Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

1 NOVEMBER 2021

Summary

Substance	Kenja
Application code	APP204047
Application type	To import or manufacture for release any hazardous substance under Section 28 of the Hazardous Substances and New Organisms Act 1996 (“the Act”)
Applicant	ISK New Zealand Limited
Purpose of the application	To import or manufacture Kenja for release
Considered by	A Decision-Making Committee of the Environmental Protection Authority (“the Committee”): Dr Kerry Laing (Chair) Dr Julie Everett-Hincks Dr Stephen Tredwell
Decision	**Approved with controls**
Approval code	**HSR101512**
Hazard classifications	Hazardous to the aquatic environment Chronic Category 3, Hazardous to soil organisms

Application dates	
Date application formally received	12 October 2020
Submission period	6 July 2021 – 17 August 2021
Consideration date	28 September 2021
Date decision signed	1 November 2021

1. Application context

Background

1.1. The applicant, ISK New Zealand Limited, submitted an application on 21 May 2020 to import or manufacture Kenja for release into New Zealand. It was given application number APP204047 and was formally received on 12 October 2020 as a notified Category C application.

1.2. Kenja is a suspension concentrate (SC) containing 400 g/L isofetamid as the active ingredient, plus other components.

1.3. Isofetamid is a new active ingredient in New Zealand, however, it is approved in Australia, Europe, Canada, Japan and the United States of America.

1.4. Kenja is intended to be used as a fungicide for the control of botrytis and powdery mildew in grapes. The applicant has proposed an application rate of 0.15 kg of isofetamid per hectare (equivalent to 0.375 L of Kenja per hectare), with a maximum frequency of 2 applications per season and a minimum of 10 days apart. The applicant sought to have Kenja approved for ground-based application methods only.

Process, consultation and notification

Application receipt

1.5. The application was formally received on 12 October 2020 under section 28 of the Act.

Notification to government departments

1.6. The following government departments were notified of the application and notified of the consultation period on 6 July 2021: the Ministry for the Environment, the Agricultural Compounds and Veterinary Medicines (ACVM) group of the Ministry for Primary Industries, and the Department of Conservation. No comments or submissions on the application were received from these parties.

1.7. WorkSafe New Zealand (“WorkSafe”) is the agency responsible for overseeing the Health and Safety at Work Act 2015 (HSW Act) and the Health and Safety at Work (Hazardous Substances) Regulations 2017 (HSW (HS) Regulations). Advice was sought from WorkSafe in order to receive their assessment on aspects of this application related to the HSW Act and the HSW (HS) Regulations.

1.8. WorkSafe noted that as Kenja is only classified as a Class 9 substance, the HSW (HS) Regulations do not apply. WorkSafe was provided with a quantitative human health risk assessment for this substance, undertaken by the EPA, and no significant health and safety issues were identified. The full advice is available in a separate report provided by WorkSafe.

Public consultation

1.9. This application was publicly notified under section 53(2) of the Act, and public submissions were sought from 6 July 2021 to 17 August 2021. The EPA did not receive any submissions on the application.

Timeframe waiver

1.10. The timeframe for the opening of the public consultation was waived on 12 October 2020 under section 59 of the Act to allow preparation of the draft Science Memorandum, which contains the EPA risk assessment, in order to allow any potential submitter to have this document at their disposal for making an informed submission.

Submissions

1.11. No Submissions were received.

Hearing

1.12. As no submissions were received, no hearing was held.

Legislative criteria for the application

1.13. The application was considered in accordance with section 29 of the Act, taking into account other relevant sections of the Act, the EPA Notices, the HSW Act and HSW (HS) Regulations and the Hazardous Substances and New Organisms (Methodology) Order 1998.

2. The EPA Staff Report

2.1. The Staff Report is the EPA review of the application and available information. It provides information to assist the Committee's decision-making process.

2.2. The EPA identified the classifications and properties of the active ingredient, isofetamid, in Kenja based on toxicological and ecotoxicological studies conducted with this active ingredient. The EPA then identified the classifications of the substance Kenja, which are based on formulation data, the composition of the substance, and the properties of its components.

2.3. The EPA conducted quantitative human health and environmental risk assessments. These assessments considered the exposure and subsequent effects on people and the environment throughout the import and use phases of the life cycle of the substance. Based on all the available information, the EPA assessed the potential risks the substance may pose to the environment, human health, the relationship of Māori to the environment, society, community and to the market economy.

2.4. The EPA also considered whether there were benefits associated with the use of the substance.

2.5. The EPA identified a suite of prescribed controls based on the hazard classifications of Kenja and considered variations to these controls, and the addition of extra controls, in accordance with sections 77 and 77A of the Act.

