

22 April 2026

Ref: OIA 26063

Nigel Gray

fyi-request-34273-xxxxxxx@xxxxxxx.xxx.org.nz

Tēnā koe Nigel

I refer to your request for official information received on 27 March 2026:

1. Definitions used by your agency

Please provide the formal definitions, criteria, or internal guidance your agency uses when describing any product, substance, or intervention as:

“safe”

“effective”

“safe and effective”

This includes any internal documents, briefing notes, communication guidelines, or risk-communication frameworks that define or guide the use of these terms.

2. Application of these terms to vaccines

Please provide all documents, advice, or communication guidelines that informed the use of the phrase “safe and effective” (or equivalent wording) in relation to COVID-19 vaccines.

3. Application of these terms to sodium fluoroacetate (1080)

Public-facing material produced by government agencies has described 1080 using the terms “safe”, “effective”, or “safe and effective”. Please provide any documents, advice, or communication guidelines held by EPA that relate to the use of these terms in connection with sodium fluoroacetate (1080), including any internal discussions or advice provided to other agencies.

4. Consistency of terminology

Please provide any documents, emails, or internal discussions that address: whether the criteria for “safe” and “effective” are applied consistently across different substances or interventions, and whether different thresholds or standards are used when applying these terms to vaccines versus hazardous substances such as 1080.

5. Risk-communication considerations

Please provide any internal risk-communication assessments, reviews, or discussions relating to:

the appropriateness of using the phrase “safe and effective” for COVID-19 vaccines, and

the appropriateness of using the terms “safe”, “effective”, or “safe and effective” in relation to 1080.

In response to questions 1 to 5, I am refusing your request under section 18(e) of the Official Information Act 1982 – EPA documents containing the information requested do not exist. The Environmental Protection Authority (EPA) does not have:

- any internal guidance, formal definitions or criteria relating to the terms “safe”, “effective” or “safe and effective”, or their use (question 1);
- any documents that relate to use of these terms in regards to vaccines (question 2) or 1080 (sodium fluoroacetate)(question 3);
- any documents relating to consistency of terminology (question 4); or
- any documents relating to appropriate use of the specified terms (question 5).

The EPA has granted approvals for the environmental release of certain vaccines and treatments. These approvals were issued under the provisions of section 381(4)(a) of the HSNO Act. These assessments are carried out from an environmental exposure perspective. The EPA cannot take into account any effect of a medicine on its recipient(s) in its determination of the application.

The EPA also undertook a statutory determination of the Pfizer SARS-CoV2 vaccine because it contains *in vitro*-manipulated nucleic acids, which is part of the definition of a genetically modified organism in the HSNO Act. The EPA determined that the vaccine was not an organism as defined the HSNO Act, and therefore no EPA approval was required. Safety and effectiveness of the vaccine were not considered, because they are beyond the scope of the statutory determination process.

Information on the use of 1080 (sodium fluoroacetate) is available on the EPA website: [1080 – use, rules, monitoring and research](#), and also includes links to the 2007 reassessment. Hazardous substance approvals under the HSNO Act are based on whether any risks of adverse effects can be sufficiently managed so that the positive effects associated with use of a substance outweigh the associated negative effects.

You have the right to seek an investigation and review by the Ombudsman of this decision under section 28(3) of the OIA. 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.

Nāku noa nā

A handwritten signature in black ink, appearing to read 'Fernando Torres-Vélez', with a long horizontal flourish extending to the left.

Fernando Torres-Vélez

General Manager, Hazardous Substances and New Organisms