File ref: APP204199

12 July 2021

Sally Anderson

[redacted]

Private Bag 63002
Wellington 6140, New Zealand

Level 10, Grant Thornton House
215 Lambton Quay
Wellington 6011, New Zealand

epa.govt.nz
+64 4 916 2426

Dear Sally,

Request for further information and consent for timeframe waiver for diazinon, fenamiphos and methamidophos reassessment (APP204199)

Thank you for your application to reassess diazinon, fenamiphos and methamidophos (reference number APP204199). This application was formally received on 01 July 2021.

The Environmental Protection Authority (EPA) is finalising the pathway and notification status for this reassessment application.

The EPA requests further information to be provided for the application and seeks your consent to waive the timeframe to commence public notification (under sections 52 and 59 respectively, of the Hazardous Substances and New Organisms Act; “the Act”).

Purpose of reassessment

The EPA understands that your desired outcome of the reassessment is to change the current date of expiry for the time limited approvals for substances containing diazinon, fenamiphos, and methamidophos.

We note that the basis for this request is that you consider that the generation of alternative substances to replace the affected substances, as envisioned in the previous reassessment APP201045, has not occurred. As such, we note that you consider that the associated decline in benefits associated with these substances has not occurred.

Therefore, you are seeking a reassessment of the benefits assessment with an aim to extend the existing expiry date of approvals a further 10 years from their current date.

Request for further information

Your application form included information in each of the required sections and so is considered mechanically complete. This check allowed your application to be formally received.

The completed form, however, did raise several questions that will need to be addressed for the EPA to complete a thorough evaluation of your application (and proposals), and to provide interested parties with sufficient information to make informed submissions. As such, the EPA requests the information below be provided under section 52(1) of the Act.

To allow the EPA to continue processing your application in a timely manner, please provide this additional information, if it is already accessible or can be easily acquired, within four weeks of this letter; that is, before the end of business on 06 August 2021. However, if you will not be able to provide the requested information within this timeframe, please advise the EPA by 5pm on 23 July 2021 and propose an alternate date. The EPA may progress your application after four weeks (or the mutually agreed alternative) on the

basis of information available at that time. If the requested information is not provided, any uncertainties and data gaps may affect the evaluation of your application.

The following questions (and associated points) should be addressed in the response to this information request.

1. **Please provide a review of any new information relating to the adverse effects and international regulatory changes.**

   The application does not provide any information to support the proposal that the risk assessment from the previous reassessment remains valid and that further assessment of the risk is not required. Part of the evaluation process is to compare the risks and benefits of the affected substances. As such, it is important that up-to-date risk information is provided to the decision makers.

   Please provide a review of any new information relating to the adverse effects (including risks) and international regulatory change regarding the use of diazinon, fenamiphos, and methamidophos which has become available since the previous reassessment of these substances (that is, July 2013).

2. **Please explain why the requested extension should not apply to all substances containing the active ingredients in question.**

   The application includes a request not to include a number of substances identified in the grounds decision in the reassessment application, citing that these substances are not associated with any registered substances. Approvals are not associated with a specific product or registrant, and new products could be registered against any of these approvals.

   If it is essential to extend the approval period for diazinon, fenamiphos, and methamidophos to retain the use of these substances, why doesn't this extend to all available approvals for these substances?

3. **Why is there an apparent low proportion of registered substances containing these actives?**

   There is a significant number of approvals containing the three active ingredients which are not in use (that is, do not have products registered against them). The proportion of unused approvals could suggest a low and/or decreasing reliance on these substances and shift to alternative insecticides.

   It would be useful if you could provide comments or information regarding why there is an apparent low proportion of registered substances containing these actives.

4. **What is the impact in limiting the uses of these substances to identified critical uses? Are there alternatives to these critical uses?**

   If specific use patterns are the critical factor in retaining these substances, what would be the impact in limiting the uses of these substances to those critical uses only? Which current use patterns could be replaced by existing alternative substances if a risk-benefit assessment was to result in reduced approved use patterns?

