Environmental Protection Authority
Te Mana Rauhī Taiao

Summary of HS application **APP204042** and Submission guidance

Date Submissions Open:	17 November 2021
Date Submissions Close:	26 January 2022
Application number:	APP204042
Purpose:	To import or manufacture Xivana for release
Applicant:	Bayer New Zealand Limited
Application Lead:	Regis Lapage

Purpose of this document

On 4 September 2020, the Environmental Protection Authority (EPA) received an application from Bayer New Zealand Limited seeking to import or manufacture Xivana for release. This substance is intended to be used as a fungicide for the control of downy mildew in onions and late blight in tomatoes and potatoes.

This application is being publicly notified to enable the public to comment and to put all relevant information before the Decision makers.

The purpose of this document is to summarise the application and to provide guidance on the submission process.

Application summary

This document has been prepared by EPA staff as a summary of the information provided in the application and the draft science memorandum, to aid submitters in preparing a submission. The final science memorandum will be completed at a later date using information from the submissions and other relevant sources.

Submission process

This document also provides guidance to the submission process. The EPA encourages all submissions. The submission period for this application will start on Wednesday 17 November 2021 and will end on Wednesday 26 January 2022 at 5pm.

In a submission you can provide information, make comments and raise issues. In this way, you contribute to the EPA decision making process on specific applications. We are particularly interested in hearing from you on the following matters:

- Adverse effects, especially adverse effects not identified in the application[1]; and
- Positive effects, especially positive effects not identified in the application[2].

Further information on the purpose of submissions is available from the EPA website using the link below: https://www.epa.govt.nz/public-consultations/.

If you have any questions, you can contact:

- The applicant directly for any question you may have on the technical information in the application or the information provided to the EPA.
  The applicant representative, Sekove Tinalevu, can be contacted by e-mail (sekove.tinalevu@bayer.com) or by phone (09 4418506).
- The EPA for any question on the application and/or submission process. The Application Lead, Régis Lapage, can be contacted by e-mail (regis.lapage@epa.govt.nz) or by phone (+64 4 474 5511).

[1] Adverse effects can include any risks and costs associated with release of the substance.
[2] Positive effects can include any benefits associated with release of the substance.

Application summary

1. Bayer New Zealand Limited has applied to import or manufacture Xivana for release. Xivana is a fungicide containing 20 g/L fluoxapiprolin as a suspension concentrate for the control of downy mildew in onions and late blight in tomatoes and potatoes.

Intended uses

2. Xivana is a fungicide intended to be applied at key growth stages. The applicant seeks for Xivana to be approved for ground-based and aerial application. The intended maximum application rate is 1 L/ha (20 g a.i/ha) with a maximum frequency of three applications per season with a minimum of interval frequency of 7 days between applications.

Regulatory history

3. Fluoxapiprolin is not currently approved in New Zealand. No overseas jurisdictions have approved this active ingredient.

Hazardous properties

4. The EPA determined the following hazard classifications for Xivana:

Hazard class/subclass	GHS Classification
Contact sensitisation	Category 1B
Aquatic ecotoxicity – Chronic	Category 3

Risk assessment

5. An assessment of the risks to human health and the environment from the use of fluoxapiprolin and Xivana was undertaken, and full details can be found in the draft Science Memorandum. The overall conclusions of the risk assessment are presented below.

Human health effects

6. It is considered that the risks to human health from the proposed use of Xivana are acceptable with the use of appropriate Personal Protective Equipment (PPE). There is no need to apply a re-entry interval control, or a need for buffer zone to protect bystanders. The expected concentration in groundwater is below the level of concern in relation to human drinking water consumption.

Environmental effects

7. Overall, based on the available data, the risk assessment demonstrates risks to be acceptable to the environment from the proposed use of Xivana as the chronic risks to aquatic organisms, soil organisms, terrestrial vertebrates and invertebrates were below the level of concern, and any risks are negligible.

Māori Impact Assessment

8. Kaupapa Kura Taiao (The EPA's Māori Policy and Operations team) has undertaken a Māori impact assessment to consider potential impacts of the application on the economic, social and cultural well-being of Māori, and the relationship of Māori with the environment, pursuant to sections 5(b), 6(d) and 8 of the HSNO Act. Full details can be found in the Māori Impact Assessment. The overall conclusions of this assessment are presented below.

9. This application is not likely to adversely affect the ability and capacity of Māori to maintain their economic, social and cultural wellbeing.

10. This application is not likely to adversely affect the relationship of Māori and their culture and traditions with their environment and taonga, including culturally significant species, resources, and places, and the customary values, practices and uses associated with this taonga.

