28 July 2020

Dr Sue Bidrose
Chief Executive
AgResearch
1365 Springs Road
Lincoln 7674
Christchurch 8140

Dear Sue,

Re: Outdoor Transgenic Programme (Our Reference: OIA 2020/09)

On 15 July 2020, the McGuinness Institute wrote a letter to the Minister for the Environment. This has since been published in our *Working Paper 2020/06: Letter to the Minister on AgResearch's approval for GM animals in light of pandemic risk*, found here. The letter also contains an OIA to the EPA (see Attachment 3).

I am writing to obtain further information on the outdoor transgenic programme, in particular ERMA 200223 (approved 2010) and the earlier approvals that were conducted under ERMA 200223 from 2010, (being GMF 98009 [approved 1999 and 2001] and GMD 02028 [approved 2002]). See more detail in Appendices 9 and 10 of our 2013 report, *Report 16 – An Overview of Genetic Modification in New Zealand 1973–2013: The first forty years,* found here).

(A) Direct and indirect costs per annum for all outdoor transgenic experiments since 1999

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.

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.

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).

(B) Collaboration per annum for all outdoor transgenic experiments since 1999

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).

(C) Board discussions on risks and benefits for all outdoor transgenic experiments since 1999

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.

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.

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

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.

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.

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.

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)?

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.

(D) ERMA 200223 – The 10-year report

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.

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.

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.

(E) COVID-19

The McGuinness Institute's *Think Piece 33 – The Long Normal: Preparing the National Reserve Supply (NRS) for pandemic cycles* notes that 'human coronaviruses have only been around since the 1960s; before that time coronaviruses were only found in animals' (see here). Given the recent pandemic is thought to have been

created when a coronavirus crossed the species barrier at a time when animals and humans were in close proximity to one another (e.g. a wet market), we ask the following questions:

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.

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?

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.

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.

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

Thank you for your time. Please do not hesitate to contact me if you have any questions.

Kind regards,

Wendy McGuinness
Chief Executive