Environmental Protection Authority
Te Mana Rauhī Taiao

ENQ-40677-Q9V4J6

15 February 2021

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[redacted]
McGuinness Institute

Via: [redacted]

Official Information Act Request

Dear [redacted]

I refer to your email received on 8 January 2021.

Aspects of your request are in the nature of an enquiry, rather than a request for official information, and we have attempted to respond in the most appropriate way to each part of your email. The response to your request follows:

1. *Do you agree with our interpretation [of the legal relationship between section 62 and Controls 11 and 12] Please provide a legal view (or legal opinion) to explain your position.*

In terms of your enquiry, this is not a question that we can respond to under the OIA, as the EPA does not hold a legal view or legal opinion on whether it agrees with your interpretation of the legal relationship between s62 and Controls 11 and 12. If the EPA was to obtain such an opinion, this would be subject to legal professional privilege.

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?*

The EPA has not reviewed any secondary research or publications on this topic, nor have we consulted any experts. Publications are generally reviewed at the point when we are assessing a new application. I am refusing this under section 18(e) of the OIA, as the document alleged to contain the information requested does not exist.

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)?*

The answers to Q3 will be in the 10-year report that will be published on the EPA's website. This is estimated to happen in the next 8 – 10 weeks. I am therefore refusing this request under section 18(d) of the OIA, on the basis that the information requested will soon be publicly available.

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?

Cloning was outside the scope of the HSNO application, but this may be an operational matter that you could raise with AgResearch.

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?*

The answers to Q5, 6, 7 will be in the 10-year report that will be published on the EPA's website. This is estimated to happen in the next 8 – 10 weeks. I am therefore refusing this request under section 18(d) of the OIA, on the basis that the information requested will soon be publicly available.

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?*

Benefits that are forecast to occur are part of the original application and the 10-year report. I am therefore refusing this request under section 18(d) of the OIA, on the basis that the information requested will soon be publicly available. I note that the forecast benefits also include the advancement of scientific knowledge.

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?*

The EPA is not considering writing such a policy. Each application is considered on its own merits, and a control does not trigger an application for grounds.

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?

An application to determine if there are grounds for reassessment is the first step in any process and is not open for public submission. However, the application itself and decision will be made publicly available on the EPA's website.

Any reassessment application (the second step, if it has been established that there are grounds to reassess) is open for submissions from the public.

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

It was received from AgResearch on 31 August 2020.

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

The 10-year report will be published on the EPA's website. This is estimated to happen in the next 8 – 10 weeks.

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.*

It is not the role of the EPA to assess the report for completeness. The report is supplied to the EPA in its final form.

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?*

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

This form is the correct form to apply for the EPA to determine if there are grounds for a reassessment. www.epa.govt.nz/assets/Uploads/Documents/New-Organisms/Forms/3dd9df7b19/Application-for-a-grounds-for-a-reassessment-decision-EPA0167.pdf

This is the first step in the reassessment process required under the HSNO Act. The EPA cannot initiate a reassessment without first determining whether there are grounds. The process of determining grounds would include any new information being provided, which would then be assessed by the EPA.

If it is determined that there are grounds for a reassessment, then a person can apply for a reassessment.

The controls placed on the ERMA200223 application require the EPA to consider the 10-year report. The information in the report will be used to make a recommendation to the Chief Executive of the EPA as to whether the Chief Executive should request that the EPA decide whether there are grounds for a reassessment.

Should the McGuinness Institute ask the EPA to determine if there are grounds for a reassessment, then the EPA would produce written documentation and information to support its decision-making. The decision would be communicated to the applicant and the outcome of the decision published on the EPA website.

An application to determine if there are grounds for reassessment is the first step in any process and is not open for public submission. Public input is only sought if an application proceeds to the reassessment stage.

You have the right to seek an investigation and review by the Ombudsman of decisions made under the OIA. 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

Siobhan Quayle
Group General Manager
Regulatory Systems and Operations