   Please provide a comprehensive review of the availability of different alternatives for each critical use noted in the reassessment application. It is suggested that this be presented to focus on the critical use patterns and what substances are available for them, rather than what use patterns are covered by each individual substance. This will provide clarity on which individual use patterns remain reliant on the continued use of diazinon, fenamiphos, and methamidophos, which use patterns have some alternatives and which can be fully replaced by alternative substances.

5. What are the benefits and costs associated with diazinon, fenamiphos, and methamidophos?

Please provide an updated assessment of the benefits of diazinon, fenamiphos, and methamidophos. It would be useful if you could incorporate an economics assessment including, where possible, any information on impacts at a regional level.

In addition, please provide an assessment of the effects of diazinon, fenamiphos, and methamidophos being unavailable.

6. Why is a longer extension of diazinon substances appropriate?

Please provide information to support the proposed longer extension of diazinon substances relative to the other two active ingredients. There are multiple factors that should be addressed here:

a. Why is a review of diazinon appropriate at this point?

Significant time is still available on the current approval time frame for diazinon substances. Please justify why a review is appropriate at this point.

Please include information to support your proposal that there will not be significant development to replace diazinon substances in the remaining interim period.

b. Why is a later date appropriate?

The application notes the timeframes for a number of research programmes as supporting information towards a proposed date of 2033 for substances containing fenamiphos and methamidophos. However, no information is provided to support extending diazinon approvals for a further 5 years, that is until 2038. Please provide information to support your proposal for a later phase-out period for diazinon relative to those for fenamiphos and methamidophos?

7. What are the effects of the proposed changes on Māori, their culture and traditions, and the principles of Te Tiriti o Waitangi?

The application form states that you provided the Kura Kaupapa Taiao team with a copy of the application form to circulate but does not provide evidence of any direct engagement with Māori by you, the applicant, having taken place so far as part of this application. Has any direct engagement been conducted as part of this application, including discussions with Māori vegetable grower groups?

Following this consultation, please provide an assessment of the effects of the proposed changes in the reassessment on Māori, te ao māori, and wahi tapu. Consideration should be given to section 5(b), section 6 (d) and section 8 of the Act ensuring the following aspects are addressed:

a. Impact on the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social, and cultural well-being
b. Impact on the relationship of Māori and their culture and traditions with their environment and taonga
c. Ngā Matapono o Te Titriri o Waitangi (Treaty of Waitangi principles)

Information provided in response to this information request will form part of your application, and as such, will be made publicly available. Information you consider to be confidential must be clearly identified, and the reasons for withholding the information from public release provided to the EPA (see sections 55 to 57 of the Act).

In accordance with section 52(2) of the Act, if you do not provide the requested information within one year of this request, your application shall lapse.

Consent for time waiver

The EPA seeks your consent to waive the timeframe for the commencement of public notification of application APP204199, as per section 59 of the Hazardous Substances and New Organisms Act. This waiver relates to the application to reassess diazinon, fenamiphos and methamidophos.

The EPA requests that the date for the commencement of public notification be postponed to allow for further information to be sought, reviewed, and included as part of the application form. This further information will then form part of your application.

Section 59(4) of the HSNO Act provides that we must not extend a time period or waive a time requirement unless we are satisfied that:

a) the applicant and the persons making submissions (if applicable) consent to that waiver; or

b) any of those parties who have not so consented will not be unduly prejudiced.

Pursuant to this section, the EPA seeks your consent to waive the timeframe above.

If you consent, please provide your consent by email. If you do not consent, please provide the reasons why you think you are unduly prejudiced by this waiver. Your response is required by 15 July 2021.

In line with section 59(5) of the HSNO Act, if you consent to the timeframe waiver, the statutory commencement of the public notification timeframe will be waived, and the EPA will proceed with the application as soon as practicable.

If consent is not obtained, the EPA has the ability to decide to waive this timeframe pursuant to s59(4)(b) if it considers that the waiver will not unduly prejudice parties to the application.

Please contact [redacted] on [redacted] or [redacted] if you wish to discuss this timeframe waiver or any other part of the application process further.

Yours sincerely

Dr Clark Ehlers
Hazardous Substances Reassessments Manager