started in 2000 as the approvals for the field trial GMF 98009 and outdoor development of 02028 were coming to their end. These trials have been closed and the animals are now no longer alive or are being maintained as part of ERMA 200223.

A response to Susie Lees from Dr James Suttie in 2008[1] regarding the application that became ERMA200223 *"on a range of transgenic animals including cattle, sheep and goats and to use genetic material from donor species, including human synthetic genes."* Dr Suttie stated the intent of the transgenic livestock programme saying:

> *"AgResearch will also seek approval to study, develop and commercialise a range of beneficial characteristics in transgenic animals…"*
>
> *"Over time we will investigate the scale of activities needed to enable viable commercial production."*
>
> *"Whilst our work with transgenic animals is intended to generate significant export income for New Zealand, we consider that the protein market will always be a niche market…"*

The Authority was told that the sale of approved monoclonal antibodies were more than USD$23B in 2006 (2012 est. USD$36B).

The Authority approved ERMA 200223 as a *"development outdoors of genetically modified goats, sheep and cows to produce human therapeutic proteins, or with altered levels of endogenous proteins for the study of gene function, milk composition and disease resistance"*.

The applicant summarized that the pharmaceutical sector commanded "high market values " and it was important to get a foothold into the 'biosimilars" market. Transgenic animals, expressing therapeutic monoclonal antibodies such as Herceptin treatment for breast cancer, had the opportunity for the cost-efficient, large-scale production of recombinant therapeutic proteins. (ERMA 200223, Application summary)[2]

In the last 20 years the mandated annual reports to EPA have recorded the transgenic animals deformities, congenital problems and illnesses that have caused immense suffering. The surrogate cows have extremely high abortion rates and suffer from ill health. The transgenic progeny are affected with a high

[1] Response to Susie Lees from Dr. James Suttie, 17.1.2008

[2] ERMA 200223 Application Summary FINAL
https://www.epa.govt.nz/assets/FileAPI/hsno-ar/ERMA200223/f80f348a18/ERMA200223-Application-summary-FINAL.pdf

level of sterility and it appears only AI of previously created embryo's can by brought to term. As there is no RAEC monitoring team these problems are not properly addressed.

The lack of staff support appears to be ongoing, as though the whole facility and experiment has been mothballed. The continued non-compliance of laboratory maintenance and hygiene and undocumented person register has led to unsafe laboratories and major breaches of containment by unauthorized people.

Development Outdoors in Containment

ERMA 200223 has now been in development for 10 years. The facility is managed as a separate small farm within the main Ruakura Farm.

Regarding the application category status of ERMA 200223 Develop (outdoors) in containment any New Organism under section 40(1)(b) of the Hazardous Substances and New Organisms (HSNO) Act 1996.
Applicant: AgResearch Limited HSNO Section 44A

(1) (a) to develop a new organism
(b) does not include field testing (ERMA200223 Decision)

The EPA and the High Court (MADGE vs. MfE, ERMA & AgResearch Ltd, 2003) have clearly defined and delineated the difference between a "field test" and "development out doors". The earlier application (GMD02028) for a generic approval made clear boundaries between a development outdoors and a field test. The traits developed after 2010 of the approval ERMA 200223 are now into their 10th year and the animals are being treated as if they were a field trial. A reply to the McGuiness Institute (27.08.2020) on the EPA website regarding the clarification on the control of "outdoor field trials" the reply stated

> *"There are **no active field test approvals other than ERMA200223** that involve GM animals in New Zealand at the current time.* (ENQ-39290-G0K2F0, point 1.a)
>
> *" Based on a review of the applications database, I can confirm that ERMA200223 is the only application for **an outdoor field trial** of a new organism with a control requiring provision of a report for the purpose of considering grounds for reassessment."* (ENQ-39290-G0K2F0, point 2.c)[3]

This statement appears to imply that in the last few years the ERMA 200223 development experiments have moved into "field tests", yet there is no EPA record of an application to approve ERMA200223 as a "field test". The development outdoors conditions as "proof of concept" time of 2 generations was reached over 5 years ago. This is a breach of the conditions for a "development outdoors" as it does not include "field tests". (HSNO 44A, 1 (b))

[3] https://www.epa.govt.nz/assets/RecordsAPI/OIA-Response-27-August-2020-field-trials-that-involve-GM-animals.pdf

