

18 February 2021

Wendy McGuinness
McGuinness Institute
Email: wmcg@mcguinnessinstitute.org

Dear Wendy

OIA Request - ERMA200223 (Your Ref: 2021/03)

Further to your email request dated **Monday, 4 January 2021** – we respond to your questions below:

EPA and MPI

- Q1: Can you advise what date the 2020 ten-year annual report was sent to the EPA?
- A1: The ERMA200223 Annual Report and 10 Year Report were submitted to the EPA together in draft (via email) on 31 August 2020. See **attached** email marked “A”.
- Q2: Can you provide a copy of any accompanying correspondence to the EPA that related directly or indirectly to the 2020 ten-year annual report?
- A2: See emails **attached**, marked “A”, “B” and “C”. Please note we are withholding the personal details of the individuals mentioned in the emails (names, positions and contact details) under section 9(2)(a) of the Official Information Act 1982 (**Act**) to protect the privacy of those individuals, and have redacted the emails accordingly. We have not included the report as it is currently in draft and is pending some minor corrections being carried out by AgResearch. It will shortly be publicly released by the EPA after submission of the final version to the EPA.
- Q3: Can you advise what date the 2020 ten-year annual report was sent to the MPI?
- A3: MPI were included in communication to EPA via the MPI Facility Supervisor – refer to “A” **attached**.
- Q4: If yes, can you provide a copy of any accompanying correspondence to the MPI that related directly or indirectly to the 2020 ten-year annual report?
- A4: See Q2 above. The MPI Facility supervisor was included in emails “A” and “B”.
- Q5: Can you advise if an early copy (draft) of the 2020 ten-year annual report was sent to either the EPA or the MPI? If yes, please advise the recipient and the date and provide a copy of any correspondence between AgResearch and the party concerned (i.e. EPA or MPI)? I am

particularly interested in whether the EPA or MPI provided any advice, comment or feedback on the content and timing of the 2020 ten-year annual report?

A5: Yes - See emails "A", "B" and "C".

Q6: Can you advise if any correspondence or conversations between yourselves, the EPA or MPI mentioned the McGuinness Institute? If yes, we would appreciate a copy of any correspondence/notes.

Q6: Not that we are aware of. All emails with the EPA and MPI in relation to the report are **attached**.

AgResearch's Governance

Q7: Did AgResearch's Board *request* a copy of the draft or final 2020 ten-year annual report?

A7: No - we have no record of a request.

Q7a: What date was the 2020 ten-year annual report provided to the Board?

A7a: The report hasn't been provided to the Board at this stage.

Q7b: If yes, did the Board provide any feedback to the CEO or the author? Please explain what feedback and to whom?

A7b: N/A.

Q7c: If yes, did the Board sign off on the 2020 ten-year annual report before it was sent to the EPA?

A7c: N/A.

Q8: If no, did AgResearch's Board see a copy of the draft or final 2020 ten-year annual report?

A8: As above, the report hasn't been provided to the Board at this stage.

If yes:

Q8a: Who instigated this?

A8a: N/A

Q8b: What date was the 2020 ten-year annual report provided to the Board?

A8b: N/A

Q8c: If yes, did the Board provide any feedback to the CEO or the author? Please explain what feedback and to whom?

A8c: N/A

Q8d: Did the Board sign off on the 2020 ten-year annual report before it was sent to the EPA?

A8d: N/A

Q9: Did the CEO sign off on the 2020 ten-year annual report before it was sent to the EPA?

A9: No

Q10: If neither the Board or the CEO signed off on the 2020 ten-year annual report, can you provide the title/role of the highest person in AgResearch who signed off on the report (before it was sent to the EPA)? In particular, we are keen to understand who was responsible for the quality of the content.

A10: The Research Director at AgResearch has overall responsibility for the submission of the report.

Q11: Was the report content independently reviewed? If yes, by whom?

A11: AgResearch has not organised an independent review.

Specific Questions

I have attached three pages of your letter, highlighted. For the purposes of clarity, I will simply refer to the specific question.

Q12: My original Question 10. Can you advise the author and date and ideally supply a copy of the market assessment report/s mentioned on the commercial demand for cetuximab?

A12: We are withholding the names of the authors of those reports under section 9(2)(a) of the Act to protect their privacy. We have also decided to withhold the reports under section 9(2)(i) of the Act, as disclosure of the reports may prejudice AgResearch's ability to carry out commercial activities in this area.

Q13: My original Question 12.

Q13a: Any news on the peer review?