2.6. The EPA Staff Report (dated September 2021) concluded that there was sufficient information available to assess the application to import or manufacture Kenja for release. The Staff Report also concluded that, with the proposed controls in place, the risks to human health and the environment from the importation, manufacture and use of Kenja would be negligible; and that the benefits of using Kenja would be significant.

2.7. The EPA Staff Report concluded that with the proposed controls in place, the benefits of the substance would outweigh the risks of the substance.

3. Consideration

3.1. The application was considered by the Committee on 28 September 2021, following the decision pathway (available in Appendix B).

3.2. The following information was considered by the Committee:

- the application form and its confidential appendices, including over 100 studies
- the Science Memorandum
- the Staff Report
- the WorkSafe assessment report
- the Cultural Risk Assessment

3.3. The Committee considered that it had received sufficient information to proceed with its consideration of the application. Further comments on different aspects of this information can be found in the following sections.

Hazard classifications

3.4. The Committee adopted the hazard classifications for Kenja as recommended in the Science Memorandum, based on the information provided by the applicant and on other available information as documented in the Science Memorandum. The EPA classifications differed slightly from those proposed by the applicant (see Table 1).

Table 1: Hazard classifications of Kenja

Hazard class	Applicant classification (HSNO)	EPA classification (GHS)
Hazardous to the aquatic environment	9.1D (fish) 9.1C (Daphnia) 9.1D (algae)	Hazardous to the aquatic environment Chronic Category 3
Hazardous to the terrestrial environment	No	Hazardous to soil organisms

Risk assessment

3.5. The Committee took into account the EPA risk assessment for Kenja as detailed in the Science Memorandum. The key points are summarised below.

3.6. The risk assessment covered the import and use phases of the life cycle of the substance, including import, packaging, transport, storage, use and disposal.

3.7. The overall risk and benefit assessment:

- considered the risks posed by Kenja;
- determined whether the risks are outweighed by the benefits;

- determined whether any variations or additions to the prescribed controls are required to manage the risks of this substance, and identified controls that may not be applicable or necessary that can, therefore, be deleted.

Risks during importation, manufacture, transportation, storage and disposal

3.8. The applicant intends to import Kenja packaged in bulk containers. Kenja will then be repackaged and relabelled into 0.2 L to 20 L high density polyethylene (HDPE) pack sizes for sale. The risks associated with the importation, transportation, storage and disposal of Kenja were considered by the Committee based on the EPA risk assessment.

3.9. The Committee considered that adherence to the proposed controls and other legislative requirements would ensure that the level of risk to human health and the environment from importation, transportation, storage and disposal of Kenja would be negligible. These include the Hazardous Substances Notices regarding packaging, identification, emergency management and disposal of hazardous substances, the Land Transport Rule 45001, Civil Aviation Act 1990, Maritime Transport Act 1994 and New Zealand's HSW requirements.

Assessment of risks to human health

3.10. The Committee noted that the quantitative risk assessment determined that risks to operators during mixing, loading and application by airblast were below the level of concern, even without the use of personal protective equipment (PPE).

3.11. The Committee noted that the EPA assessment determined that the risks to re-entry workers and bystanders were below the level of concern.

3.12. The Committee noted that WorkSafe assessed the available information for Kenja and considered that the HSW (HS) Regulations do not apply as the substance only has eco-toxicological classifications.

Assessment of risks to the environment

3.13. The Committee noted that the EPA had conducted a quantitative risk assessment. The risk assessment considered the effect of the proposed use of Kenja on target and non-target organisms in the environment.

Aquatic organisms

3.14. The Committee noted that the EPA assessment showed that the calculated risks were below the level of concern for the aquatic environment. The Committee noted that the classification of Kenja (Hazardous to the aquatic environment Chronic Category 3) triggers prescribed controls, which will mitigate any residual risks. They also noted that no additional controls were necessary.

Sediment-dwelling organisms

3.15. The Committee noted that the EPA assessment showed that the risks to sediment-dwelling organisms were below the level of concern.

Ground water

3.16. The Committee noted that risks associated with the drinking of groundwater were identified by the EPA as being below the level of concern.

Soil organisms

3.17. The Committee noted that risks to threatened and non-threatened earthworms from the proposed use of Kenja were identified by the EPA as being below the level of concern.

3.18. The Committee noted that the risks to soil micro-organisms from the proposed use of Kenja were identified by the EPA as being below the level of concern.

Non-target plants

3.19. The Committee noted that the risks to non-threatened and threatened non-target plants from isofetamid were identified as being negligible, when applied to grapevines as the formulated product Kenja.

