Environmental Protection Authority
Te Mana Rauhī Taiao

APPLICATION FORM

Section 26 Determination

To obtain a determination of whether an organism is a new organism

Send to Environmental Protection Authority preferably by email (neworganisms@epa.govt.nz) or alternatively by post (Private Bag 63002, Wellington 6140)
Payment must accompany final application; see our fees and charges schedule for details.

Application Number

APP204176

Date

Completing this application form

1. This form is used when you wish to apply for a statutory determination under section 26 of the Hazardous Substances and New Organisms (HSNO) Act 1996 as to whether or not an organism is a new organism (i.e. whether the organism is regulated under the HSNO Act or not).
2. If you wish to make an application for approval of for use of a new organism, a different form will have to be used. All forms are available on our website.
3. It is recommended that you contact an Advisor at the Environmental Protection Authority (EPA) as early in the application process as possible. An Advisor can assist you with any questions you have during the preparation of your application.
4. Unless otherwise indicated, all sections of this form must be completed for the application to be formally received and assessed. If a section is not relevant to your application, please provide a comprehensive explanation why this does not apply. If you choose not to provide the specific information, you will need to apply for a waiver under section 59(3)(a)(ii) of the HSNO Act. This can be done by completing the section on the last page of this form.
5. Any extra material that does not fit in the application form must be clearly labelled and cross-referenced, and included with the application form when it is submitted.
6. Please add extra rows/tables where needed.
7. You must sign the final form (the EPA will accept electronically signed forms) and pay the application fee (including GST) unless you are already an approved EPA customer. To be recognised by the EPA as an “approved customer”, you must have submitted more than one application per month over the preceding six months, and have no history of delay in making payments, at the time of presenting an application.
8. Information about application fees is available on the EPA website.
9. All application communications from the EPA will be provided electronically, unless you specifically request otherwise.

Commercially sensitive information

10. Commercially sensitive information must be included in an appendix to this form and be identified as confidential. If you consider any information to be commercially sensitive, please show this in the relevant section of this form and cross reference to where that information is located in the confidential appendix.
11. Any information you supply to the EPA prior to formal lodgement of your application will not be publicly released. Following formal lodgement of your application any information in the body of this application form and any non-confidential appendices will become publicly available.
12. Once you have formally lodged your application with the EPA, any information you have supplied to the EPA about your application is subject to the Official Information Act 1982 (OIA). If a request is made for the release of information that you consider to be confidential, your view will be considered in a manner consistent with the OIA and with section 57 of the HSNO Act. You may be required to provide further justification for your claim of confidentiality.

Definitions

Genetically Modified Organism (GMO)	Any organism in which any of the genes or other genetic material: • Have been modified by *in vitro* techniques, or • Are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by *in vitro* techniques
New Organism	A new organism is an organism that is any of the following: • An organism belonging to a species that was not present in New Zealand immediately before 29 July 1998; • An organism belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar prescribed as a risk species, where that organism was not present in New Zealand at the time of promulgation of the relevant regulation; • An organism for which a containment approval has been given under the HSNO Act; • An organism for which a conditional release approval has been given under the HSNO Act; • A qualifying organism approved for release with controls under the HSNO Act; • A genetically modified organism; • An organism belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar that has been eradicated from New Zealand; • An organism present in New Zealand before 29 July 1998 in contravention of the Animals Act 1967 or the Plants Act 1970. This does not apply to the organism known as rabbit haemorrhagic disease virus, or rabbit calicivirus A new organism does not cease to be a new organism because: • It is subject to a conditional release approval; or • It is a qualifying organism approved for release with controls; or • It is an incidentally imported new organism

1. Applicant details

1.1. Applicant

Company Name: (if applicable) Pfizer New Zealand Limited

Contact Name: Kristen J. Perry

Job Title: Regulatory Affairs Manager

Physical Address:

Level 1, Suite 1.4
Building B
8 Nugent Street
Grafton
Auckland 1023

Postal Address (provide only if not the same as the physical):

PO Box 3998
Auckland 1140

Phone (office and/or mobile): +61 432 842 877

Fax: +61 295 057 247

Email: RegulatoryAffairs.ANZ@Pfizer.com

1.2. New Zealand agent or consultant (if applicable)

Company Name:

Contact Name:

Job Title:

Physical Address:

Postal Address (provide only if not the same as the physical)**:**

Phone (office and/or mobile):

Fax:

Email:

2. Information about the organism

2.1. Name of organism

Identify the organism as fully as possible

Organism name: **COMIRNATY™ COVID-19 Vaccine (BNT162b2 [mRNA])**

Briefly describe the biological characteristics of the organism:

We seek a determination that the Pfizer/BioNTech COVID-19 Vaccine (BNT162b2 [mRNA]), tradename COMIRNATY™, is not an organism.

