agresearch
āta mātai, mātai whetū

11 September 2020

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Kia ora Wendy

Official Information Act request

Thank you for your OIA request on 28 July for a range of information on our work in relation to the approved application ERMA200223. Please find answers to the questions we were able to answer below and note also that, in light of the wide-ranging scope of others, we have provided a commentary to provide some context and insights, and invite you to rethink the scope of the other questions we could not answer.

As you are aware, there are provisions in the Act that can be invoked when the time, expense and volume of information sought become too large. We believe some of your questions (see below) fit this definition and are too broad for us to effectively and efficiently answer as they are currently worded.

We take our obligations under the Act seriously and strive to be as transparent as possible. Therefore, if after reviewing the information below you are unsatisfied with the information provided, we'd like to join in a dialogue (over the phone or in person) to frame practical parameters for future questions, and provide some information on the search tools and record-keeping at our disposal, to add context to what is realistic in terms of information-gathering and meeting our legislative obligations.

Please note you have the right to seek an investigation and review by the Ombudsman of this decision. Information about how to make a complaint is available at www.ombudsman.parliament.nz or freephone 0800 802 602.

Yours sincerely

Jo Brady
Communications and Marketing Director
AgResearch Limited

1. What have been the total direct costs to AgResearch for outdoor transgenic experiments annually since 1999? Note: The Institute estimates this may be in the vicinity of $100 million in total (see footnote 6, page 12, of Working Paper 2020/06) but it would be useful to have the actual figure per annum.

The accumulated operating total cost to run AgResearch's outdoor Animal Containment Facility from 2005 to 2020 was $6.6 million. Please note, we have chosen to use 2005 as the starting point to answer this question simply because this is when our financial record keeping, in its current form, dates back to. Our operating costs are defined as the direct overheads from the facility (the base for transgenic livestock experiments) to the organisation. Note, the figure doesn't include associated costs for gaining such things as EPA approvals or costs associated with genetic cloning research.

2. What have been the total indirect costs to AgResearch for outdoor transgenic experiments annually since 1999? Note: This should include legal and media costs that are outside the approval process.

AgResearch is unable to provide a specific financial figure that would accurately reflect indirect costs associated with our "outdoor transgenic experiments". As a Crown Research Institute, we maintain our own inhouse legal and communications teams. Their work is monitored and reported on. However, the cost of managing requests, liaising with media and other public-facing relationship management work, including Official Information Act responses, is not, as an independent work stream, accounted for. Certainly, there is a cost to maintaining this inhouse capability. However, the amount that could be attributed indirectly to "transgenic experiments" over the time frame specified would be insignificant.

3. What government grants have been received annually by AgResearch for outdoor transgenic experiments since 1999? This might be from Callaghan Innovation, MBIE or any other government entity. If yes, please place the following information in an Excel sheet or Word table: a. Name of the individual or entity that provided AgResearch the grant/s, b. When the grant/s were provided, c. The type of grant/s that was/were provided, d. The total amount of funds provided, and e. Any reporting requirements or other controls that formed part of the grant process (before, during and after the grant was approved).

Funding Agency	Dates	Grant type	Total funding	Reporting/controls
MBIE	2017-2021	Endeavour Smart Idea	$1.17M	annual reporting
MBIE	2015-2018	High Value Manufacturing & Services	$1.2M	annual reporting
MBIE	2011-2019	Core / SSIF	$10M	annual reporting
MSI/MBIE	2008-2011	NERF	$3.6M	external peer review after 2 years, annual reporting

MoRST	2005-2007	AR&C	$380K	quarterly reporting final report
FRST/MSI	2003-2008	NERF	$6M	mid-term review annual reporting
FRST	1999-2003	PGSF/NERF/NSOF	$2.2M	annual reporting

Please note this table excludes the recent Climate Smart Cattle (MBIE Research Programme 2019-2024 ; total funding $10M) as this involves genome editing of endogenous genes and not "transgenic animals". It also excludes research on Auckland Island Pigs (MBIE Smart Idea 2019-2022 Total Funding $1M). This is a xenotransplantation project.