Birds

3.20. The Committee noted that the acute risks to threatened and non-threatened species of birds from the proposed use of Kenja were below the concern.

3.21. The Committee noted that in the initial screening assessment the chronic risks to threatened species of birds were above the level of concern. However they also noted, that after the EPA undertook a further refinement with a higher tier assessment taking into consideration more specific exposure scenarios, potential chronic risks were below the level of concern for both non-threatened and threatened species. Therefore, the Committee did not propose any conditional controls as the risks were considered negligible.

Pollinators and non-target arthropods

3.22. The Committee noted that the risks to pollinators from the proposed use of Kenja were identified by the EPA as being below the level of concern.

3.23. The Committee noted that the risks to non-target arthropods from the proposed use of Kenja were identified by the EPA as being below the level of concern for both off-field and in-field exposure.

Māori Impact Assessment

3.24. The Committee noted that Kaupapa Kura Taiao (The EPA's Māori Policy and Operations team) undertook a Māori impact assessment (MIA) 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. The MIA included tangible and intangible taonga, such as culturally significant species, resources, and places, and the customary values, practices and uses associated with these taonga. Key findings of the assessment are outlined below.

Impact on the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social and cultural well-being

3.25. This application is not likely to adversely affect the ability and capacity of Māori to maintain their economic, social, and cultural well-being.

Impact on the relationship of Māori and their culture and traditions with their environment and taonga

3.26. 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 these taonga.

Treaty of Waitangi principles

3.27. The Principles of the Treaty of Waitangi have been considered in relation to this application, as summarised below.

The active protection principle: the Crown has a duty to actively protect Māori interests.

3.28. No issues arise.

The informed decision-making principle: the Crown has a duty to make informed decisions.

3.29. No issues arise.

The partnership principle: to act fairly, reasonably, and in good faith.

3.30. No issues arise.

Assessment of risks to society, the community and the market economy

3.31. The Committee considered that the overall level of risk to society, the community and the market economy after taking into account the controls would be negligible.

New Zealand's international obligations

3.32. The Committee noted no international obligations have been identified that may be impacted by the approval of Kenja.

Assessment of benefits

3.33. The applicant referred to several benefits of the substance in their application:

Reducing the risks of fungi developing fungicide resistance

3.34. The applicant has explained that tolerance and resistance of fungi to existing fungicides is an ongoing problem in the grape industry. The applicant further explained that introducing isofetamid as a new active ingredient would be a benefit for reducing the risks of fungi developing fungicide resistance.

3.35. The EPA considers that reducing the risks of fungi developing fungicide resistance would be a significant benefit, however, the level of this benefit is underdetermined because ACVM assesses

efficacy data. Nevertheless, the EPA notes that Kenja contains a new active ingredient, which could provide an additional tool for grape growers, therefore, this is considered a significant benefit.

Absence of human health hazard classification

3.36. The applicant has identified that Kenja has no human health hazard classifications and explained that Kenja is less toxic to users than existing fungicides.

3.37. The EPA considers that the absence of human health classifications is a significant benefit, which may provide users with a greater variety of fungicides with low hazard classifications for treating powdery mildew and botrytis in grapes.

Benefits to wine regions

3.38. The applicant referred to the major grape growing areas in New Zealand and explained that Kenja will likely benefit these regions and will produce economic and operational benefits for those working with these crops.

3.39. The EPA considers that an efficacious product would be a significant benefit to grape growing areas, however, efficacy data is assessed by ACVM. The EPA cannot determine the extent of the potential economic benefit for these regions. Therefore, the level of this benefit is undetermined.

Conclusions on the assessment of benefits

3.40. After considering the information that was presented, the Committee considered that there are potential benefits that will be derived for New Zealand by allowing the import or manufacture of Kenja.

4. Controls

4.1. The hazard classifications of Kenja determine a set of prescribed controls specified by the EPA Notices under section 77 of the Act. There are also requirements in the HSW (HS) Regulations. Note: the HSW (HS) Regulations requirements are not set for the substance under this approval but apply in their own right.

4.2. The prescribed controls/requirements set the baseline for how the substance must be managed and include specifications on how the substance is to be packaged, labelled, stored, disposed, transported, handled and used. The prescribed controls also set information requirements (eg Safety Data Sheets), signage and emergency management. These controls are specified in the Appendix of the approval document.

4.3. Clause 17 of the Labelling Notice requires that certain toxic or corrosive components are identified on the product label. Section 3 of the Schedule in the Safety Data Sheet (SDS) Notice requires that certain toxic, corrosive or ecotoxic components are identified on the SDS. Section 8 of the Schedule in the SDS Notice requires occupational exposure limits to be identified on the SDS. One component of Kenja has a Workplace Exposure Value (WES).

