

## Darryl Ward

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**From:** Tim Strabala <Tim.Strabala@epa.govt.nz>  
**Sent:** Thursday, 4 February 2021 11:42 am  
**To:** Kerry Laing; Julie Everett-Hincks  
**Subject:** DMC\_Cover\_Letter.docx REF:0526695  
**Attachments:** DMC\_Cover\_Letter.docx

Good morning both,

Please find attached a cover letter with a few explanatory points for the documents you received on Board Books.

Thanks once again for agreeing to consider this application.

Kind regards, Tim

**Tim Strabala, PhD**

Principal Scientist, New Organisms

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## Cover letter – APP204176: Pfizer SARS-CoV-2 vaccine BNT162b2 (COMIRNATY™)

4 February 2021

Dear Kerry and Julie,

The section 26 statutory determination APP204176 to on the new organism status of the Pfizer SARS-CoV-2 vaccine BNT162b2 (COMIRNATY™) is now ready for your review and should now be on Board Books. As I'm sure you're aware, Medsafe granted provisional approval to the vaccine yesterday, February 3, so it would be appreciated if you could let me know your comments as soon as possible. However, there is no statutory time frame regarding a s26 determination.

Because we think this determination is relatively straightforward, and in the interests of expediency, I have provided a draft decision for your perusal. Please note that this is exactly what it is stated to be – a draft – you may alter it as you see fit. I am of course available for a teleconference or a Zoom meeting to discuss the application and advice with you, if you wish. If I receive no comment from either of you regarding the draft decision, I will assume that you find it acceptable in its current form (barring addition of dates and other administrative aspects).

You should have received an e-response form from Matina Ma via a separate email. Please indicate your decision using this form to Matina, also cc'ing me.

Please feel free to contact me directly if you require more information or would like to discuss anything.

Thank you,

**Tim Strabala, PhD**

Principal Scientist, New Organisms



Environmental  
Protection Authority  
Te Mana Rauhi Taiao

[Tim.strabala@epa.govt.nz](mailto:Tim.strabala@epa.govt.nz)

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**From:** Tim Strabala

**Sent:** Thursday, February 11, 2021 12:34 PM

**To:** Julie Everett-Hincks [s 9\(2\)\(a\) OIA](#); Kerry Laing [s 9\(2\)\(a\) OIA](#) Diane Totton  
<Diane.Totton@epa.govt.nz>

**Cc:** Miriam Robertson <Miriam.Robertson@epa.govt.nz>; Christopher Hill  
<Christopher.Hill@epa.govt.nz>; Erina Marwick <Erina.Marwick@epa.govt.nz>

**Subject:** RE: APP20476 - revised draft decision (changes tracked) REF:0596254

Thank you, Julie. Thanks to both you and Kerry for your diligent work on this determination.

Kind regards,

Tim

**Tim Strabala, PhD**

Principal Scientist, New Organisms

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**From:** Julie Everett-Hincks [s 9\(2\)\(a\) OIA](#)

**Sent:** Thursday, 11 February 2021 12:13 pm

**To:** Tim Strabala <[Tim.Strabala@epa.govt.nz](mailto:Tim.Strabala@epa.govt.nz)>; Kerry Laing [s 9\(2\)\(a\) OIA](#) Diane Totton  
<[Diane.Totton@epa.govt.nz](mailto:Diane.Totton@epa.govt.nz)>

**Cc:** Miriam Robertson <[Miriam.Robertson@epa.govt.nz](mailto:Miriam.Robertson@epa.govt.nz)>; Christopher Hill  
<[Christopher.Hill@epa.govt.nz](mailto:Christopher.Hill@epa.govt.nz)>; Erina Marwick <[Erina.Marwick@epa.govt.nz](mailto:Erina.Marwick@epa.govt.nz)>

**Subject:** RE: APP20476 - revised draft decision (changes tracked) REF:0596254

Dear Kerry, Tim and Diane

I have reviewed the attached document pertaining to the Section 26 statutory determination of APP204176.

I accept the changes made herein.

Following the discussion this morning, I have resolved that BNT-162b2 is not an organism as defined by the HSNO Act (s2).

My E-Response is copied here:

**E-RESPONSE**

**APP204176 To determine whether Pfizer SARS-CoV-2 vaccine is a new organisms for the purpose of the HSNO Act.**

I determine that *BNT-162b2 vaccine* is **not a new organism** under section 26 of the HSNO Act.