4. Has AgResearch entered into a collaboration with any other party/ies to progress AgResearch's outdoor transgenic experiments? For example, this would include the joint venture with Scottish company PPL Therapeutics (see footnote 5, page 12, of Working Paper 2020/06). If yes, please place the following information in an Excel sheet or Word table: a. Name of the individual or entity that AgResearch has entered into a collaboration, b. When the collaboration started (and finished if appropriate), c. How the collaboration was/is legally constituted (e.g. a joint venture contract, a shareholding or an agreement that enables a party to have shares in a future profit making entity if the research proves profitable). d. The type of obligation the collaboration created/creates in terms of benefits/risks/costs to AgResearch per annum: (i) Since 2010 to 30 June 2020, and (ii) From 1 July 2020. e. The total amount of money provided as part of the collaboration (being funds the collaborator has provided or has promised to provide) per annum, and f. Any requirements or other controls placed on AgResearch that formed/form part of the collaboration agreement (before, during and after the grant was approved). This could include confidentiality, right to bring the product to market, profit share, profit margin on amount of product sold and reporting requirements).

Entity	Dates	Collaboration type	Obligations	Funding	Requirements
PPL Therapeutics, UK	2000-2003	A proposed joint venture didn't go ahead due to PPL going into liquidation	N/A	N/A	A confidentiality agreement to protect commercial interests of both parties
AborVita Associates	2014-	Material Transfer Agreement (MTA)	Exchange of research materials and	N/A	Confidentiality agreement

			In-kind support		
AgGenetics	2019-21	Service Agreement	Collaborative research Scientific exchange	$260K	Confidential contracted milestones
Bio Sidus S.A.	2007-	Confidentiality Agreement	Collaborative opportunities	N/A	Confidential
China Agricultural University	2012-	Confidentiality Agreement	Collaborative opportunities	N/A	Confidential
CSIRO, Australia	2013-	Researcher to Researcher	Collaborative opportunities Scientific exchange	N/A	Confidential
FBN Dummerstorf	2006	Collaboration Agreement	Sample Analyses	Visiting Researcher travel grant	Confidential
GTC Biotherapeutics / rEVO Biologics / LFB USA	2003-	Confidentiality Agreement Collaboration Agreement Service Agreement	FTO In-kind support Collaborative research	$1.29M	Confidential Contracted milestones
Institute of Animal Science and Veterinary Medicine, China	2014-	Researcher to Researcher	Collaborative research Scientific exchange	Visiting Scholar grants, Chinese Government	Confidential
Institute of Farm Animal Genetics, Germany	2014-	Researcher to Researcher	Collaborative opportunities Scientific exchange	Visiting Researcher travel grants	Confidential
Islamic Azad University, Isfahan, Iran	2007-	MOU	Collaborative opportunities	N/A	Confidential
LIC	2013-14	MTA	Sample Analysis	N/A	Confidential
Massey Uni	2010-11	MTA	Sample Analysis	N/A	Confidential

Max-Planck-Institute for Molecular Genetics, Germany	2013-15	Collaboration Agreement	In-kind support Collaborative research Scientific exchange	Visiting Researcher travel grants	Confidential
Pharming	2005-15	HOA MTA Service Agreement	FTO In-kind support Care of animals Germplasm	$423K	Confidential
Recombinetics, USA	2013-	Joint research MTA	FTO In-kind support Collaborative research	N/A	Confidential
University of Auckland	2016-	MoA	Joint Research Centre Scientific exchange	$58K pa	Teaching
	2017-19	Research sub-contract	Collaborative research Scientific exchange	$175K	Contracted milestones
	2015-18	Service contract	Collaborative research Scientific exchange	-$534K	Contracted milestones
Université Laval, Canada	2018-	Researcher to Researcher	Collaborative research Scientific exchange	Visiting Researcher travel grant, Canadian Government	

5. Please identify the actual date of all board meetings since 1999 (i.e. DD-MM-YYYY) and identify those meetings that specifically discussed AgResearch's outdoor GM experiments? Note: An asterisk is adequate to identify those specific meetings.

Please see the answer to question 6*

6. For each meeting that discussed AgResearch's outdoor GM experiments (e.g. asterisked) we request: a. A soft copy of all relevant board papers that specifically discussed AgResearch's outdoor GM experiments, and b. A soft copy of all relevant minutes that resulted from those meetings that specifically discuss the outdoor GM experiments.

AgResearch holds a database of board and executive management meetings from 1999 to the present day. A search of this database yielded nine matches relating to "transgenic" animal research - the focus of this OIA.

Seven of these related to transgenic forage research (AgResearch is a leader in transgenic forage research, more commonly referred to as HME ryegrass). As this research does not yet include outdoor field trials involving animals, we considered these seven papers outside the scope of this request.