Development controls on Breeding

> *9.6 - Breeding shall be limited to the minimum necessary to complete development. In the case of genetically modified cattle developed to study gene function and gene performance, no breeding of animals is authorised, except where necessary to develop homozygous transgenic cattle. In the case of cattle modified to express therapeutic proteins in milk, genetically modified cattle may be bred, where necessary a) to produce one subsequent generation to investigate stability of inheritance or b) to produce two subsequent generations to develop homozygous transgenic cattle…" (ERMA Decision GMD02028, p46/62)*

Under the heading Decision: ERMA stated

> *2. To ensure that work covered by this decision is implemented as a development, controls on breeding are imposed. These are intended to ensure that the applicant does not increase, beyond that necessary for development, the number of animals of a particular construct through breeding. (ERMA Decision GMD02028, p46/62)*

However, correspondence with the EPA on ERMA200223 state that the GM animals are now considered "development field trials". However, there has been no application for a field trial on any of the animals that have undergone the requisite development criteria. The annual reports state that there have been successive generations of the animals, this breaches the conditions set down by the EPA's conditions for a "development outdoors".

The decision on ERMA200223 is extraordinary as the Authority felt that they could identify a genetically modified organism and its risks from 732 pages of genetic constructs. The extreme lethal pandemic spread of SARS-Cov19 shows that unknown viruses can spread to others by contact with surfaces and exhaling, they can also mutate and become more virulent. Yet the EPA Authority felt they had the scientific knowledge to know how these thousands of viral genetic fragments could be contained. In decisions prior to ERMA200223 there was a condition that when a new trait is developed the Chief Executive would be provided with the characterization of the genetic material of the construct so there can be some external oversight and understanding of the function and potential gene products.

> *"…Prior to any breeding of transgenic cattle, the Chief Executive of ERMA New Zealand shall be advised of the intention to breed and the reasons for the breeding." (ERMA Decision GMD02028, p46/62)*

> *9.2* Before *artificial insemination or transfer of embryos or nuclear transplantation, all genetic material in the insert vector shall be characterised (that is, the DNA has been sequenced and there is an*

understanding of the potential gene products and their function) and the details of the genetic material (including source) and each construct shall be provided to the Chief Executive of ERMA New Zealand. (ERMA Decision: Application GMD02028, p.59/62

There is no record that this has been submitted or of any prior development approval under a 67A application to the EPA on the traits that are in development. It is also concerning that prior traits that have failed are not recorded.

This should be considered as a major breach of controls.

The area that these animals are raised on is considered as a "small farm" of 200 acres. It appears that neither MPI nor the EPA has a carried out their "duty of care" by regular monitoring of new traits, genetic material or of scrutinizing the breeding activities as specified for an "outdoor development" under ERMA 200223.

2. AgResearch 10-Year Report concerns

The Committee considered that the benefits of this research would primarily be in the form of increased scientific knowledge and skills enhancement. (Decision ERMA 200223, 6.2.80, p 34)

The ten-year report does not provide any details on the skills gained in the research that are above normal animal husbandry of AI and day-to-day farming. There was $8 million put aside for the research to employ 8 people for 5 years. The facility is almost non-functional and there appears to be only two people recorded in the 2020 Annual report who were managing the facility. From 2016-2020 there have been ongoing staff shortages leading to continued major and minor non-compliance. The MPI audit raised this as an ongoing problem.

"The operating Manager also voiced concerns over the additional delays in handing over his role in the management of the containment facility" (MPI Verification Services Audit Report, 01.03.2017)

"…AgResearch staff are dealing with increasing workloads and workplace uncertainty". (MPI Verification Services Audit Report, 01.03.2017)

"The non compliance for internal monitoring was continued: this has been a recurring theme for the last three inspections… although the Operating manager is resigned to the fact that he is unable to relinquish his role as there has been no suitable replacement is found after several months. With the resignation of the Compliance Advisor there is a lack of support for the Operating manager and no one currently accountable for providing containment support or resourcing a replacement for his role."
(MPI Verification Services Audit Report, 24.8.2017)

"No progress has been made to replace the Operating Manager (MPI Verification Services Audit Report, 21.02.2018)

"…AgResearch is lacking in leadership for support key roles in the management of the containment facility, staff are initiating succession planning on their own". (ERMA200223 MPI Audit, 14.02.2019)

"…the operator is not in substantial compliance with regulatory requirements evidenced by in adequate operator controls (Key issue /Non-compliant)
(ERMA200223 MPI Audit, 14.02.2019)

"…19 January 2020, AgResearch tenant was given unsupervised access to the SAC without the knowledge of the Facility Operator. The tenant had not undergone the site or SAC specific training, nor was the person training in the use of equipment accessed (autoclave), instruction was given by a third party" (ERMA200223 MPI Audit, 02.03.2020)

A full re assessment of the facility should be immediately enforced. The serious problem in staff support and relationships is compromising the safety of the facility and the greater community of Hamilton.