BNT162b2 consists of highly purified single-stranded messenger ribonucleic acid molecules (mRNAs) encapsulated in lipid nanoparticles (LNPs) in a buffer solution (see section 3 of the application). The only genetic material contained within BNT162b2 is the nucleoside-modified (N1-methylpseudouridine in place of uridine) mRNA which encodes a single gene, comprising a codon-optimised sequence based on the SARS-CoV-2 surface glycoprotein sequence (see GenBank QHD43416.1) and contains two proline mutations in place of lysine and valine codons. The translated region is flanked by a 5' region to enhance translation and guide translocation and a 3' region comprising a stabilisation element and a poly-adenosine (poly-(A)) tail to increase mRNA stability and enhance translational efficiency.

The mRNA, which is the active component of the vaccine, is unable to self-replicate, but is translated in the cell to produce the SARS-CoV-2 surface glycoprotein (the so-called "spike protein"), which generates an immune response in recipients.

It does **not** meet the definition of an organism (nor of a genetically modified organism) and therefore cannot be considered a new organism under section 26 of the Hazardous Substances and New Organisms (HSNO) Act 1996.

2.2. Regulatory status of the organism

Is the organism that is the subject of this application also the subject of:

An innovative medicine application as defined in section 23A of the Medicines Act 1981?

☒ Yes* ☐ No

* Yes, an innovative medicine application in order to register the vaccine in New Zealand is currently under evaluation by Medsafe. Please note that Pfizer does not consider that the BNT162b2 mRNA is an organism.

An innovative agricultural compound application as defined in Part 6 of the Agricultural Compounds and Veterinary Medicines Act 1997?

☐ Yes ☒ No

3. Evidence regarding whether the organism meets the definition of a new organism

Does the organism meet the definition of a new organism under the HSNO Act?

For example, does it belong to a species that was not present in New Zealand before July 29 1998? Is it a genetically modified organism? etc.

Describe the evidence you have to support this view, providing supporting materials in an appendix as appropriate.

COMIRNATY™ COVID-19 Vaccine (BNT162b2 [mRNA]) is not an organism as defined in the Hazardous Substances and New Organisms Act 1996.

The interpretation of 'organism' is defined in the Hazardous Substances and New Organisms Act 1996 as:
"organism—
(a) does not include a human being:
(ab) includes a human cell:
(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:
(d) includes an entity (other than a human being) declared to be an organism for the purposes of the Biosecurity Act 1993:
(e) includes a reproductive cell or developmental stage of an organism"

COMIRNATY™ COVID-19 Vaccine (BNT162b2 [mRNA]):
(a) Does not include a human being;
(ab) Does not include a human cell (or animal or plant cell);
(b) Does not include a micro-organism (e.g. bacteria or viruses);
(c) Does not include a genetic structure capable of replicating itself*;
(d) Does not include an entity declared to be an organism for the purposes of the Biosecurity Act 1993;
(e) Does not include a reproductive cell or developmental stage of an organism (e.g. sperm, oocytes, embryos);
And is not capable of living, reproducing or germinating.

*The only genetic material contained within BNT162b2 is single-stranded mRNA encoding for the spike protein of SARS-CoV-2 which is unable to self-replicate. There is no other genetic structure or vector present. A further detailed description of the mRNA is appended to this form as this information is considered commercially sensitive and should remain confidential.

4. Checklist

This checklist is to be completed by the applicant

Application		**Comments/justifications**
All sections of the application form completed or you have requested an information waiver under section 59 of the HSNO Act	☒ Yes ☐ No (If No, please discuss with an Advisor to enable your application to be further processed)	
Confidential data as part of a separate, identified appendix	☒ Yes ☐ No	
Supplementary optional information attached:		
• Copies of additional references	☐ Yes ☐ No	
• Relevant correspondence	☒ Yes ☐ No	Australian Office of Gene Technology Regulator (OGTR) email correspondence dated 30 November 2020.
Administration		
Are you an approved EPA customer?	☐ Yes ☒ No If Yes are you an: Applicant: ☐ Agent: ☐	
If you are not an approved customer, payment of fee will be by: • Direct credit made to the EPA bank account (preferred method of payment) Date of direct credit: **To follow** • Cheque for application fee enclosed	☒ Yes ☐ No ☒ Payment to follow ☐ Yes ☐ No ☐ Payment to follow	
Electronic, signed copy of application e-mailed to the EPA	☒ Yes	

Signature of applicant or person authorised to sign on behalf of applicant

☒ I am making this application, or am authorised to sign on behalf of the applicant or applicant organisation.

☒ I have completed this application to the best of my ability and, as far as I am aware, the information I have provided in this application form is correct.

29 January 2021

Signature **Date**

Request for information waiver under section 59 of the HSNO Act

☐ I request for the Authority to waive any legislative information requirements (i.e. concerning the information that has been supplied in my application) that my application does not meet (tick if applicable).

Please list below which section(s) of this form are relevant to the information waiver request:

Appendices and referenced material (if any) and glossary (if required)

Appendix 1: Characteristics of COMIRNATY™ COVID-19 Vaccine (BNT162b2 [mRNA]) under separate cover.

Appendix 2: Determination received via email from the OGTR under separate cover.