Kind regards  
Julie

Dr Julie Everett-Hincks

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**From:** Kerry Laing [s 9\(2\)\(a\) OIA](#)  
**Sent:** Wednesday, 10 February 2021 1:25 pm  
**To:** Diane Totton <[Diane.Totton@epa.govt.nz](mailto:Diane.Totton@epa.govt.nz)>; Julie Everett-Hincks [s 9\(2\)\(a\) OIA](#)  
**Cc:** Tim Strabala <[Tim.Strabala@epa.govt.nz](mailto:Tim.Strabala@epa.govt.nz)>  
**Subject:** RE: APP20476 - revised draft decision (changes tracked) REF:0596254

Hi Diane

I am satisfied with the current Decision Report. Subject to hearing Julie's approval, I give approval for the use of my electronic signature.

Kind regards

**From:** Diane Totton [<mailto:Diane.Totton@epa.govt.nz>]  
**Sent:** Wednesday, 10 February 2021 9:47 a.m.  
**To:** Kerry Laing [s 9\(2\)\(a\) OIA](#) Julie Everett-Hincks [s 9\(2\)\(a\) OIA](#)  
**Subject:** FW: APP20476 - revised draft decision (changes tracked) REF:0596254

Good morning Kerry and Julie,

I don't expect that the below link will work for you, so I've attached the decision document for your further consideration.

(I've told Tim many times that he shouldn't work so late but he just won't listen to me.)

Kind regards,

**Diane Totton** (she/her)

Applications Administrator

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**From:** Tim Strabala

**Sent:** Tuesday, 9 February 2021 11:45 pm

**To:** Kerry Laing s 9(2)(a) OIA Julie Everett-Hincks s 9(2)(a) OIA

**Cc:** Diane Totton <[Diane.Totton@epa.govt.nz](mailto:Diane.Totton@epa.govt.nz)>; Miriam Robertson <[Miriam.Robertson@epa.govt.nz](mailto:Miriam.Robertson@epa.govt.nz)>

**Subject:** APP20476 - revised draft decision (changes tracked)

Hello Kerry and Julie,

Please find below the link to the revised draft decision for APP204176, statutory determination regarding the new organism status of the SARS-CoV-2 vaccine BNT162b2. I have tracked Kerry's requested changes for your ease of examination.

[http://epa/edrms/apps-2020/1/APP204176/c/APP204176\\_Decision\\_FINAL.docx](http://epa/edrms/apps-2020/1/APP204176/c/APP204176_Decision_FINAL.docx)

This is an intranet link that cannot be externally accessed.

If you are both satisfied with the way the decision reads in its current form, please simply advise us of that via email. Kerry, if you could also advise that you authorise the use of your electronic signature on the document, then Diane can proceed with preparing the final documents for publication on the EPA website, and initiating processes for publication of the decision in the New Zealand Gazette.

Please note that the determination does not take effect until the Gazette notice is published. This should take place within one or two days after you authorise your decision with us.

Please let me know if you have any further questions or comments.

Kind regards, Tim

**Tim Strabala, PhD**

Principal Scientist, New Organisms

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## Darryl Ward

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**From:** Tim Strabala  
**Sent:** Wednesday, 10 February 2021 2:20 pm  
**To:** Julie Everett-Hincks; Kerry Laing; Diane Totton  
**Cc:** Miriam Robertson; Christopher Hill; Erina Marwick  
**Subject:** RE: APP20476 - revised draft decision (changes tracked) REF:0596254  
**Attachments:** APP204176\_Decision\_FINAL\_changes\_tracked.docx

Hi Julie,

Diane would have sent you this as well, but please find the requested document attached.

Kind regards, Tim

**Tim Strabala, PhD**  
Principal Scientist, New Organisms

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**From:** Julie Everett-Hincks s 9(2)(a) OIA  
**Sent:** Wednesday, 10 February 2021 2:14 pm  
**To:** Kerry Laing s 9(2)(a) OIA Diane Totton <Diane.Totton@epa.govt.nz>; Tim Strabala <Tim.Strabala@epa.govt.nz>  
**Cc:** Miriam Robertson <Miriam.Robertson@epa.govt.nz>; Christopher Hill <Christopher.Hill@epa.govt.nz>; Erina Marwick <Erina.Marwick@epa.govt.nz>  
**Subject:** Re: APP20476 - revised draft decision (changes tracked) REF:0596254

Dear Tim

Can you please email the document to me, with Kerry's changes? I am unable to access the document through the link provided.

Many thanks

Julie

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