3. Alternative similar substances are on the market

HSNO s:62 (2)(b) requires the EPA and AgResearch to consider if there are similar substances available on the market.

Human Follicle Stimulating Hormone (hFSH) cows instead of the hormone being produced in the mammary gland after lactation, it caused raised levels in the blood stream. The pre pubertal cows suffered from early activation of the hormone causing long-term ovarian problems, sterility, obese and enlarged bone structure ending in arterial rupture causing death.
Dr Gluckman outlines in a letter to Hon Wayne Mapp, Minister of Science and Technology in 2010 that there was inadequate safeguards and oversight from an external scientific body and no consultation with clinical medics in the decision to create cows to produce the human Follicle Stimulating Hormone (hFSH) analogue. He referred to the report by Dr Watson and Beagle report[4] on the cows that questioned AgResearch's technical and commercial rationale for the production of hFSH in cows. This was because earlier studies on mice had shown ovarian abnormalities and, the product was already on the market. These animals were created without the proper oversight from an external scientific body or

[4] https://www.gefree.org.nz/assets/pdf/Gluckmanreportoncattledeaths-.pdf

consultation with appropriate health professionals on whether the product would be of any clinical value. [5]

ERBITUX (Cetuximab) cows and goats, the pharmaceutical drugs that have undergone stringent clinical tests are now in common use and were already on the market before the GM traits were engineered into the animals.[6] Due to the nature of the generic application it appears that the EPA failed to consider under the approval 44A(2)(b) that there were alternative products available on the market.
The transgenic ERBITUX animals suffer from ill health effects and deformities from the day they were born. The cow is now all euthanased due to poor outcomes. The FAESB Biosciences report by Liable *et al* (2020) on *gCetuximab*[7] shows that commercial interests are involved in the experiment and the report highlights the conflicts of interest.

> *"GL, SC, BB, PM, and DNW are employees of AgResearch, and LHC, DPP, NCM, WGG, HMM, NF, and CDR are employees of LFB–USA and LFB Biotechnologies, respectively. All these organizations have a commercial interests or potential commercial interests in the production of gCetuximab. LC has no conflict of interest or financial conflict to disclose."*

It does not however consider the ERBITUX goats suffering from adverse effects, the high abortion rate or the extremely limited milk production and quality.

The report on GE Animals in New Zealand: the first 15 years[8] collated all information from OIA replies and Annual Audits. This report highlights the serious adverse effects relating to animal health of the experiments, however the EPA did not even register any concern. This highlights the question "who is responsible for oversight for considering the circumstances for closing down the facility when the are breaches of controls relating to unsafe conditions and inhumane animal treatment?"

The earlier generic approval regarding transgenic goats was GMD09016 detailing an indoor experiment should have been ended and all animals euthanased in 2012. The decision point 3.4 says:

---

[5] https://www.gefree.org.nz/assets/pdf/Agreserach-and-Biopharma.pdf

[6] https://www.medsafe.govt.nz/profs/Datasheet/e/Erbituxinf.pdf

[7] Laible, G., Cole, S., Brophy, B., Maclean, P., How Chen, L., Pollock, D. P., Cavacini, L., Fournier, N., De Romeuf, C., Masiello, N. C., Gavin, W. G., Wells, D. N., & Meade, H. M. (2020). Transgenic goats producing an improved version of cetuximab in milk. *FASEB bioAdvances*, *2*(11), 638–652.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7655094/

[8] GE Animals in New Zealand: The first fifteen years (2000-2015)
https://www.gefree.org.nz/assets/pdf/GE-Animals-in-New-Zealand.pdf

> *"Unlike the applications discussed above that were publically notified, this application is only for:*
> *a) a project of limited scope, that being the development of a limited number of GM goats designed to investigate the production of human therapeutics;*
> *b) work that will be carried out within an indoor containment structure;*
> *c) research and development, not for commercial production;*
> *d) the development of a limited number of founder goats (15 founder goats);*
> *e) a limited time period of two years, this is to allow time for the publically notified application ERMA200223 to be decided." (Decision GMD09016, 2009)* [9]

There is a requirement prior to a GM animal development, all details of the new traits are to be submitted to the Chief Executive regarding; the experimental procedures, biological material, expression of foreign nuclear acid material and the effects of the organism on the environment as specified in HSNO sec: 40. This major non-compliance has led to unacceptable inhumane conditions for the animals and high costs the taxpayer.

