Environmental Protection Authority
Te Mana Rauhī Taiao

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[redacted]
McGuinness Institute Te Hononga Waka
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Via: [redacted]@mcguinnessinstitute.org

Official Information Act Request

Dear [redacted]

I refer to your email of 20 July 2020, in which you asked us to:

"…*treat 'Appendix 3: OIA Request to the EPA' as an information request under the Official Information Act 1982*."

The response to your request follows.

1. Outdoor developments and field trials of GM animals

a. Can you provide a comprehensive list of outdoor developments and field trials in New Zealand that involve GM animals?

There are no active field test approvals other than ERMA200223 that involve GM animals in New Zealand at the current time. As regards the link to the Environmental Protection Authority (EPA) web page that you provided, there are six approvals listed under the heading "Approvals for field tests or outdoor developments of GM animals". Two of these are for sheep (GMF98001 and GMF99004), both of which are either completed or never commenced. Two more approvals (GMF98009 Parts I & II), and GMD02028, are for cattle, both of which are not being used any longer, and activities formerly carried out under these approvals are now carried out under ERMA200223, as stated on this web page. The final approval is for ERMA200223 itself, and it refers to cows, goats, and sheep, as seen on this web page.

As regards the reference to your report 16, we cross-referenced all the approvals listed on page 50 and 51 of this report, and found that all approvals for the outdoor development and field tests for GM animals are listed on our website at the link you provided above. The King Salmon approval GMD99003 does not appear on this list, because the approval was for genetically modified salmon in indoor containment.

2. ERMA 200223 approval

b. Can you advise that in addition to the review of grounds for reassessment in 2019/2020, whether there is any other mechanism that would give the EPA or indeed the Government, grounds to withdraw the approval? Please refer to specific legislation.

The Ten Year annual report on ERMA200223 will provide information that will be available to the Chief Executive of the EPA to decide whether to request that the EPA decides whether there are grounds for reassessment of the approval under section 62 of the HSNO Act. As set out in section 62, a request to the EPA may be made at any time, by any person or the Chief Executive of the EPA to decide whether there are grounds to reassess any new organism in containment, any conditionally

released new organism, or any qualifying organism released with controls, where that organism has previously been assessed by the EPA. If grounds for reassessment are found to exist, any person or the Chief Executive of the EPA may then request the EPA to proceed with a reassessment under section 63 of the HSNO Act. There is no other mechanism in the HSNO Act by which a new organism approval may be withdrawn by the EPA before it expires.

c. *Please provide the policy for a review of the grounds for reassessment. We believe this is the first time that this has been made a control, could you please clarify this? Further, could you outline the process the EPA will undertake in completing this review and ideally make it public?*

There is no EPA policy regarding a determination for grounds for reassessment of a new organism approval. First, a person or the Chief Executive of the EPA must request that the EPA decides whether there are grounds for reassessment. The Ten Year report will provide information that will be available to the Chief Executive of the EPA to decide whether to make such a request. Section 62 of the HSNO Act then sets out the matters that must be taken into account when the EPA is considering whether there are grounds for reassessment. For further information, please refer to our response to your question 2.b.

The process for undertaking a reassessment can be found on the EPA's website at: https://www.epa.govt.nz/industry-areas/new-organisms/applying-for-approval/amend-or-reassess-approvals/

You asked whether this is the first time a control requiring an applicant to provide a report for the purpose of considering grounds for reassessment has been put in place. On 26 August 2020, you clarified that your interest is in outdoor field trials only. This part of question 2.c, is now:

"We believe this is the first time that this has been made a control in outdoor field trials, could you please clarify this?"

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.

d. *Has the EPA received the tenth annual report from AgResearch – for the period 1 July 2018 to 30 June 2019 (and was due 31 August 2019)? If yes, can you please forward this report to the Institute and ideally make it public on your website. If no, can you confirm whether you have requested this copy from AgResearch? Can you also confirm the current status and the plans to action given this failure to report on time? We would appreciate copies of any correspondence that has taken place between the EPA and AgResearch discussing the ten year assessment and the tenth annual report during the last three years.*

The Ten Year Report, specified in Controls 11 and 12 of the ERMA200223 decision, is due on 31 August 2020. As the decision was made on 13 April 2010, the first report provided to the EPA on 31 August 2010 merely described the transition of activities under other approvals held by AgResearch in the six weeks between the decision and the reporting cut-off date of 30 June 2010. We did not consider this to be the first annual report. The 2019-2020 report covers the tenth full year of activities under the approval, and we consider that the additional information required under Control 12 is due at the end of August 2020. All annual reports are published on the EPA website, usually within three to four weeks of receipt.