A13a: The paper has been published: Götz Laible, Sally Cole, Brigid Brophy, Paul Maclean, Li How Chen, Dan P. Pollock, Lisa Cavacini, Nathalie Fournier, Christophe De Romeuf, Nicholas C. Masiello, William G. Gavin, David N. Wells and Harry M. Meade (2020). Transgenic goats producing an improved version of cetuximab in milk. FASEB BioAdvances 2(11): 638-652.
<https://faseb.onlinelibrary.wiley.com/doi/10.1096/fba.2020-00059>

Q13b: Can you provide a list of all the articles you refer to, with links? Note: Such a list will provide more clarity on risks, costs and benefits.

A13b: The report includes a list of publications (with links) which will be available when the report is publicly released by the EPA.

Q14: My original Question 18. What evidence are you relying upon to make the following statement: 'There is no increased risk created by having animals of the same species and gender together

[e.g. two different types of modified cattle] in this manner in our secure animal containment facility'?

A14: Animals of the same gender are unable to breed together so there is no increased risk created by keeping them together in containment.

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

A handwritten signature in blue ink, appearing to read 'John O'Dea', is written over the 'Yours sincerely' text. The signature is stylized and includes a large loop at the end.

John O'Dea
Infrastructure and Instructure Management Director

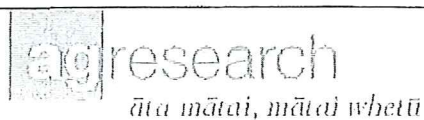
"A"

Rose Ashby

From: [REDACTED]
Sent: Tuesday, 1 September 2020 8:18 AM
To: monitoring@epa.govt.nz
Cc: [REDACTED]
Subject: RE: Draft Annual and 10 year reports for ERMA200223 for period ending 30th June 2020 C Letter 1/09/2020
Attachments: Cover letter 10y report F.pdf

As advised yesterday the attached is a cover letter for the 10 year report.

[REDACTED]
[REDACTED]
[REDACTED]



Based at Ruakura Campus agresearch.co.nz



From: [REDACTED]
Sent: Monday, 31 August 2020 4:44 PM
To: monitoring@epa.govt.nz
Cc: [REDACTED]
Subject: Draft Annual and 10 year reports for ERMA200223 for period ending 30th June 2020

Good afternoon,

Please find attached the draft Annual Report for the ERMA200223 approval for the period 1/07/2019 to 30/06/2020.

As previously there are some ethics reports in the supporting information to be added, these are in progress and at this stage should be available once approved by the Ruakura animal ethics committee at its meeting on the 3rd of September.

Also attached is the draft 10 year report for the ERMA200223 approval as required by Control 12 of the decision. A covering letter will be sent tomorrow.

This report contains some confidential sections which will need to be amended prior to public release for commercial sensitivity reasons.

As per previous years -The process we have normally followed with this report is to submit draft by due date, the EPA reviews and often asked questions or for further information.

We would respond to these and complete / confirm acceptance of draft elements of the report.

EPA confirms it is satisfied the report meets requirements and we confirm it is in its final version.

I send a PDF version which EPA uploads to your website (we may need to take some names out of public version), we are advised of planned upload date so both communications teams can be ready for any query's (normally from GE Free).

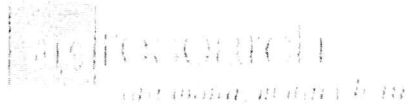
Regards

[REDACTED]



Based at Ruakura Campus agresearch.co.nz





31 August 2020

██████████
Environmental Protection Authority
Private Bag 63002
Wellington 6140

Re: Ten-year report, ERMA200223

Dear ██████████

We are submitting, as required under the approval for ERMA200223 and specified in control 12, the ten-year report to provide the Authority with information whether there are grounds for reassessment of the approval.

The ten-year report briefly summarises the outdoor activities in cattle, goat and sheep, as well as iwi liaison activities, animal numbers, Ruakura Animal Ethics Committee oversight and MPI audits. During the ten-year period, no unforeseen adverse effects and no breaches of containment were identified. No restrictions on the ACF's ability to operate were imposed by MPI

The report also contains information on the progress of proof-of-concept research, any adverse and beneficial effects of the organisms as specified in control 12. Following the generation of the animals, characterisation of the full impact of the genetic modification is still ongoing but has already generated substantial benefits in the form of new scientific knowledge. Lists of scientific publications, presentations and media reports have been included to indicate the scale and impact of the scientific knowledge gained by the activities. During the ten-year period, we have not identified any adverse effects caused by the GM animals.