A further commercial rationale and lack of scientific and farmer consultation can be seen in the latest developments on the cows, goats and sheep. AgResearch has not submitted any genetic information to the EPA under a HSNO: S.67A to develop Coat Colour cattle, KDM4B cattle and NANOS2-deficient sheep, immune-compatible sheep and immune-compatible anephric sheep. These experiments are frivolous especially as there are cattle with light coat colour, and the creation of only female sheep is of concern especially as these animals suffer from serious abnormalities related to the genetically engineered changes.

Animal Welfare Concerns

The final decision of ERMA200223 the Committee acknowledged submitters concerns, on animal welfare and stated that they would be "overseen by the AgResearch Animal Ethics Committee appointed under the Animal Welfare Act 1999". (Decision ERMA 200223, 1.1.6)

It has come to our understanding that the RAEC no longer receives animal welfare reports. They are recorded direct to the EPA in the ERMA200223 Annual Reports. This information came directly from a response to an OIA from AgResearch and said

> *"On 13 July, my staff contacted you to confirm that all Ruakura Animal Ethics Committee reporting on ERMA200223 is through the EPA annually,*

[9] https://epa.govt.nz/assets/FileAPI/hsno-ar/GMD09016/463e0232a5/Decision-GMD09016.pdf

we do not provide quarterly reporting to the NAEAC or NAWAC on this".
(AgResearch OIA 21.8.2020, AGR/20-21/01)

This failure to report to the RAEC is a serious violation of the controls that were understood to be a condition of oversight in the experiments. It is also a serious dereliction of inspection and monitoring, by both the EPA and MPI regarding the animal welfare and ethics of the level of health problems faced by the animals.

4. Non Compliance of controls set down in the decision of ERMA200223

Control 4.
Containment:
Subject to the other controls in this appendix, the approval holder must ensure that containment facilities that hold:

a) E. coli, mammalian cell lines, embryos, sperm and ova are compliant with the requirements of the MAF/ERMA New Zealand Standard Facilities for Microorganisms and Cell Cultures: 2007a (the Microorganism Standard);
b) laboratory animals are compliant with the requirements of the MAF/ERMA New Zealand Standard Containment Facilities for Vertebrate Laboratory Animals (the Vertebrate Standard);
c) E. coli, mammalian cell lines, embryos, sperm, ova and laboratory animals are compliant with the Australian/New Zealand Standard 2243.3:2002 Safety in laboratories Part 3: Microbiological aspects and containment facilities (AS/NZ 2243.3:2002); and
d) sheep, goats, and cattle are compliant with the requirements of the MAF/ERMA New Zealand Standard Containment Standard for Field Testing of Farm Animals (the Field Test Standard).
(ERMA200223 Decision)

The MPI 6 monthly Verification Services Audit reports from 2017-2020 years on ERMA200223 have found that there are continual Major non-compliance issues that are chronic.

"Laboratories are not maintained to meet the requirements of section 4.7 of As/NZS 2243.3.2002 as required by the Micro2007a and Biological Products standards."(ERMA200223 MPI Audit, 06.08 2018)

"A number of laboratories had dusty windowsills, midges on the sills and benches. Windowsills were peeling indicating …poor hygiene. South Wing 101, rust stains and rusty tweezers on sink bench. Dairy Science Room had absorbents on the floor; wallpaper was peeling off all wall areas, screw holes and cobwebs were noted. Non-compliance has been issued.
(ERMA200223 MPI Audit, 14.02.2019).

"… failure to comply with the facility manual (4.2) and MPI Standard for Biological products (4.8) Transfer without current approval and failure to notify of transfer under a multiple transfer." (ERMA200223 MPI Audit, 28.08.2019)

"… failure to comply with the requirements of section 52d of the Biosecurity Act, control 9 of HSNO Act Approval (APP201857 and APP201858), section 4.4 of the EPA Standards: Facilities for Microorganism and Cell Culture (8.8) and section 4.2 of the containment manual. (8.8) " (ERMA200223 MPI Audit, 28.08.2019)

"Laboratory practices were not demonstrated to an acceptable standard" (ERMA200223 MPI Audit, 28.08.2019)

"Laboratories at level 1 and 2 physical containment (ASNZS 2243.3) were not maintained at an acceptable level. (ERMA200223 MPI Audit, 28.08.2019)

"Hygiene not maintained to an acceptable level."