Controls

Prescribed controls

11. The hazard classifications of Xivana determine a set of prescribed controls specified by the EPA Notices. There are also requirements in the Health and Safety at Work (Hazardous Substance, HSW (HS)) regulations under the HSW Act.

12. The prescribed controls set the baseline for how the substance should be managed and include specifications on how the substance is to be packaged, labelled, stored, disposed of, transported, handled and used. The prescribed controls also set information requirements (e.g. Safety Data Sheets), signage and emergency management.

13. The Hazardous Substances Labelling, Safety Data Sheet, Packaging, Disposal and Hazardous Property Controls (HPC) Notices Part 1, Part 3, Part 4A and Part 4B 2017 apply to Xivana.

Additions and variations to prescribed controls

14. The following additional controls or modifications to the EPA notices are proposed under section 77 and 77A of the Act to manage the risks of use of Xivana.

Maximum application rate

15. The maximum application rate for Xivana is 20 g fluoxapiprolin/ha with a maximum of three applications per year and a minimum interval of seven days between applications.

Benefits

16. The following is a summary of the applicant's overall evaluation of the benefits associated with the release of Xivana:

    - Additional choice for farmers
    - High level of efficacy on onions, tomatoes and potatoes
    - Level of residues on treated crops expected to be below limit of quantification (LOQ)
    - Lower hazard profile compared to other fungicides with the same use pattern

17. For greater detail, please refer to the application form.

Please let us know whether you consider that there are additional adverse effects that we should be aware of, or additional information related to the described effects.

When identifying adverse effects, it is important that you provide us with reasons as to:

- What other adverse effects are ***likely*** to be caused by the use of Xivana
- How ***likely*** these adverse effects are and their potential scale
- How you think the adverse effects could happen (i.e. the series of events that would have to happen for the adverse effects to occur)
- Options and proposals for managing the adverse effects
- Any uncertainty you have on the scope of the information we will use to assess the adverse effects.

Please let us know whether you consider that there are additional positive/beneficial effects that we should be aware of, or additional information related to the described effects.

When identifying positive/beneficial effects, it is important that you provide us with information on:

- Other positive effects ***likely*** to be caused by the use of Xivana
- How ***likely*** these positive/beneficial effects are and their potential scale
- How you think the positive/beneficial effects could happen (i.e. the series of events that would have to happen for the positive/beneficial effects to occur)
- Options and proposals for ensuring the positive/beneficial effects occur, and
- Any uncertainty you have on the scope of the information used to assess the positive/beneficial effects.

Other information

18. If there is other information you wish us to be aware of, please also include this in your submission.

Draft Science Memorandum

19. Interested parties can view the draft Science Memorandum to inform their submission on this application. The draft Science Memorandum outlines the detailed environmental and human health risk assessment of Xivana, carried out by the EPA.

20. The draft Science Memorandum will be finalised after the public consultation, if required.

Making a submission

What is a submission?

We encourage anyone to make a submission, regardless of how much detail you are able to put into it. In your submission, you can also request a hearing if you would like to strengthen your views in person before the Decision-making Committee.

Submissions are publicly available and will be displayed on the application web page after submissions close. If you have confidential information you wish to provide, please contact the Application Lead, Régis Lapage, can be contacted by e-mail (regis.lapage@epa.govt.nz) or by phone (+64 4 474 5511).

How to make a submission?

The EPA website provides guidance on how to make a submission. This is preferably done via the EPA submission form but may be sent as a letter or email to the EPA. This information and the submission form can be accessed from the EPA website using the link below:

https://www.epa.govt.nz/public-consultations/how-to-make-a-submission/

What happens after you make a submission?

When the submission period closes, all submissions will be summarised and made available to the Decision-making Committee together with the EPA Staff Assessment Report.

You are entitled to bring witnesses who may speak to your submission at a hearing. If you choose this option, you should provide the EPA with a list of the witnesses, their areas of expertise, and the elements of the submission or application they will talk to.

You are also entitled to speak at the hearing in one of the three official languages of New Zealand: English, Māori or New Zealand Sign Language. Please advise the Application Lead at least two weeks prior the hearing in order for the EPA to organise for an interpreter. The Application Lead, Régis Lapage, can be contacted by e-mail (regis.lapage@epa.govt.nz) or by phone (+64 4 474 5511).

At least two weeks prior to the hearing, both the applicant and submitter(s) need to provide the EPA with copies of any information they intend to present at the hearing.

A decision will be made by the Decision-making Committee at the end of the consideration period. This will be made public on the EPA website.