



MEMORANDUM

Application	APP204024
Applicant	Hopkirk Research Institute, AgResearch, Palmerston North
To	Dr Clark Ehlers, Acting GM, HSNO
Purpose of the Memorandum	Discretion to publicly notify application APP204024 to develop in containment the incidentally imported new organism, <i>Mycoplasma bovis</i> to research the development of diagnostic tests.
Date of Advice	10 September 2020

Purpose of this memo

1. This memorandum provides advice and requests a decision on whether this application will be publicly notified.

Background

Discretion to notify

2. Under section 53(2) of the Hazardous Substances and New Organisms (HSNO) Act, the EPA has the discretion to notify APP204024 if it considers that there is likely to be significant public interest.
3. The purpose of public notification is to ensure that the decision-maker is informed on all relevant matters and has heard the views of those affected by the decision, including the views of the public, technical information, the effect of the decision on the public or specified groups, and any additional information the public can provide. This ensures that the decision may be made following a fully informed consideration of all relevant factors.
4. The EPA Board has delegated the decision to publicly notify applications under section 53(2) to the Chief Executive, who has sub-delegated decision-making power to the General Manager of Hazardous Substances and New Organisms, under an instrument of delegation that took effect 6 March 2020.

The application

5. Application APP204024 from the Hopkirk Research Institute was formally received on 10 September 2020. This application seeks approval to develop, by deliberate isolation, aggregation, multiplication, or other use of the organism, the incidentally imported new organism, *Mycoplasma bovis* to research the development of diagnostic tests. There will be no genetic modification of the new organism undertaken if this development application is approved.

Discussion

Potential for public interest

6. While a full assessment of the application has yet to be completed we have outlined below the matters that may influence the level of public interest in this application, including those related to the core provisions of the HSNO Act (sections 5, 6 and 8) and the threshold of significant public interest outlined in section 53(2) of the HSNO Act.

Is the application for novel new organisms or activities?

7. The detection of *M. bovis* occurred in 2017 in farms in Southland. Subsequently, there has been a major national biosecurity effort to control and eliminate *M. bovis* present in New Zealand beef and dairy herds. *Mycoplasma bovis* is classified as an unwanted organism under the Biosecurity Act 1993 and is currently subject to a major national phased eradication program. The bacterium is considered an Incidentally Imported New Organism (IINO)¹ and as such approval from the EPA is required for certain development activities.
8. The applicant seeks EPA approval to develop² in containment *M. bovis* to further their research efforts in the development of novel diagnostic tests for the detection of the bacterium in infected cattle. To meet this outcome, the applicant would like to be able to grow, store and experiment with *M. bovis* samples in their laboratory. This research will also include the use of *in vitro* cell culture techniques to develop novel methods of detecting and identifying the protein profiles of potentially infected animal by, for instance, the analysis of exosomes (extracellular vesicles) produced by *M. bovis* infected cells *in vitro*.
9. The applicant has previously obtained a s52 permission from a Chief Technical Officer under the Biosecurity Act 1993, to move the IINO to their laboratory for diagnostic testing (see the appendix of the application). As such, the applicant has experience in the containment of environmentally collected *M. bovis* samples for diagnostic testing purposes. The applicant has described a similar enhanced containment facility that will be used for the development work if this application is approved.
10. Only isolates derived from New Zealand environmental samples will be used and no novel *M. bovis* strains that are not an IINO have been requested to be developed by the applicant. The applicant has also clarified with the EPA that they are not wanting to import *M. bovis* from overseas into containment.

¹ Incidentally imported new organism means a new organism that is imported in or on goods, but it is not –

- an essential or constituent part of the those goods
- imported in or on the goods with the intention of concealing the presence of the new organism
- a genetically modified organism

² 'Develop in relation to an incidentally imported new organisms also includes the deliberate isolation, aggregation, multiplication or other use of the organism

How does the application compare to previous applications that have been notified?