"Surfaces are not maintained to meet the requirements of section 4.7 of As/NZS 2243.3.2002 as required by the Micro2007a and Biological Products standards. (ERMA200223 MPI Audit, 02.3.2020)

Major non-conformity shows a system failure and calls into question the credibility of AgResearch to operate within its conformity process and MPI to allow the continued non-compliance to persist. In conventional audit situations corrections are required to be completed within 30 calendar days and corrective actions are required to be completed within 60 calendar days from the date of notification. As shown in the Annual Report on 200223 these actions have not been addressed for the last 3 years

The continual serious nature of these non-compliance issues has been left unaddressed for the last 3-4 years. The skeleton staff and tenancy breaches has made this a dangerous experiment. It is unacceptable that laboratory conditions have not been properly complied with and liability penalties issued. The facility is so badly run that it should be immediately closed down and appropriate quarantine of the small farm facility. Immediate horizontal gene testing should be reinstated and testing for escape of GM material in blood and excretion products into the water and soil be carried out for the next three years.

Control 5.
The approval holder must ensure that any animals used to control grass in the space between the double perimeter fences are not of the same species as the animals being held within paddocks, which are adjacent to the inner fence. (ERMA200223 Decision)

This has been breached in 2019 and 2020 with conventional animals (1 year old bulls and sheep). The 2020 AgResearch annual report stated –

> *"For cattle there has been one movement of conventional animals out of the facility during the period. This was 5 steers of 64 conventional beef animals, under 2 years of age on the facility for grass control purposes."*

This is of concern as there does not appear to have been any EPA approval for the animals of the same species being moved in and out of the facility grazing on paddocks that have previously grazed GM animals.

Control 8.
Production and use of replication-deficient viral particles:

> All open container use and production of viral particles must occur within a Class II Biological Safety Cabinet. (ERMA200223 Decision)

The annual report records the transfer of hundreds of genetically modified embryos. As the MPI Audits show there have been continuing non-compliance issues (2017-2020) that have not been addressed in the laboratory facilities. The condition of the laboratories and the hygiene compliance is cause for serious concern for the spread of GM material outside of containment.

Control 11.
Annual reporting: The approval holder must provide an annual report to ERMA New Zealand by 30 June of each year while this approval is in use. Each annual report will be made available to the public and must include a description of:

a) any outdoor development activities;
b) any unforeseen adverse effects resulting from the geneticmodifications; and
c) any relationship development and management initiatives undertaken with any iwi liaison group. (ERMA200223 Decision)

In the last four years the Annual reports have been 2-5 months late. They 2019 Annual report is missing from the EPA website. All reports have reported on-going serious adverse effects of the GM animals. These problems of abortions, sterility deformities show that large sentient animals are not suitable for bio-pharming. At no stage has the EPA taken these into account and the RAEC does not receive these reports so the adverse effects on the animals have never been considered or addressed. As confirmed in an email from the EPA -

> *On 6/11/2020, at 2:17 PM, Ministerials <Ministerials@epa.govt.nz> wrote:*
> *Good afternoon Claire*
> *This has now been prepared and signed off for publication; it is now available on our website at: https://www.epa.govt.nz/resources-and-publications/monitoring-and-reporting/*
> *Kind regards,*

[redacted]
Official Correspondence Advisor, Government Engagement and Official Correspondence

From: *president@gefree.org.nz [mailto:president@gefree.org.nz]*
Sent: *Sunday, 25 October 2020 2:35 pm*
To: *Ministerials <Ministerials@epa.govt.nz>*
Subject: *Fwd: EPA Annual reports of ERMA 200223, ERMA200479*

Kiaora Lisa,

I still have not received the ERMA 200223 Annual Report for 2020. Please could you send immediately. It report is now over 8 weeks late. I refer you to your letter of the 1 September.
Claire

The 10 year Annual report was not added to the website until 9.11.2020. These delays are unacceptable and a breach of control 11.