There has been no correspondence between the EPA and AgResearch during the last three years discussing the ten year assessment and the tenth annual report.

e. *Under what legislation could (i) the Minister, (ii) the EPA or (iii) a member of the public decide to call in (or go to court over in regard to (iii)) an approved development (such as ERMA 200223)? If yes, please list the section and identify grounds that could apply for each of these scenarios above*

(e.g. poor governance by AgResearch, new evidence on risks or new information on benefits being less than initially envisaged).

As stated in the answer to Question 2.b., sections 62 and 63 of the HSNO Act provides the mechanism by which a new organism decision may be reassessed. Any person can request that the EPA consider whether grounds for reassessment of a new organism approval exist under section 62 of the HSNO Act, and then if grounds are found to exist, request a reassessment under section 63 of the HSNO Act. If the EPA proceeds to a reassessment the Minister may choose to exercise their call-in power under section 68 of the Act to call in the application. The criteria for exercising that power are set out in section 68. Appeal provisions in relation to approvals are set out in section 126 of the HSNO Act.

f. *Can you clarify to what extent the EPA completes a case-by-case assessment of each experiment under ERMA200223 (rather than approving the applicant or the containment facility)?*

As stated in section 1.1.2 of the decision, the ERMA200223 Decision-making Committee "decided to grant AgResearch approval to conduct research into the production of therapeutic proteins using genetically modified bacterial and mammalian cells, mice, goats, sheep and cattle". The approved organisms and allowed genetic modifications are described in Appendix 1 of the decision. This decision was made to allow the approval holder to conduct a range of experiments within the bounds of the purpose of the approval, the approved organisms and genetic modifications, and the stringent controls imposed on the approval. The EPA does not further conduct any case-by-case assessments of individual experiments under this approval. The Ministry for Primary Industries (MPI) is responsible for the approval of both containment facilities and facility operators.

g. *What level of assurance do you have that this approval has been implemented correctly?*

The EPA is not responsible for compliance with or enforcement of new organism approval conditions. MPI is the agency responsible for compliance and enforcement. Therefore, this part of the OIA has been transferred to MPI.

3. Risks

h. *Has the EPA (or their agent, consultant or service provider) reviewed the science since the approval ten years ago? If yes, please expand.*

The EPA actively monitors scientific developments both domestically and internationally, and reviews the significance of any new information as it becomes available. However, the EPA has not reviewed the scientific basis of the approval since it was granted. The EPA will review the Ten Year Report for the purposes of identifying whether there may be any grounds for reassessment of the approval.

i. *Are there any plans to review the science in the future (this is particularly relevant given the experiment has another ten years to run)? If yes, please explain.*

As stated in the answer to the previous question, the EPA actively monitors scientific developments and reviews the significance of any new information as it becomes available. The EPA will review information in the Ten Year Report for the purposes of identifying whether there may be any grounds for reassessment of the approval. The EPA has no plans to review the science in the future, as there is no basis in the HSNO Act by which it may carry out such a review, other than by a reassessment.

j. *We are particularly concerned about the risks of DNA or RNA viruses crossing the species barrier, have these specific risks been reviewed in the last ten years, and whether the EPA is planning a review in the near future (particularly given the current pandemic). If so, please advise how those risks were identified, measured and mitigated and to what extent has the probability and magnitude of that risk been identified and reduced by the EPA? If this information is in a report, please direct us to the report/s.*

