

Official Information Act Request

Requester's details

Date: 2 December 2021

Name: [REDACTED]

Email: [REDACTED]

Reference number: ENQ-42912-Y9M7R9

Dear [REDACTED]

I refer to your requests for information to the Ministry of Health and Crown Law, which were each partially transferred to the Environmental Protection Authority on 9 November and 12 November 2021 respectively. You have requested the following information:

Transferred from Ministry of Health

6 Medsafe states if any "COVID-19 vaccines arriving into New Zealand contain a new organism, the Environmental Protection Authority (EPA) will be involved. They'll need to approve the import, development and field testing or release under the Hazardous Substances and New Organisms Act 1996 (HSNO Act).

7 Was EPA involved? (The same question was also transferred from Crown Law.)

10 Did EPA review the Pfizer safety data on each ingredient as they may have been approved by the American FDA or other regulatory bodies where the NZ imported Pfizer was manufactured?

Transferred from Crown Law

11 Are there any plans to review this retrospectively under proposed amendment to the Hazardous Substances and New Organisms Act 1996 currently before the house. Has this review considered or altered following the finding in US Senate that Covid Virus may have originated from laboratory involved in gain of function which in this context is defined as genetically grafted spike proteins — the viral keys that grant access to mammalian cells — from eight different, naturally occurring coronaviruses onto another coronavirus from the wild, called WIV1. — the widely expressed ACE2 receptor — that is used by SARS-CoV and SARS-CoV-2.

15 EPA has a rapid approval pathway for any vaccines that are, or contain, new organisms which includes genetically modified organisms. They can look at applications at pace where needed and are working with Medsafe and the Ministry for Primary Industries (MPI) in preparation for the vaccines. What was the scientific basis for this and are there any plans to approve this with retrospective legislation,

specifically the Hazardous Substances and New Organisms Act 1996 (HSNO Act) as it is being amended (2020) and is currently before parliament procedures?”

The information you have requested is below.

Transferred from Ministry of Health

6 This statement is correct.

7 While this is correct, EPA was involved only in making a statutory determination under section 26 of the Hazardous Substances and New Organisms Act (the HSNO Act) that the Pfizer/BioNTech vaccine was not an organism, and therefore was not subject to regulation as a GMO under the HSNO Act.

10 The Pfizer vaccine was not assessed for classification as a hazardous substance under the Hazardous Substances and New Organisms Act 1996 (the Act) because human medicines are exempt from the hazardous substances provisions of the Act, as per clause 6 of the Hazardous Substances (Hazard Classification) Notice 2020:

https://gazette.govt.nz/assets/pdf-cache/2020/2020-au4842.pdf?2020-12-17_22%3A50%3A42=.

Transferred from Crown Law

11 We understand that the Ministry for the Environment will be responding to this question, as that is the agency responsible for policy and for legislative changes.

15 We understand that the Ministry for the Environment will be responding to this question, as that is the agency responsible for policy and for legislative changes.

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

If you have any further queries, please do not hesitate to contact us via ministerials@epa.govt.nz

We may publish your request and our response on our website, 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.

Yours sincerely



Dr Christopher Hill
General Manager, Hazardous Substances and New Organisms