Control 12.
Ten year report: In addition to the annual reporting requirements, and for the purposes of providing the Authority with information relating to whether there are grounds for reassessment of the approval, the tenth annual report must include additional information about:

a) any progress that the approval holder has achieved towards completion of the proof-of-concept research;
b) any adverse effects of the organisms that have occurred, including any effects which relate to the matters described in section 6(d) and the principles of the Treaty of Waitangi (Te Tiriti o Waitangi); and
c) any beneficial effects of the organisms that have occurred in the first ten years, or that are forecast to occur over the next ten years. (ERMA200223 Decision)

The ten-year AgResearch Annual Report to the EPA regarding 200223 does not meet the requirements of control 12. Namely proof-of concept this term is not defined in the HSNO Act and therefore has the possibility of misleading the public as to the understanding. The Mothers Against Genetic Engineering vs. Minister for the Environment (2002)[10] tried to differentiate the boundaries between a development out doors and a field test. The implicit understanding was that a development outdoors was for proof-of-concept research.

The dictionary term for proof of concept -

[10] Mothers Against Genetic Engineering Inc v. Minister for the Environment and ors HC CIV.2003-404-673 [7 July 2003]

> ***Proof of Concept*** *means, with respect to any product, the demonstration of the reasonable technical and commercial efficacy and feasibility of such product for its intended application. (*LawInsider*).*[11]

This was limited to two generations of progeny and required no environmental testing; once proof-of concept was validated the experiment could reapply to field test the animals. In 2012 the previous two GM applications (GMF98009 and GMD02028) were subsumed into ERMA200223. The 2020 AgResearch ERMA200223 Annual Report does not identify any validation for proof-or concept or any beneficial effects of the organisms or those forecast for the next ten years.

Control 13:
Māori cultural effects: The approval holder must establish an iwi liaison group as a forum for ensuring that iwi/Māori cultural matters relating to the approval are addressed. The approval holder Environmental Risk Management Authority Decision: Application ERMA200223

a) must invite mandated representatives of Ngāti Wairere and Waikato-Tainui to participate in the group;
b) may invite any other interested iwi/Māori groups to participate in the group; and
c) must establish a Terms of Reference (including regularity of meetings) by agreement with the mandated representatives of Ngāti Wairere and Waikato Tainui. (ERMA200223 Decision, p.44)

There has been a serious breach in undertaking control 13. The mandated ERMA200223 Liaison Group has still not officially met since December 2011. Though there has been informal contact with original monitoring group members and regular contact with Tainui Group Holdings on their development activities for Ruakura. There has been no effort to further implement any consultation with Maori for all developments regarding the GE facility and animals for 9 years.

5. Summary:

GE Free is filing for a reassessment under HSNO 62A of the ERMA200223 GM animal development outdoors experiment on the grounds that

(a) There is a continuing breach of controls required by the EPA decision. and
(b) an alternative similar substance on the market. The reasons are

1. AgResearch's 10th annual report raises significant concerns regarding information on the viability of the whole ERMA200223 experiment.

2. Alternative similar substances are on the market

[11] Proof-of-concept https://www.lawinsider.com/dictionary/proof-of-concept

3. The risks of diseases moving from animals to humans are unmonitored in a development outdoors.

4. The facility and animals are no longer viable and breakdown of reporting and hygiene protocols pose a serious risk to the environment, worker health and the larger environment.

5. There is no benefit to the Government, taxpayer or scientists who conduct this experiment.

6. Breaches of controls
    - **Controls on approval.** The ERMA200223 GE animals are being run as a "field test" and not as a "development outdoors".
    - **Animal Welfare:** There has been no reporting to the REAC for oversight on ethical animal husbandry issues.
    - **No details** submitted prior to animal development to Chief Executive.
    - **Alternative substances** are in use on the market.
    - **Control 4.** Containment: continued breaches in laboratory hygiene and maintenance.
    - **Control 5.** Grazing of conventional same species adjacent to GM animals. These animals removed from the facility with no monitoring.
    - **Control 8.** Laboratory hygiene and maintenance has been non-compliant over 4 years.
    - **Control 11.** Annual Audit reports on ERMA 200223 continually late.
    - **Control 12.** Ten Year 2020 AgResearch ERMA200223 Annual Report is lacking in mandated information as to the benefits and risks of the experiments. It does not identify any validation for proof-or concept or any beneficial effects of the organisms or those forecast for the next ten years.
    - **Control 13**. The Maori monitoring body has not met since 2012. There has been no effort to further implement any consultation with Maori for all GM developments regarding animals for 9 years.

These breaches are major non-compliance issues; the facility and the GM animals are no longer viable and they pose serious risk to the environment. There is no benefit to the Government, taxpayer or scientists who conduct this experiment.

Yours Sincerely

Claire Bleakley
President GE Free NZ in Food and Environment
027 348 6731
12.3.2021