

# Official Information Act Request

## Requester's details

**Date:** 14 August 2023

**Name:** Chris McCashin

**Email:** [fyi-request-23558-34853b64@requests.fyi.org.nz](mailto:fyi-request-23558-34853b64@requests.fyi.org.nz)

**Reference number:** ENQ-46512-V1G5K2

Tēnā koe Chris

I refer to your request, which was transferred to the Environmental Protection Authority (EPA) on 7 August 2023. You have asked for:

Covid-19 Vaccine Approval. Please provide the following:

- Pfizer application to ERMA per the HSNO Act
- Approval / reporting documents

The information you have requested concerns the BioNTech/Pfizer SAR-CoV-2 vaccine BNT162b2 (COMIRNATY™).

The Environmental Risk Management Authority (ERMA) was the predecessor of the EPA. The EPA is now responsible for regulating new organisms under the Hazardous Substances and New Organisms Act 1996 (HSNO Act). If a vaccine contains a new organism or a genetically modified organism, it must be approved by the EPA for release into the environment.

The Determination request, the EPA Staff Assessment, and the Decision document for BNT162b2, may all be found at the following link, under the 'Application Documents' heading: [HSNO application register | EPA](#)

Further information describing the characteristics of the BioNTech/Pfizer vaccine, and the regulatory role of the EPA is available here: [The spike protein and the Pfizer vaccine | EPA](#)

I hope this information is helpful. You have the right to seek an investigation and review by the Ombudsman of this decision. You can contact the Ombudsman on 0800 802 602, or by email at [info@ombudsman.parliament.nz](mailto:info@ombudsman.parliament.nz)

If you have any further queries, please do not hesitate to contact us via [ministerials@epa.govt.nz](mailto:ministerials@epa.govt.nz)

We may publish your request and our response on our website, [www.epa.govt.nz](http://www.epa.govt.nz). 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.

Nāku noa nā

A handwritten signature in blue ink that reads "Chi Hill". The signature is written in a cursive, flowing style.

Dr Christopher Hill

**General Manager, Hazardous Substances and New Organisms**