In paragraph 2.4.2 of the decision document, the DMC noted that the work involving viral vectors would only be carried out using "… *replication-deficient lentiviral and recombinant adeno-associated virus vectors*". In a footnote in this paragraph, it is stated that "…*'replication-deficient' means that once produced, the viral vector cannot replicate"*. Thus, although the viral vector particles resemble viruses on the outside, they do not carry the genetic material that allows them to make more copies of themselves, and can be used safely without concern that more copies of the genetic material and viral particles can be created. Thus, they are not viruses as such, but genetic material that is packaged into a viral coat to facilitate its delivery to cells. On this basis, Decision-making Committees later determined that replication-defective viral vectors (with "replication-defective" having the same meaning as "replication-deficient" as discussed above) are not organisms as defined in the HSNO Act, and they are therefore not regulated as organisms under the HSNO Act, per statutory determinations APP202122 (replication-defective adeno-associated viral vectors) and APP202444 (replication-defective adenoviral vectors of genus *Mastadenovirus* and replication-defective retroviral (including lentiviral) vectors). These decisions were made in 2015 and 2016, respectively. However, living cells treated with such vectors, and animals derived from such cells are considered to be GMOs as defined in the HSNO Act.

k. *Can you advise why MPI is not inspecting Control 8: 'All open container use and production of viral particles must occur within a Class II Biological Safety Cabinet'? Please give the name of the organisation completing this check and/or the reasons why it is not being inspected/checked.*

The EPA is not responsible for compliance with or enforcement of new organism approval conditions. MPI is the agency responsible for compliance and enforcement. Therefore, this part of your OIA request has been transferred to MPI.

4. Benefits

l. *Has the EPA identified who gains the benefits of the application? If yes, please advise or indicate where those benefits are listed and quantified.*

The EPA identified benefits in the initial staff assessment for the application, but does not monitor benefits after an approval is granted.

m. *Has the EPA undertaken a recent review of those benefits? If yes, please advise or indicate where those benefits are listed.*

The EPA has not reviewed the benefits of the application since it was approved. In Paragraph 1.1.8 of the decision, the DMC noted that they considered that "the main benefit of this research will be an increase in scientific knowledge and the capacity for innovation in New Zealand". The EPA will review the Ten Year Report, which will include discussion of the benefits of the research, as part of its consideration of whether there may be grounds for reassessment of the approval.

n. *What health care/medical scientist has been engaged to advise on the benefits of this science pathway? This was a weakness of the original AgResearch application. Please advise if the EPA has done any further research/inquiry into the benefits claimed by the applicant.*

As stated above, the EPA has not reviewed the benefits of the application since it was approved. It is not aware of any health care/medical scientist engaged to advise on benefits.

o. *We note that the latest audit report mentions collaborators. Can you advise if they have a benefit in this experiment and if yes, whether this benefit dilutes the so called benefit to New Zealand identified by the applicant. Our understanding is that at the time of the application there were no other entities that had a shareholding or reagreed benefit from the experiment. Please can you provide an update as this would dilute the benefits to New Zealand, as assessed under the legislation.*

The EPA holds no information on collaborators and whether they have a benefit in this approval. This part of your request has been transferred to AgResearch

p. *The article in Attachment 5 notes 'the need to be sure that drugs derived from animal milk has the same standard and purity as normal'. In earlier research we found that the purity and quality control issues regarding drugs derived from animal milk would be a major obstacle and exceed manufacturing costs made in a laboratory. Has the EPA undertaken any recent secondary research to try and assess the likelihood that these obstacles could be overcome? If yes, we would like to review this research.*

The EPA has undertaken no research relevant to this issue.

5. Costs

q. *Has the EPA identified costs in terms of the accumulated costs to AgResearch to implement the experiments since 2010? If not, can you ask AgResearch to provide detailed costs?*

The EPA has no information about this issue. This part of your request has been transferred to AgResearch

r. *Has the EPA identified the costs (for the EPA) to monitor and manage the risks of those experiments since 2010? If yes, what is the actual cost to the EPA? If not, can you estimate this? Lastly, if you are unable to estimate these costs, can you advise the estimated cost of all monitoring of outdoor GMDs?*

The EPA is not responsible for monitoring new organism approvals. MPI is the compliance and enforcement agency for new organism approvals. This part of your request has been transferred to MPI.

s. *Can you advise the costs of monitoring all AgResearch experiments by year for the last twelve years? (Note: This will provide an estimate of additional costs to the EPA).*

As stated above, the EPA is not responsible for monitoring new organism approvals. MPI is the compliance and enforcement agency for new organism approvals. This part of your request has been transferred to MPI.

t. *The 2018 annual report notes that there were 76 GM animals (37 cows, 39 goats and no sheep) as at 30 June 2018. Given the experiments originally started in 1999 (these earlier applications were rolled into the 2010 application) and the EPA is required to consider costs; what is the EPAs calculation of the actual costs of each of these 76 GM animals to be?*

The EPA holds no information on this issue.

