Email to EPA, OIA 2021/04, Sent 8 January 2021

From: Wendy McGuinness <wmcg@mcguinnessinstitute.org>
Date: Friday, 8 January 2021 at 10:36 AM
To: "Ministerials@epa.govt.nz" <Ministerials@epa.govt.nz>
Subject: AgResearch's transgenic outdoor experiments ERMA200223 (Our OIA 2021/04)

Attention: Dr Clark Ehlers

Dear Clark,

Thank you for your response to our 20 July 2020 OIA request (copy attached). For your information, a copy of our correspondence to Hon Minister Parker of 4 January 2021 is also attached.

I am writing to explain our interpretation of the reporting and reassessment controls and the obligations these controls place on the parties concerned (e.g. AgResearch, MPI and the EPA), to reiterate the need for a reassessment of ERMA200223 based on new information and to seek answers to specific questions on AgResearch's ten-year annual report.

A: The legal relationship between section 62 and Controls 11 and 12
We note your OIA response (under our Q2) states:

> *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.*

Our initial view is that the list in section 62 is different from the information listed in Controls 11 and 12 (Appendix 2) and that the list in Controls 11 and 12 includes the consideration of costs and benefits of the application. Under the HSNO Act *controls* are defined as:

> *any **obligations** or restrictions imposed on … a new organism, **or on any person** in relation to any … new organism … for the purposes of **controlling the adverse effects** of that substance or organism **on people or the environment**.* [emphasis added]

These two reporting and reassessment controls aim to do that. They do not arise out of section 62, but out of section 45. In practice Control 12 (under section 45) places a mandatory obligation on AgResearch to report, MPI to review and the EPA to make a one-off decision as to whether 'grounds for reassessment' exist – being the first ten-year anniversary of the ERMA200223 decision. This obligation on the EPA is also broader than the narrower obligations set out in section 62. Section 62 only places a requirement to look at the need for reassessment under certain circumstances any time in the 20 years, e.g. 'significant new information relating to the effects of the organism'. This can be interpreted very narrowly. In contrast, Control 12 refers to adverse effects and beneficial effects, both past and future.
Importantly, our view is that this additional obligation to look for grounds for reassessment exists even if no *person* raises the need for the EPA to consider grounds for reassessment (because it is a control).

The ERMA 2010 decision states in Control 12 that the information is required:

> ***In addition** to the annual reporting requirements* [Control 11], *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** …* [emphasis added]

In our view this means the EPA must look beyond the types of information listed in section 62. We therefore believe the statement made in the EPA's response to our OIA request (under our Q2 and included above) could be misconstrued. A more accurate statement would be to state that Controls 11 and 12 place an additional obligation on the EPA, on the first ten-year anniversary of ERMA200223, to consider information beyond that which is stipulated in section 62 and that the obligation to do so is mandatory.

Further, if a reassessment was to take place, this additional type of information would need to be assessed. Otherwise why would the committee expect the EPA to assess benefits and costs in order to make a decision on a reassessment, but not go on to take this type of information into account when making the actual assessment.

1. Do you agree with our interpretation outlined in A above? Please provide a legal view (or legal opinion) to explain your position.

B: Significant new information has become available

The process of assessment is important. The starting point is to identify each risk, then minimise each risk (e.g. via controls) and next assess each risk (that remains once controls have been put in place). Importantly the assessment needs to include an understanding of the probability (of the risk occurring), the magnitude (of the risk if it did occur) and the timeframe (in which the risk might occur). It is vital that any remaining risk is then assessed in terms of certainty and caution (e.g. section 7 of the HSNO legislation, being the precautionary approach). Finally, when all the outstanding risks are combined, they must then be balanced against an assessment of the costs and the benefits. Only when the above process has been followed (as outlined in the Hazardous Substances and New Organisms (Methodology) Order 1998) can a final decision be made.

Below we discuss new information that has become available in terms of risks, costs and benefits. This is not an exhaustive list but instead aims to illustrate the type of information we are aware of in relation to reassessment. Importantly, we believe a public hearing would enable the optimal decision to be made, as it would ensure the decision is based on timely, accurate and relevant information.

(a) Risks

One of the reasons we believe the 2010 committee hearing application ERMA200223 decided to include Control 11 and Control 12 (the reporting and reassessment controls) was because the science of creating and managing the risks of transgenic animals was in its infancy, and our understanding of how these types of experiments might weaken the species barrier and enable cross-species transmission of viruses and bacteria was poor. Concern over accidental transmission between animals of the same species is further evidenced by the committee's Control 5 (see the attached correspondence to the Minister).