Exposure limits

4.4. The Committee noted that the EPA has not set a Tolerable Exposure Limit (TEL) for Kenja, or any element or compound in the substance. This is because it is not considered that exposure is likely to result in an appreciable toxic effect based on the quantitative risk assessment. However, the Acceptable Daily Exposure (ADE) and Potential Daily Exposure (PDE) shown below are proposed by the EPA as health-based exposure guidance values that can be used to inform risk assessments as well as the setting of controls, such as Maximum Residue Levels (MRLs) under the Agricultural Compounds and Veterinary Medicines Act 1997.

4.5. The following values have been provided for isofetamid:

- ADE = 0.05 mg/kg bw/day
- PDE (food) = 0.035 mg/kg bw/day
- PDE (drinking water) = 0.01 mg/kg bw/day
- PDE (other) = 0.005 mg/kg bw/day

4.6. No Environmental Exposure Limit (EEL) values are proposed for isofetamid at this time. This is because it is not considered that, with controls in place, environmental exposure is likely to result in an appreciable ecotoxic effect based on the quantitative risk assessment.There are Workplace Exposure Standard (WES) values currently set for components of Kenja but, as they are not Prescribed Exposure Standard (PES) values, they are guidance values used for the management of health risk. No PES has been set for any component of Kenja.

Changes to prescribed controls

Maximum application rate

4.8. The Committee noted that the environmental assessment was based on the application rates proposed by the applicant, and therefore agreed with the EPA recommendation to propose a maximum application rate and number of applications. Therefore, the maximum application rate of Kenja is 0.375 L/ha (equivalent to 150 g isofetamid/ha), with a maximum frequency of two applications per year, and an interval of 10 days between applications.

Application method

4.9. The Committee noted that the environmental risk assessment was based on the application methods specified by the applicant. The restriction to apply Kenja via ground-based methods only, and the restriction to favourable wind conditions are key factors in minimizing exposure to aquatic environments. The Committee agreed with the following EPA recommendations:

- Kenja can only be applied by ground-based methods.
- Kenja must not be applied when wind speeds are less than 3 km/hr or more than 20 km/hr as measured at the application site.

Additional label statements

4.10. The Committee noted the EPA's recommendation to require an additional label statement to limit off-target exposure. The Committee agreed with the following recommended label statement:

- *"**DO NOT** apply when wind speeds are less than 3 km/hr or more than 20 km/hr as measured at the application site."*

Review of additional controls and variations

4.11. The Committee reviewed the additional controls and variations to the prescribed controls mentioned above and considered them necessary to achieve their purpose of effective risk management of the use of Kenja in New Zealand.

4.12. The full suite of controls, including variations, can be found in Appendix A of the approval document.

4.13. The applicant was given an opportunity to comment on the proposed controls as set out in the Science Memorandum. The applicant had no concerns with the controls, and the Committee has not made any changes to the controls recommended by the EPA.

5. Conclusion

5.1. After taking into account the assessment of the potential risks and benefits associated with Kenja, the Committee considered that, with all of the controls in place:

- The overall risks to human health and the environment arising from the hazardous properties and the use of Kenja are negligible.
- Significant adverse impacts on the social or economic environment from the use of Kenja are not anticipated.
- If Kenja is applied in the proposed manner, it would likely be consistent with the principles of Te Tiriti o Waitangi (the Treaty of Waitangi). Significant impacts on Māori culture or traditional relationships with ancestral lands, water, wāhi tapu, valued flora and fauna or other taonga have not been identified.
- Significant benefits will be derived for New Zealand by allowing the use of Kenja.

5.2. Therefore, the Committee considered that benefits of the substance, based on the assessment of the information available, outweigh the risks of the substance.

6. Decision

6.1. Pursuant to section 29 of the Act, the Committee has considered this application for approval under section 28 of the Act. The Committee has considered the effects of this substance throughout its life cycle, the controls that may be imposed on this substance and the likely effects of this substance

being unavailable. The Committee has also taken into account the considerations set out in Part 2 of the Act.

The Committee consider that, with controls in place, the risks to human health and to the environment are negligible, and the benefits associated with the release of this substance will outweigh the adverse effects. Therefore, the application to import or manufacture Kenja for release is approved with controls in accordance with section 29 of the Act and clause 26 of the Hazardous Substances and New Organisms (Methodology) Order 1998.

Dr Kerry Laing **Date: 1 November 2021**

Chair, Decision Making Committee
Environmental Protection Authority