Environmental Protection Authority
Te Mana Rauhī Taiao

Official Information Act Request

Requester's details
Date: 13 May 2021
Name: [redacted]
Email: [redacted]
Reference number: ENQ-41366-T9H9F5

Dear [redacted]

Thank you for your request received on 20 April 2021 for the following information:

> "(1) process taken, the information required and the criteria to be met at the "Assess Risks" stage of an application under the rapid pathway application process.
>
> (2) process taken, the information required and the criteria to be met at the "Risk Assessment" stage of an an application under the notified application process."

The Environmental Protection Authority (EPA) undertakes risk assessments for both the rapid pathway process and notified application process for the release of new organisms. The processes for applications to release new organisms will differ depending on the complexity and nature of the application and how much information is provided by the applicant. Both types of application can be very applicant-driven. The generic process for risk assessment for both types of applications is set out below.

During the pre-application stage, the New Organisms team liaises with the potential applicant about the request and the organism(s) involved, and provides information about pathway(s) under the Hazardous Substances and New Organisms Act 1996 (the Act).

The New Organisms team will also review draft applications, scientific literature on the organism(s) and research other information that may assist in the risk assessment stage for both types of applications.

Where areas of uncertainty exist, the New Organisms team will seek more information from the applicant. The information sought will be in line with the scope and requirements of the Act. This is to ensure that the applicant has a consolidated evidence-based case, with the least amount of uncertainty regarding scientific facts.

Rapid pathway application ‘assess risks’

Applications under the rapid pathway are measured against section 35 of the Act. They are required to satisfy sections 35(2) of the Act to continue under the rapid pathway and the minimum standard described in section 36 of the Act to be approved for release. If an application does not satisfy sections 35(2) of the Act they can still proceed under the notified application process.

Below is a link to section 35 of the Act.

https://www.legislation.govt.nz/act/public/1996/0030/latest/DLM383526.html

The decision on an application that has been formally received is required within 10 working days. The final decision is made by the General Manager, Hazardous Substances and New Organisms. The risk assessment is undertaken during this 10 working day period.

The risk assessment for a rapid pathway application involves assessing the organism(s) against section 35 and 36 of the Act and incorporating the views of the Ministry for Primary Industries (MPI) and the Department of Conservation (DOC). The application must provide relevant information to satisfy all criteria set out in section 35 and 36 of the Act to be approved under the rapid release pathway.

Below is a link to section 36 of the Act.

https://www.legislation.govt.nz/act/public/1996/0030/latest/DLM383527.html

Notified application process ‘risk assessment’

A notified application needs to satisfy the criteria set out in section 38(1)(a) of the Act.

Below is a link to section 38 of the Act.

https://www.legislation.govt.nz/act/public/1996/0030/latest/DLM383529.html

During the pre-application stage the New Organisms team will review the information provided by the applicant against section 36 of the Act. They will also undertake an assessment of the risks and benefits of the matters relevant to the purpose of the Act that are set out in section 6 of the Act.

Below is a link to section 6 of the Act.

https://legislation.govt.nz/act/public/1996/0030/latest/DLM382993.html

The notified application process will involve a public consultation period which will last for 30 working days. If a submitter asks to be heard then a public hearing will be arranged. The applicant, the EPA and submitters are then given the opportunity to present their evidence

and whether they are in support or opposition to the release of the organism(s) in front of the Decision-making Committee (DMC).

Once the hearing has concluded the DMC will convene and decide if the organism(s) have met the minimum standards as set out in section 36 of the Act and whether the benefits of the release will outweigh the risks or costs as set out in section 38 of the Act. They will then make the final decision on the application.

If you would like to discuss application processes further, you are welcome to contact the Manager, New Organisms Applications.

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 will publish your request and our response on our website, www.epa.govt.nz, within 10 working days from today. 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

Chris Hill
General Manager,
Hazardous Substances and New Organisms