The other two documents found as part of the search mentioned "transgenic research". The first was an "Animal Science Roadmap" (June 2017), a discussion paper that focuses on the scientific capability of AgResearch and its scientists of their performance. We have decided under section 9(2)(a) of the Official Information Act to withhold the paper to protect the privacy of these individuals. We do not consider the public interest considerations that may be in favour of releasing this information outweigh the need for privacy in this instance.

The second paper was tabled at a board meeting in 2014. This paper, titled "Revised Farm Strategy to meet the needs of Future Footprint", discusses AgResearch's farm holdings, their commercial performance, and strategic importance and alignment with our research goals. After careful consideration, we have decided to withhold the paper under section 9(2)(i) of the Official Information Act because it contains commercially sensitive information that, if released, would prejudice AgResearch's commercial activities. We do not consider the public interest considerations that may be in favour of releasing this information outweigh the need for privacy in this instance.

A keyword search of board and executive meeting papers for references to genetic modification produced over 1000 different results which would take an unreasonable amount of time to review for the purposes of public release. We therefore invite the Institute to redefine the scope of this part of the request.

*The AgResearch board has met either monthly or bimonthly every year since 1999. Requests for information relating to all board meetings since 1999 are wide ranging and broad, and in our view lack the specificity required for us to effectively and efficiently provide the information requested. We therefore believe, without a significant rescope, that question five and six would require a substantial collation of material taking many hours and that, as they stand at the moment, this would place an unreasonable burden on AgResearch in terms of resource and expense.

7. Can you advise the dates the board (or board members) visited the paddocks where the GM animals are placed outdoors?

AgResearch maintains a record of all visitors to our containment facility to meet compliance requirements. These records date back to 1999. As you would appreciate, a page-by-page search of

21 years of visitor records would take a considerable amount of time, effort and expense. However, I can advise that our current containment facility manager does not have any record or recollection of the board having, with the express purpose, visited or inspected our GM large animal containment facility in Ruakura.

For completeness, I can also confirm that several board members have visited the facility over the past two decades, as part of routine campus tours. The visits are designed to introduce and familiarise directors with our research, people and their places of work. Animals housed in the facility can be viewed from enclosed vantage points, including offices and observation posts. Visits by non-science staff do not therefore include direct inspections of "paddocks" as outlined in your question or areas animals access for grazing.

8. Control 12 (a) and (c) relates specifically to benefits (see Attachment 1 of Working Paper 2020/06). Can you advise whether an independent medical/pharmaceutical expert is (i) on the board or (ii) has been employed by the board or executive team to advise on any of the following key issues: a. Progress on the proof of concept research, b. The demand for current and potential medical products made from GM animal milk, and in particular, the demand for cetuximab made from the mammary gland of goats? c. The efficacy of such products in terms of purity and quality standards (see comments at the bottom of the article in Attachment 5, page 15, of Working Paper 2020/06) and d. The expected timeline and obstacles to FMA approval? If yes, we request copies of the report and papers. If yes, we request their name, expertise and copies of all their reports and papers.

The AgResearch board has not employed or contracted an independent medical or pharmaceutical expert to advise on the issues summarised in question eight.

9. Further to Question 8, has AgResearch undertaken any other work (in addition to the independent medical/pharmaceutical expert mentioned above) to assess the points (a) to (d) raised in Question 8? If not, can you explain what expertise the board is relying upon in regard to potential benefits. We would like copies of all additional papers on benefits that are being relied upon by the executive team and/or the board.

No. A review of our board papers – as per question 6 - did not yield any reports on the subject of "potential benefits" of transgenic research. However, the board annually reviews AgResearch's science strategy and financial allocation to research programmes, including research to advance New Zealand's scientific understanding of GM technology.

10. More specifically, can you advise whether any work has been undertaken to assess the demand and supply of the drug cetuximab (sold under the drug name Erbitux). Note: The article (found in Attachment 5, page 15 of the letter), implies there is high demand for the drug and that the current manufacturing costs are excessive with no competing/emerging technology that will lower the costs of manufacturing the drug in a laboratory in the foreseeable future.

AgResearch has been provided with market assessments information for the demand of cetuximab by independent commercial entities.

11. Medsafe have a fact list, found here. It states that 'Erbitux® is a trademark of ImClone LLC, used under license by Merck KGaA and its affiliates'. Can you advise whether AgResearch has had discussions with ImClone LLC or any other seller or license holder that makes or sells cetuximab? If yes, please explain the purpose of this discussion and whether in AgResearch's view, ImClone LLC or Merck is a collaborator or a possible competitor)?

No, we not had discussions with the companies referred to in question 11.

