ERMA New Zealand

Evaluation and Review Report

Application for approval to import or manufacture GF-2574 for Release

Application Number: ERMA200467

Executive Summary

Background information

- Dow AgroSciences New Zealand Limited Ltd are seeking approval to import or manufacture GF-2574 for use as a herbicide containing aminopyralid and trichlopyr for commercial use on pastures to control broadleaf weeds.

Classification

- The Agency has classified GF-2574 based on the composition of GF-2574 and the effects of its components. The Agency's classifications are different from the applicants proposed HSNO classifications.

Hazardous Property	Applicant's Assessment	Agency's Assessment
Metallic corrosivity	8.1A	8.1A
Acute Toxicity (Oral)	6.1D	6.1E
Eye Irritancy/Corrosivity	8.3A	8.3A
Contact Sensitisation	6.5B	6.5B
Target Organ Toxicity	6.9B	6.9B
Aquatic Ecotoxicity	9.1A	9.1A
Soil Ecotoxicity	9.2A	9.2A
Ecotoxicity to terrestrial vertebrates	9.3C	9.3C

- The Agency's 6.1 classification is different from the applicant as the applicant has used the incorrect data to classify for this sub-class.

Risk Assessment

- The Agency's assessment of the risks posed by GF-2574 to the environment and to human health, during the substance's lifecycle, is based on qualitative and quantitative assessment.
- The Agency considers that, with the default and additional controls in place, there are ***negligible*** risks to human health and to the environment and no potentially significant costs associated with the release of GF-2574.

Controls

- The Agency has proposed that the default controls for GF-2574 be modified such that:
    - no Tolerable Exposure Limits (TELs) are set for GF-2574 at this time;
    - Workplace Exposure Standards (WESs) have been set for Component C of GF-2574;
    - no Environmental Exposure Limits (EELs) are set at the present time and default values are deleted;
    - further controls relating to stationary containment systems are added.
- The following additional controls are proposed for GF-2574:

- The maximum application rate for GF-2574 is set at 2 L/ha, applied once per season to the same plant;
- GF-2574 is to be applied via ground-based methods only;
- GF-2574 is not to be applied onto or into water;
- Use of GF-2574 is restricted to agricultural/commercial horticultural use and excludes use in respect of turf management.

- The Agency considers that it is appropriate for certain other variations to be made to the default controls. These variations are discussed in section 4 of the E&R Report and further in Appendix 3.

Overall evaluation and recommendation

- The Agency considers that with controls in place, there are negligible risks to human health and to the environment and potentially significant benefits associates with the release of GF-2574. Therefore, the Agency considers that it is evident that the benefits of releasing GF-2574 outweigh the costs and the application may be approved in accordance with clause 26.

Table of Contents

1. The Application

1.1. The application details are summarised in Table 1.1.

Table 1.1 Details of the application ERMA200467

Application Code	ERMA200467
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")
Application Sub-Type	Notified – Category A
Applicant	Dow AgroSciences New Zealand Limited
Date Application Received	18 May 2010
Submission Period	26 May 2010– 8 July 2010
Consideration	5 August 2010
Purpose of the Application	To import or manufacture GF-2574 as a herbicide containing aminopyralid and trichlopyr for commercial use on pastures to control broadleaf weeds.
Parties Notified	On the 26th of May 2010, the following were notified • the Minister for the Environment, • interested parties listed in Appendix 5, • the public[1].
Submissions received	None
ERMA staff involved in the assessment	Matthew Allen - Advisor (Hazardous Substances) Margaret Keane - Advisor (Hazardous Substances) Sekove Tinalevu - Advisor (Hazardous Substances) Apostolos Koutsaftis - Advisor (Hazardous Substances) Patrick Gemmell- Senior Advisor (Kaupapa Kura Taiao)
ERMA staff member responsible for review	Noel McCardle – Senior Advisor (Hazardous Substances).
Information assessed	• The application • Confidential appendices.

1.2. This report should be read in conjunction with the attached Supplementary Information which contains information on:

- The legislative criteria
- Approach to risk assessment.

[1] The application was advertised in the Dominion Post, the New Zealand Herald, The Christchurch Press and the Otago Daily times and placed on the ERMA New Zealand website.

- Decision pathway used in the decision process.

1.3. The Agency considers that it accessed sufficient information to undertake a full assessment of the substance from a scientific and technical perspective and that there are no other significant uncertainties that need to be considered by the Authority.

