Environmental Protection Authority
Te Mana Rauhī Taiao

New Zealand Government

Decision

07 December 2021

Summary

Item	Detail
Substance	Fluazinam
Request number	APP204188
Request type	Grounds for reassessment
Applicant	Environmental Protection Authority (EPA)
Purpose of the request	To determine whether there are grounds for the reassessment of fluazinam under the Hazardous Substances and New Organisms Act 1996 (“the Act”)
Date request received	18 October 2021
Consideration Date	07 December 2021
Considered by	A Decision-making Committee of the Environmental Protection Authority (“EPA”)
Decision	Grounds exist for the reassessment of fluazinam

1. Background

1.1. The hazardous substance, fluazinam ("the substance") was transferred into the Hazardous Substances and New Organisms Act (the Act) under the Hazardous Substances (Chemicals) Transfer Notice 2006. It has the HSNO approval number HSR002852.

1.2. The approval for fluazinam was reissued under clause 4 of Schedule 7 of the HSNO Act on 30 April 2021 to reflect New Zealand's adoption of the GHS system of hazard classifications.

1.3. Fluazinam is a fungicide active ingredient used in the production of fruit and vegetable crops, for the control of a wide range of diseases mainly in grapes, vegetable brassicas, potatoes, field tomatoes and onions.

1.4. Details of all currently approved substances containing fluazinam are listed in Table 1 below. Any future reassessment application will include full details of the scope of the reassessment and substances included in the reassessment.

Table 1: Fluazinam-containing substances

Active Ingredient	Substance name	Approval number	ACVM registered products and registration number
Fluazinam	Suspension concentrate containing 500 g/kg fluazinam	HSR000500	Shirlan (P003504)
	Gem fungicide	HSR007763	Gem fungicide (P007673), Nando (P007980)
	Ohayo	HSR100383	Ohayo 500 SC (P008151), Preguard (P008789), Agpro Fluazinam 500 (P009049)
	Resolve	HSR100514	Pinnacle (P007697), Curalan (P008299)
	Flick 500 SC Fungicide	HSR100977	Flick 500 SC Fungicide (P009037)
	Flufixer	HSR101200	Flufixer (P009540)
Fluazinam and fludoxonil	TNL 2903	HSR100629	Nexus (P008558), Florid (P009160), Nexigro (P009573)
Fluazinam and pyrimethanil	TNL3015	HSR100838	Apex (P009012)

1.5. The substance is classified as follows:

- acute inhalation toxicity Category 2
- serious eye damage Category 1
- skin sensitisation Category 1
- reproductive toxicity Category 2
- specific target organ toxicity – repeated exposure Category 2
- hazardous to aquatic environment acute Category 1
- hazardous to the aquatic environment chronic Category 1
- hazardous to terrestrial vertebrates

1.6. The controls that apply to the substance include default controls applicable to a substance having these hazard classifications, as well as a number of additional or varied controls.

1.7. The Environmental Protection Authority (EPA) ("the applicant") has applied for grounds to reassess fluazinam. The purpose of this request is to decide whether there are grounds for reassessment of the substance.

2. Request process

2.1. The request was formally received by the EPA on 18 October 2021 and the information supplied evaluated by EPA staff.

2.2. The request was considered on 07 December 2021 by a Decision-making Committee ("the Committee") of the EPA

3. Legislative criteria

3.1. The Act specifies a number of factors that the EPA has to take into account when considering whether grounds exist for a reassessment. At least one of these factors must be present before the EPA can use its discretion to determine whether there are grounds for a reassessment.

Significant new information relating to the effects of the substance has become available (section 62(2)(a))

3.2. The applicant, the EPA, has provided information about the risks associated with the use of fluazinam containing substances.

3.3. The information provided includes recent overseas regulators reports that highlight the actions they took. The reports and descriptions of what they contain is below:

- Rotterdam convention. (December 2010). PIC Circular XXXII.
- Pest Management Regulatory Agency (PMRA), Canada. (2016). Special review decision
- The European Food Safety Authority (EFSA). (2019). Draft renewal assessment report

3.4. The Rotterdam convention. (December 2010) PIC Circular XXXII includes a summary of Norway's decision to prohibit all uses of fluazinam.

3.5. The special review decision report by Pest Management Regulatory Agency (PMRA) contains information related to the special review of fluazinam that was initiated in Canada following the Norwegian prohibition. This decision allowed the continued use of fluazinam in Canada subject to mitigation measures.

3.6. The Draft renewal assessment report was published in 2019 by the European Food Safety Authority (EFSA) to evaluate renewal of fluazinam in Europe. This report includes summaries of new study data which would support various changes to the hazard classifications of fluazinam and fluazinam-containing substances in any future reassessment in New Zealand.

3.7. The Committee noted that the information supplied was published by overseas regulators since the year 2010 and was therefore not available during the initial approval of the substance. Therefore, the Committee considered it to be "new" information.

3.8. The EPA has highlighted new information regarding risks to human health and the environment. These risks were identified during the processing of a recent application for a new fluazinam-containing substance (which did not proceed to a formal decision).

3.9. The Committee considered the new information on human health and environmental risks to be "significant" as it is relevant to the currently approved fluazinam-containing substances in New Zealand, and it indicates that additional controls may be necessary to mitigate the risks associated with their use. This would be evaluated most appropriately in a future reassessment to ensure the risks to human health and the environment from the existing uses are mitigated to the appropriate level.

A change in controls under the Health and Safety at Work Act 2015 (section 62(2)(aa))

3.10. This factor is not relevant to this request

Another substance with similar or improved beneficial effects and reduced adverse effects has become available (section 62(2)(b))

3.11. This factor is not relevant to this request

Information showing a significant change of use, or a significant change in the quantity manufactured, imported, or developed has become available (section 62(2)(c))

3.12. This factor is not relevant to this request.

Other reasons for requesting a reassessment under section 62(2)

3.13. This factor is not relevant to this request.

4. Achieving the purpose of the Act

4.1. The Committee has observed that all relevant matters in Part 2 of the HSNO Act need to be taken into account when exercising functions, powers and duties under the Act.

4.2. The Committee has noted that, if this request is approved and a subsequent reassessment is applied for, these matters will be considered comprehensively in the context of that application. In particular, the following considerations from sections 6, 7 and 8 will be taken into account:

a) the sustainability of all native and valued introduced flora and fauna
b) the intrinsic value of ecosystems
c) public health
d) the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna, and other taonga
e) the economic and related benefits and costs of using a particular hazardous substance or new organism
f) New Zealand's international obligations
g) the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects; and
h) the principles of the Treaty of Waitangi (Te Tiriti o Waitangi)

5. Consideration

5.1. The Committee considered that there is significant new information relating to the effects of the substance in view of the actions undertaken by overseas regulators and the risks highlighted during the quantitative risk assessment undertaken by the EPA.

5.2. Taking that into account, the Committee considered that grounds exist under section 62 of the Act for the reassessment of fluazinam, on the basis that significant new information about the effects of the substance has become available (section 62(2)(a))

For the Decision-making Committee:

Signed by	Date: 07 December 2021
Dr Kerry Laing **Chair, Decision-making Committee** **Environmental Protection Authority**