12. The Institute has found an article on the GM goats on the bioRxiv service, found here (posted 10 June 2020), however this means it is not peer-reviewed. The publishers note that 'Because this process can be lengthy, authors use the bioRxiv service to make their manuscripts available as "preprints" before completing peer review and consequent certification by a journal. This allows other scientists to see, discuss, and comment on the findings immediately. Readers should therefore be aware that articles on bioRxiv have not been finalized by authors, might contain errors, and report information that has not yet been accepted or endorsed in any way by the scientific or medical community.' a. Are you aware when and if this article will be peer reviewed? b. Are you aware of any other articles published by scientist and staff at AgResearch on the outdoor GM experiments? If yes, can you please provide a list of the date, name, publication and ideally a link.

A. Yes, the paper has been accepted for publication in FASEB BioAdvances following peer review.

B. AgResearch has published numerous articles about GM research over the last two decades to advance scientific understanding of this field of research. These journals are publicly available resources therefore not covered by the OIA.

13. Has AgResearch prepared the 10-year report (as per Control 12)? The 10-year report was due 31 August 2019. If yes, has that report been provided to the EPA? If yes, please advise the date the report was sent to the EPA. If yes, we request a soft copy of the 10-year report.

Yes, our report was due at the end of August 2020, (not August 2019). It will be made publicly available on the EPA website in due course.

14. Has there been any correspondence between AgResearch and the EPA about the 10-year report? If yes, we request a soft copy of all correspondence.

Yes, we received a reminder email earlier this year that our report was due at the end of August. A duplicate of the email is provided below. The phone numbers of staff members have been deleted under section 9(2)(a) of the Official Information Act to protect the privacy of these individuals.

15. Has there been any correspondence between the AgResearch board (including the Chair) and AgResearch staff about the 10-year report? If yes, we request a soft copy of all correspondence.

No.

16. Has the risk of AgResearch accidentally creating a novel virus been a part of the executive team or Board's agenda in 2020? If yes, has this led AgResearch to reconsider its outdoor transgenic programme? We request any relevant papers, minutes or correspondence.

No.

17. Our understanding is that AgResearch currently enables different modified animals to co-exist in the same paddock (e.g. two types of modified cattle). Can you clarify if this is current practice?

Yes, animals of the same species are permitted to co-exist in our animal containment facility.

18. Further to Question 17, if this is current practice, would the board consider keeping each modification type in a separate paddock to reduce risks (e.g. if two types of modified cattle were created, each type would be placed in a separate paddock)? This is our preference.

No. There is no increased risk created by having animals of the same species and gender together in this manner in our secure animal containment facility.

19. Has the board requested from the executive team at AgResearch a reassessment of ERMA 200223 regarding the risks of accidentally creating a virus that might spread between animals or between animals and humans: (i) this year (since the arrival of COVID-19) or (ii) any previous year since 1999? Please explain.

No. Our GM research has no correlation or connection - scientific or otherwise – to COVID 19.

20. Are there any further controls/requirements/actions being placed on the GM animals since the arrival of COVID-19?

No. Our GM research has no correlation or connection - scientific or otherwise – to COVID 19.

Appendix:

Email correspondence from the EPA to AgResearch, Wednesday 29/07/2020 6:13 pm

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Hi Tim,

I know you're still a month away from the due date for the ERMA200223 annual report, but I wanted to send you a reminder that, with this being the 10th full year that ERMA200223 has been in use, the Ten Year report is due this year per Control 12 of the approval. I've provided the text of the control for your convenience below:

Ten year report:
12. 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.

12 a) "Proof of concept" is described in section 2.2.3 of the Decision document, and the text is below:

2.2.3 The scope of the application is limited to undertaking research and development activities to completion of proof-of-concept. The applicant is not seeking regulatory approval to maintain transgenic animals for the commercial production of therapeutic proteins, and states that none of the proposed activities meet the definition of a field test. The application does not specify the duration of the project.

Thus, it's essentially a progress report on the research undertaken under the auspices of ERMA200223.

12 b) Section 6(d) refers to the HSNO Act, which states:

"All persons exercising function, powers, and duties under this Act shall, to achieve the purpose of this Act, take into account the following matters:

...

(d) the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga

Thus, the description of any adverse effects must explicitly take section 6(d) of the HSNO Act into account in its description.

12 c) appears to be essentially self-explanatory.

Please let me know if you have any questions regarding these requirements for this year's report.

Kind regards,

[Name of staff member]

[Name of staff member]

Acting Manager and Principal Scientist, New Organisms

Environmental Protection Authority
Te Mana Rauhī Taiao