6. Methodology

u. *The risk management methodology that ERMA (and now the EPA) is required to apply is contained within the Hazardous Substances and New Organisms (Methodology) Order 1998. Can you advise where we can find any supporting documentation on how the EPA implements the methodology? Previously there has been a guide for this.*

The EPA does not currently use any guide on how the Methodology is to be implemented in its new organism assessments, and there is no other supporting documentation that we hold.

v. *What is the process for the grounds for the reassessment and if found, that reassessment?*

Any person, or the Chief Executive of the EPA, must request that the EPA decide whether there are grounds for reassessment. The information in the Ten Year Report will be available to the Chief Executive to decide whether to make such a request. Section 62 of the HSNO Act then sets out the

matters that must be taken into account when the EPA is considering whether there are grounds for reassessment. For further information, please refer to our response to your question 2.b.

The process for undertaking a reassessment can be found on the EPA's website at: https://www.epa.govt.nz/industry-areas/new-organisms/applying-for-approval/amend-or-reassess-approvals/

w. Will the public be invited to contribute regarding the 'grounds for the assessment' and the 'reassessment' proper? Please advise.

Determination of the grounds for reassessment is not a publicly notified process. If grounds for reassessment are found, then a decision as to whether or not to publicly notify the reassessment will be made by the EPA in accordance with section 53 of the HSNO Act. If a decision to notify the reassessment is made, then submissions will be invited from interested parties.

The process for undertaking a reassessment can be found on the EPA's website at: https://www.epa.govt.nz/industry-areas/new-organisms/applying-for-approval/amend-or-reassess-approvals/

7. Interested Parties Register

x. If it is GMD02032 (see below), please clarify if there have been amendments to GMD02032 that the Institute is not aware of. It was our understanding that the Institute would be kept informed of all changes and had the ability to discuss any significant changes with ERMA (and the EPA). Can you clarify if a register of interested parties still exists and if so, whether the Institute's name or [redacted] *name remains on it? If there is such a register and we are not on it, can you please add us?*

[redacted] is on the list of interested parties for non-GM publically notified applications and also GM publically notified parties. The email address that we have on file is [redacted]@mcguinnessinstitute.org with contact details as chief writer for Sustainable Future. EPA is happy to update any out-of-date information. Please contact us at NewOrganisms@epa.govt.nz with any information that needs to be updated.

8. Other parties interested in creating GM animals

y. Has the EPA received applications or enquiries to create GM animals in New Zealand (i) from New Zealand companies or (ii) overseas companies in the last ten years? If yes, please elaborate.

Over this period, the EPA received enquiries about:

- the correct application form for development of genetically modified pigs in indoor containment. This enquiry led to the application APP203942 (see below), which was approved on 14 February 2020.
- the potential for gene-edited cattle with no off-target changes to be successful in a release application.

The EPA also approved a GM development application, APP203942 from AgResearch, for the development of gene-edited pigs on 14 February 2020. The application documents can be found at the following link on our website:

https://www.epa.govt.nz/database-search/hsno-application-register/view/APP203942

We also identified enquires and applications involving the creation of various genetically modified animal cell lines. However, we did not consider these to be in scope of your request, since you asked about animals, so we have not included them.

For the avoidance of doubt, please note that we did not undertake a search of matters currently in the "pre-application" phase as the OIA does not apply to that information pursuant to section 55 of the HSNO Act.

You have the right to seek an investigation and review of this decision by the Ombudsman. You can contact the Ombudsman on 0800 802 602, or by email at info@ombudsman.parliament.nz.

If you have any further queries, please do not hesitate to contact us via ministerials@epa.govt.nz.

We will publish your request and our response on our website, www.epa.govt.nz, within 10 working days from today. We make OIA responses available so others can read more about the work we do and the questions we are asked. Any information that might identify you will be removed to protect your privacy.

Yours sincerely

Dr Clark Ehlers
Acting General Manager, Hazardous Substances and New Organisms
Regulatory Systems and Operations