



Decision

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| Date | 11 February 2021 |
| Application number | APP204176 |
| Application type | Determination of whether or not any organism is a new organism under section 26 of the Hazardous Substances and New Organisms Act 1996 (the Act) |
| Applicant | Pfizer New Zealand Limited |
| Date Application received | 29 January 2021 |
| Consideration date | 4 February 2021 |
| Considered by | A decision-making committee of the Environmental Protection Authority (the Committee) ¹ <ul style="list-style-type: none">• Dr Kerry Laing (Chair)• Dr Julie Everett-Hincks |
| Purpose of the application | To determine under section 26 of the Hazardous Substances and New Organisms Act 1996 if the SARS-CoV-2 vaccine BNT162b2 (COMIRNATY™) is a new organism |

Decision

1. The Committee has determined under section 26 of the Hazardous Substances and New Organisms Act 1996 (the Act) that the SARS-CoV-2 vaccine BNT162b2 (COMIRNATY™) **is not** a new organism for the purpose of the Act.

¹ The Committee referred to in this decision is the subcommittee that has made the decision on this application under delegated authority in accordance with section 18A of the Act.

Purpose of the application

2. Pfizer New Zealand requested a determination from the EPA as to whether the SARS-CoV-2 vaccine BNT162b2 (COMIRNATY™) is considered an organism for the purpose of the Act, and therefore potentially a new organism.

Application and consideration process

3. The application was formally received on 29 January 2021.
4. The information that the Committee took into consideration included:
 - the application form
 - a confidential appendix submitted by the applicant
 - the Environmental Protection Authority (EPA) Staff Advice Report which included comments from the Department of Conservation (DOC) and the Ministry for Primary Industries (MPI).
5. The determination was made in accordance with section 26 of the Act. The Committee noted that the HSNO Methodology Order 1998 relating to the identification, assessment and evaluation of risks, costs and benefits is largely not applicable to section 26 determinations. They also noted that determinations made under section 26 of the Act do not require public notification.
6. In accordance with section 26(5)(b) of the Act, DOC, MPI, and Medsafe were informed of the application and given the opportunity to comment.
7. DOC considered that BNT162b2 did not appear to meet the definition of a new organism. MPI stated that it was satisfied that the information presented by the applicant supports the contention that BNT162b2 is not an organism. Medsafe stated that it had no comment on the application.
8. The EPA considered that, for the purposes of section 26(2)(b) of the Act, no other relevant information would be held by other government departments or Crown entities.
9. The Committee began its consideration of the determination on 4 February 2021, and concluded its consideration on 11 February 2021.

Reason for the decision

Interpretation of statutory criteria

10. The Committee recognised that for BNT162b2 to be considered a new organism as defined in section 2A of the Act, it must be considered an organism for the purposes of the Act. Therefore the Committee first considered BNT162b2 with respect to the definition of an organism as set out in the HSNO Act.
11. The Committee noted that section 2 (Interpretation) of the Act provides a list of what is included within the meaning of the term “organism” for the purposes of the Act. The Committee agreed that the descriptions from the list in section 2 that are relevant to this determination concerning viral vectors are:

“(b) includes a micro-organism:”;

“(c) includes a genetic structure, other than a human cell, that is capable of replicating itself, whether that structure comprises all or only part of an entity, and whether it comprises all or only part of the total genetic structure of an entity: and;

“(e) includes a reproductive cell or developmental stage of an organism”

12. The Committee considered that the term “micro-organism” in the context of the Act’s definition of an organism would comprise (amongst others) bacteria, fungi, and viruses. The Committee noted that whether BNT162b2 is a micro-organism is a question of fact for them to determine. The Committee further noted that the description of BNT162b2 as *“highly purified single-stranded messenger ribonucleic acid molecules (mRNAs) encapsulated in lipid nanoparticles²”* bears at least a superficial similarity to viral particles, and considered the plain and ordinary meaning of the term ‘virus’ as “an infective agent that typically consists of a nucleic acid molecule in a protein coat, is too small to be seen by light microscopy, and is able to multiply only within the living cells of a host” (as defined by the Oxford English Dictionary).
13. The Committee noted that BNT162b2 is an artificial mRNA molecule that encodes the amino acid sequence of the SARS-CoV-2 spike protein. The committee considered that, while viruses use host cell functions to reproduce themselves, they contain all the genes necessary to produce new viable viral particles. The Committee further considered that BNT162b2 does not contain any genes allowing its self-replication, nor any genes that would allow it to produce new copies of either the mRNA molecule, or the lipid nanoparticle capsule. The Committee therefore concluded that BNT162b2 cannot be considered to be a virus and, by extension, BNT162b2 cannot be a micro-organism.
14. The Committee also considered whether BNT162b2 would fulfil the description of a “genetic structure ... that is capable of replicating itself”, in terms of part (c) of the ‘organism’ definition in the Act. The Committee noted that the natural meaning of ‘capable’ is that the genetic structure has ‘the ability, fitness, and necessary qualities’ to replicate. Additionally, the term ‘itself’ was interpreted to mean automatically, spontaneously, and with a degree of autonomy. The Committee considered that ‘a genetic structure ... that is capable of replicating itself’ is a genetic structure that has the ability, fitness, and necessary qualities to replicate, and that human intervention is not required for replication to occur.
15. The Committee therefore rejected the notion that BNT162b2 could be considered to be a ‘genetic structure, other than a human cell, that is ‘capable of replicating itself’. This is because the BNT162b2 mRNA molecule only possesses the genetic information to enable the production of the SARS-CoV-2 spike protein, and lacks genes of any kind that would allow the molecule to replicate itself or recreate anything remotely resembling the original vaccine formulation.
16. The Committee further considered description (e) and agreed that BNT162b2 is a genetic structure that is artificially created. Because such an mRNA is constructed so that it can neither replicate itself nor re-form into the structure of the vaccine formulation, it does not constitute “...a developmental stage of an organism”.

Consideration of BNT162b2

17. The Committee determined that because BNT162b2 is not an organism, it cannot be a new organism under the Act.
18. Therefore, the Committee further determined that it was not necessary to consider BNT162b2 against the definition of a new organism (section 2A of the HSNO Act).

²Section 2.1 of the application.

Other matters considered

19. The Committee noted that none of the other definitions of “organism” in the Act are applicable to BNT162b2. Furthermore, no mRNA molecules of any kind have been declared to be organisms for the purposes of the Biosecurity Act 1993.
20. The Committee considered that the modifications made to the chemistry of the BNT162b mRNA molecule relative to a naturally-occurring mRNA, ie the substitution of N1-methylpseudouridine in place of uridine, as well as the two proline codon substitutions, had no bearing on the relevant criteria in the definition of ‘organism’ in the HSNO Act.
21. The Committee noted that there is no other legislation or Order-In-Council that is relevant or applicable to this determination.
22. The Committee acknowledged that the purpose of the Act is to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms. They agreed that the current decision is consistent with the purpose of the Act.

Conclusion

23. In accordance with section 26 of the Act, and having regard to the relevant information, the Committee determined that BNT162b2 (COMIRNATY™) is not an organism, and therefore **is not** a new organism for the purpose of the Act.



11 February 2021

Dr Kerry Laing

Date

**Chair, Decision-making Committee
Environmental Protection Authority**