It is therefore important to note the work of University of Otago and ESR virologist Dr Jemma Geoghegan. Geoghegan has been part of New Zealand's science response to the COVID-19 pandemic. In previous research she and others found that viruses that 'jumped' to humans typically came from other mammals. Notably, ERMA200223 involves cattle, sheep and pigs (all mammals). A recent article about Geoghegan's work notes: 'One major finding was that cross-species transmission has played a major role in the evolution for 19 virus families she analysed, while "co-divergence" – where a virus stuck with its hosts, evolving and mutating along the way – remained relatively rare. Leaps between species were especially frequent in virus families in which genetic

material was encoded in RNA rather than DNA – such as coronaviruses like SARS-CoV-2 and closely-related SARS and MERS.'

Further, she discusses a range of new science tools available to scientists, such as meta-transcriptomic RNA sequencing – or what is frequently called 'deep' RNA sequencing. Geoghegan stated that this new method is 'driving breakthroughs around the world in virus discovery, [and] could quickly reveal the entire "virome" or virus composition within an individual. More importantly, it allowed her to pinpoint those ecological traits that aided host-jumping.' (See https://www.nzherald.co.nz/nz/jumping-viruses-what-strains-lie-hidden-in-nzs-own-species/A56IYYXEZCCXW5QVLU4JBUJPNM/; also attached as a pdf). We believe the EPA should seek out Geoghegan and other experts in this area in order to gain a deeper understanding of viruses that might exist in New Zealand livestock and the extent to which those viruses are capable of 'jumping' to humans or other animals.

2. Can you list any secondary research/publications the EPA has reviewed on cross-species transmission in the last three years and any experts you have consulted with?

3. Regarding Control 12, what 'adverse effects' over the last ten years have occurred, in particular:
   a. any effects on each of the genetically modified organisms (i.e. a summary of effects), including
   b. any effects which relate to the matters described in section 6(d) [the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga], and
   c. any effects which relate to the principles of the Treaty of Waitangi (Te Tiriti o Waitangi)?

(b) Costs

New information about costs is included in AgResearch's OIA response (see 11 September 2020, Q3 table). Here we learn that AgResearch has received $12.37 million in government grants since 2011 and $25 million since 1999. The latter figure is the most relevant given previous applications by AgResearch were in effect rolled into ERMA200223 by ERMA. This dollar figure is in addition to the normal operating costs funded by AgResearch (a crown Crown-owned company), which is largely funded by government.

The opportunity cost of this amount of public money invested elsewhere (e.g. investing in science education in schools or improving New Zealanders' access to medicines through PHARMAC) requires consideration.

(c) Benefits

The purpose, as stipulated in the original application, was:

> *… to develop in containment (indoor and outdoor) goats, sheep and cows* ***genetically modified****:*
>
> - *to produce* ***human therapeutic proteins****, and*
> - *to* ***alter levels of gene activities and proteins*** *for the* ***study of gene function, milk composition and disease resistance****.* (p. 6 of the application) [bold added]

4. The purpose above relates to 'genetically modified' goats, sheep and cows. However, we understand cloning (which is not genetic modification) has also taken place. Can you clarify whether goats, sheep and/or cows have been cloned over the last ten years? And what experiments over the last ten years, if any, are outside the original purpose of the application?

5. Regarding Control 12, what 'proof-of-concept' research exists regarding the production of 'human therapeutic proteins'?

6. Regarding Control 12, what 'proof-of-concept' research exists regarding the altering of gene activities and proteins for the study of:
   a. gene function,
   b. milk composition and
   c. disease resistance?

7. Regarding Control 12, what benefits, if any, occurred over the first ten years in regard to:
   a. human therapeutic proteins,
   b. gene function,
   c. milk composition and
   d. disease resistance?

   To this end, we have asked AgResearch to provide a list of articles they mention in answer to our OIA request (see 11 September 2020, Q12, B). Their position is that these articles are publicly available resources and therefore are not covered by the OIA. We disagree; such a list is not in the public arena and the institute has found only one article to date (which we discuss in the July 2020 OIA, Q10).

8. Regarding Control 12, what benefits, if any, are forecast to occur over the next ten years in regard to:
   a. human therapeutic proteins,
   b. gene function,
   c. milk composition and
   d. disease resistance?

These are the types of questions we expected to be answered in AgResearch's ten-year annual report.

C: Specific questions on your responses to our original OIA request

These questions relate to your responses to our 20 July 2020 OIA request (attached).

9. In (c), you note: 'There is no EPA policy regarding a determination for grounds for reassessment of a new organism approval.' Can you advise whether the EPA is considering writing such a policy?