Please note that the detailed science section includes specific information under 'Summary of Science Activities for the 10-year period to 15th April 2020', section 'a), any progress that the approval holder has achieved towards completion of the proof-of-concept research', sub-heading '9. Genetically engineered goats capable of producing female' and section 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, sub-heading '9. Genetically engineered goats capable of producing female only offspring', that is confidential and not suitable for public dissemination. The relevant sub-sections 9. have been marked as 'CONFIDENTIAL' and relate to commercial plans and activities that have been shared with AgResearch under a Non-Disclosure Agreement and are not in the public domain.

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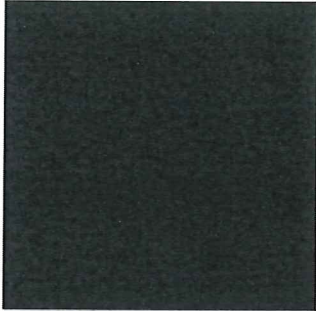
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Heipunk Research Institute
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Hamilton +64 6 361 5000

Research Agricultural Centre
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Private Bag 5033, Mosgiel 9053
+64 3 439 1809

In summary, the ten-year report shows that the controls and MPI oversight are appropriate to manage the residual risk posed by the GM animal activities in outdoor containment, the activities generated substantial benefits through advancing science and no adverse effects of the animals have occurred.

Yours sincerely



"B"

Rose Ashby

From: [REDACTED]
Sent: Tuesday, 15 September 2020 10:20 AM
To: [REDACTED]
Cc: monitoring@epa.govt.nz; [REDACTED]
Subject: RE: Draft Annual and 10 year reports for ERMA200223 for period ending 30th June 2020 15/09/2020
Attachments: Annual Report ERMA200223 June 2020 Draft2.docx

Good morning [REDACTED],

Attached is the updated version of the Draft Annual Report – addition of the animal ethics reports which have been accepted by the RAEC.

Regards
[REDACTED]

From: [REDACTED]@epa.govt.nz>
Sent: Monday, 31 August 2020 5:01 PM
To: [REDACTED]
Subject: RE: Draft Annual and 10 year reports for ERMA200223 for period ending 30th June 2020

Thank you, [REDACTED]

I'll have a look at it, and get back to you.

Kind regards, [REDACTED]

[REDACTED]
[REDACTED]
RSOP - New Organisms Applications

+ [REDACTED] | [REDACTED]



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Sent: Monday, 31 August 2020 4:44 PM
To: Monitoring <Monitoring@epa.govt.nz>
Cc: [REDACTED]
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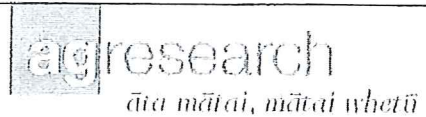
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Regards



Based at Ruakura Campus agresearch.co.nz



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↑ C "

Rose Ashby

From: [REDACTED]@epa.govt.nz>
Sent: Friday, 5 February 2021 4:04 PM
To: [REDACTED]
Subject: 10 year Report ERMA200223 June 2020 Draft-TS.docx
Attachments: 10 year Report ERMA200223 June 2020 Draft-TS.docx

CAUTION: External sender

Hi [REDACTED]

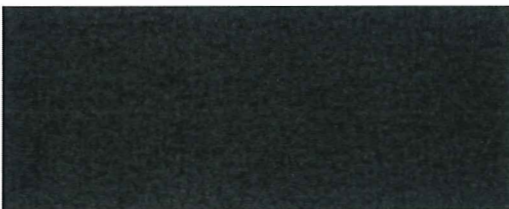
I'm just preparing to finalise things for giving the 10 year report to our CE, and thought I had only a couple of minor comments regarding things that needed fixing. However, I'm afraid that I've found a lot of problems with the in-text citations not being found in your list of references.

It hadn't been my intention to go through the references systematically, but I went to look for the McLean et al, 2019 reference under Germline complementation of sheep on page 6, and noted it wasn't in the references. I thought I'd best check some of the other citations, and very quickly found problems, as you'll see in the comment boxes. After finding problems relatively quickly, I didn't go through the rest of the document, and decided to refer it back to you to correct, especially as this is something we intend to publish on our website. I think it would also be helpful for the references to be in alphabetical order by first author.

I know my timing on this email is on a Friday just before a long weekend, but I would really like to finalise all of this sometime soon, If you could return it to me as soon as you can after the holiday, I'd appreciate it.

Please let me know if you have any questions, or if you otherwise wish to discuss.

Have a great Waitangi weekend!



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