11. To our knowledge, no previous application to develop an IINO in containment has been publically notified.
12. The following are examples of applications that were found to be of significant public interest:
 - Application NOC03005 from the Ministry of Agriculture and Forestry: to import the bacterium *Melissococcus pluton* (the causal agent of European foulbrood in introduced honey bees) for diagnostic testing purposes, including the development of new laboratory test methods and for surveillance in New Zealand. Three public submissions were received.
 - Application NOC04012 from the Ministry of Agriculture and Forestry: to import strains of microorganisms that could potentially cause exotic and emerging diseases of animals into containment for diagnostic and testing purposes. Four public submissions were received.
13. The notified decisions were based on the facts that:
 - both applications involved the importation of causal agents of unwanted and notifiable animal diseases in New Zealand;
 - both applications were the first with regard to the type of organisms and research to be conducted, hence a novel or unusual application;
 - information provided in the applications, including published articles, specified that there could be potentially significant adverse effects on the livelihood of people and communities should the organism escape; and
 - they were unlikely to proceed with field testing or release and, therefore, no further opportunity would be provided for notification and submissions from the public.
14. The major concern raised by the submitters for both of these applications was the adequacy of the containment regime. The applicants have described the containment measures as international best practice.
15. The decision was made to notify these applications on the basis that they involved known causal agents of unwanted and notifiable diseases for animals.
16. In summary, these applications involved the importation into containment of a new organism that may cause serious impact to animals and was not considered to be an incidentally imported new organism.
17. Other notified applications involved the field testing of genetically modified animals and as such, are not similar to this application to develop an IINO in containment to research the development of diagnostic tests.

How does the application compare to previous applications that have not been notified

18. This application is similar to other applications to develop IINOs in containment. The following are examples of similar applications that were not considered to meet the definition of significant public interest:
 - Application APP203015 from Plant and Food Research to develop incidentally imported pea weevil (*Bruchus pisorum*) and pea pods containing pea weevil pupae in containment.
 - Application APP203338 from Scion to develop incidentally imported *Paropsisterna variicollis* and *Paropsisterna beata* in containment to assist with research on pest management.
 - Application APP203239 from AgResearch Ltd to develop incidentally imported low-risk microorganisms in containment.

- Application APP202186 from Landcare Research to import *Oulezia bakeri* into containment and/or develop in containment incidentally imported *Oulezia bakeri*.
19. The application APP204024 is similar to other applications/approvals to develop an IINO in containment, including one of which (APP203015) that is an unwanted organism under an eradication program and was declared successfully eradicated in February 2020³. None of these applications involving the development of an IINO in containment were publicly notified.

Have any significant cultural, economic, environmental, ethical, health, international, or spiritual effects be identified?

20. Significant cultural, economic, environmental, ethical, health, international, or spiritual effects were not identified. The Kaupapa Kura Taiao (KKT) review for this application concluded that the application with its proposed controls, is not likely to significantly affect the ability and capacity of Māori to maintain their economic, social and cultural well-being.

Is there any other relevant information?

21. The EPA has provided both the Department of Conservation (DOC) and the Ministry for Primary Industries (MPI) with a draft application during the pre-application stage with the applicant's permission. DOC replied that they were not opposed to the application. MPI suggested several changes to the application for clarity, some of which were relayed to the applicant. Both DOC and MPI have also been provided with the formally accepted final application for review and any additional comments will be taken into account should they be provided.

Overall Conclusion

22. Based on the information in the application, KKT advice, comments from external agencies and previous EPA decisions to develop an IINO in containment, we conclude that this application is not likely to be of significant public interest.

³ <https://www.beehive.govt.nz/release/biosecurity-minister-announces-world-first-eradication-pea-weevil>

Recommendation

We recommend that:

- This application does not meet the threshold of significant public interest as set out in section 53(2) of the HSNO Act.

Please indicate your decision below.

10 September 2020

██████████

Date

Senior Advisor, New Organisms Group
Hazardous Substances and New Organisms

Decision

I decide that application:

<input checked="" type="checkbox"/>	Will not be publicly notified as there is not likely to be significant public interest in the application
<input type="checkbox"/>	Will not be publicly notified as there is not likely to be significant public interest in the application; however, targeted notification should be undertaken (for the reason/s specified below).
<input type="checkbox"/>	Will be publicly notified as there is likely to be significant public interest in the application (for the reason/s specified below).

Comments/Reasons



14 September 2020

Dr Clark Ehlers

Date

Acting General Manager
Hazardous Substances and New Organisms
Environmental Protection Authority