10. Also in (c), you provide a link to your website, see here. The website states: 'An application to determine if there are grounds for reassessment is not publicly notified. However, the reassessment application will be open for public submission.'

    Could you explain this in detail? For example, does this mean if the EPA *receives* a request from the Minister or another person to reassess a previously approved application (e.g. ERMA200223), the application for reassessment is not publicly notified? However, if the EPA then *decides* to reassess a previously approved application, is it automatically open for public submission?

11. Can you provide the date the ten-year annual report was received by the EPA, and from whom it was received?

12. Can you provide the date the ten-year annual report was uploaded to the EPA website?

13. Can you clarify whether the report was assessed for completeness by staff at the EPA (or any third party) before it was uploaded to the website? If yes, was the report sent back to AgResearch or MPI for further changes? If yes, please explain the actual process and provide any further detail.

14. Now that AgResearch's ten-year annual report has been received and uploaded on the EPA website, what are the next steps in the process? Will the EPA review the application for grounds of reassessment? As indicated in my correspondence to the Minister, my hope is that if the EPA decides not to undertake a review that the Minister will request a review. If the Minister decides not to do this, the McGuinness Institute will request a reassessment. To this end, can you clarify the following:
    a. Is the application form on your website here the correct form?
    b. When would you need to receive the form?
    c. Can you explain the process in detail? You might like to answer this question with regard to your answer to Question 1 above.
    d. Will the EPA produce a report on the review of grounds for reassessment? Will that report be made public? If yes, when is the report expected to be made public and will the public be invited to comment on a draft?

Thank you for all your help. I appreciate this is a completely new process and as such the EPA will be considering how best to efficiently and effectively complete the intent of the 2010 committee decision and their package of controls.

Best wishes,

Wendy
PS: Please note the 2019 annual report is currently missing from your website; see link and image below. It may have been accidentally removed when the 2020 report was added.

McGuinness Institute Te Hononga Waka
Level 2, 5 Cable Street, Wellington 6011 | PO Box 24-222 Wellington 6142
+64 4 499 8888 | www.mcguinnessinstitute.org

Application documents

Application ERMA200223 Appendix II[1].pdf (PDF, 3.8 MB)

ERMA200223_2010 AgResearch cattle sheep and goats annual report.pdf (PDF, 56 KB)

ERMA200223_2011 AgResearch cattle sheep and goats annual report.pdf (PDF, 722 KB)

ERMA200223_2012 AgResearch cattle sheep and goats annual report.pdf (PDF, 2.4 MB)

ERMA200223_2013 AgResearch cattle sheep and goats annual report.pdf (PDF, 1.3 MB)

ERMA200223_2014_Agresearch_annual_report.pdf (PDF, 3 MB)

ERMA200223 2015 AgResearch cattle sheep and goats annual report.pdf (PDF, 675 KB)

ERMA200223 2016 AgResearch cattle sheep and goats annual report.pdf (PDF, 648 KB)

ERMA200223 2017 AgResearch cattle sheep and goats annual report.pdf (PDF, 2.2 MB)

ERMA200223 2018 AgResearch cattle sheep and goats Annual Report.pdf (PDF, 1.6 MB)

ERMA200223 2020 AgResearch cattle sheep and goats annual report.pdf (PDF, 1.3 MB)

ERMA200223 Appendices to application.pdf (PDF, 1.5 MB)

ERMA200223 -Appendix IV ICS Report to AgResearch (Maori Consultation)[1].pdf (PDF, 318 KB)

ERMA200223 Application summary - FINAL.pdf (PDF, 58 KB)

ERMA200223 EandR.pdf (PDF, 479 KB)

ERMA200223_ERMA200223 Application Form signed.pdf (PDF, 8.6 MB)

ERMA200223_ERMA200223 decision FINAL.pdf (PDF, 556 KB)

Errata sheet.pdf (PDF, 94 KB)

Hearing schedule as at 23 Feb.pdf (PDF, 151 KB)

NKTT report Final (2010.02.08).pdf (PDF, 546 KB)

Supporting Documents for EandR.pdf (PDF, 1.1 MB)

From: Ministerials <Ministerials@epa.govt.nz>
Date: Friday, 28 August 2020 at 1:34 PM
To: Wendy McGuinness <wmcg@mcguinnessinstitute.org>
Cc: Alison Welch <Alison.Welch@epa.govt.nz>
Subject: RE: Acknowledgment of OIA sent 20/06/2020

Good afternoon
Please find attached a response to your request.
Kind regards,

Lisa MacKenzie
Official Correspondence Advisor, Government Engagement and Official Correspondence