2. Risk management context

The substance and its lifecycle

2.1. GF-2574 is intended for import or manufacture as a herbicide for commercial use on pastures to control broadleaf weeds. GF-2574 is a clear blue liquid containing the active ingredients aminopyralid and trichlopyr, and other excipients.

2.2. The applicant has provided the following details about the lifecycle of GF-2574.

2.2.1. **Importation/manufacture.** GF-2574 would be manufactured either outside New Zealand or at the established Dow AgroSciences pesticide manufacturing plant in New Plymouth, for proposed commercial release in New Zealand.

2.2.2. **Storage/transportation**. The substance would be packaged according to the requirements of the Hazardous Substances (Packaging) Regulations 2001 or in packages that comply with the importing country requirements, and stored at the New Plymouth facility until transport by road using dedicated chemical transport companies to retail farm supply distributors or the point of export. The substance may be stored by distributors until sold to farmers, who will transport the substance to their property for secure storage until used according to uses approved by the ACVM Group of the NZFSA.

2.2.3. **Use.** The substance is to be used by mixing with water and sprayed with conventional ground boom or spot spraying equipment. No aerial application is proposed. The substance mixed with water is applied directly to pastures as directed on the label. The applications are made according to the Management of Agrichemicals (NZS 8409). Only one application will be made to the target weeds, therefore it is anticipated only one application will be made to the same area in any 12 month period.

2.2.4. **Disposal**. The label instructs the end user to decontaminate the application equipment to avoid damage to desirable plants when the equipment is reused. The cleaning water is to be discharged onto a designated disposal area or onto wasteland away from desirable plants and sources of water. Label instructions also advise on disposal of empty containers and unused product. The triple-rinsed empty containers would also be suitable for the collection by the Agrecovery container recycling programme.

Classification of the substance

2.3. The Agency has classified GF-2574 based on the composition of GF-2574 and the effects of its components. The Agency's classifications are different from the applicant's proposed HSNO classifications (Table 2.1).

Table 2.1: The applicant's and Agency's classifications of GF-2574

Hazardous Property	Applicant's Assessment	Agency's Assessment
Metallic corrosivity	8.1A	8.1A
Acute Toxicity (Oral)	6.1D	6.1E
Eye Irritancy/Corrosivity	8.3A	8.3A
Contact Sensitisation	6.5B	6.5B
Target Organ Toxicity	6.9B	6.9B
Aquatic Ecotoxicity	9.1A	9.1A
Soil Ecotoxicity	9.2A	9.2A
Ecotoxicity to terrestrial vertebrates	9.3C	9.3C

2.4. The Agency's 6.1 classification is different from the applicant's as the applicant has used the incorrect data to classify for this sub-class.

Regulatory context

2.5. The Agency notes that the importation, transport, use and disposal of the substance will also be subject to other legislation such as the Health and Safety in Employment Act 1992, The Resource Management Act 1991 and the Land Transport Act 1998.

2.6. Before the substance can be released for sale and use in New Zealand, it must be registered under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997. This process will assess the substance for food residue implications and potentially set withholding periods and residue limits.

Default controls

2.7. The HSNO Regulations specify a number of controls based on the classification of the substance. These default controls are designed to mitigate the potential risks associated with each of the hazardous properties and are listed in Appendix 3. The Authority is able to vary the default controls and impose controls under section 77 and 77A to produce a set of controls for GF-2574. Variations and additional controls are considered in section 4 of this report.

2.8. The analysis of risks takes into account the Agency's HSNO classifications and the controls that derive from the HSNO Regulations (in particular the default controls identified in Appendix 3) and from other legislation. The identification and assessment of effects is based on the default controls and the additional controls being in place.

Assessment by overseas regulatory authorities

2.9. The Agency notes that triclopyr (CAS#55335-06-3) has been recently reviewed by EFSA (2005). This report highlighted the following environmental concerns:

2.9.1. FOCUS groundwater modelling indicated a high potential for groundwater contamination (for the intended uses on pasture and non-recreational amenity grassland) in vulnerable situations over a wide range of geoclimatic conditions across the EU for triclopyr. Modelling also indicates that the major soil metabolite 3,5,6-trichloro-2-pyridinol may also contaminate groundwater but the range of vulnerable geoclimatic conditions where this might happen is less wide spread.

2.9.2. A data requirement for the notifier to submit at least an algal study with this metabolite was set.

2.9.3. A high acute risk to aquatic invertebrates was identified and EFSA proposed that risk mitigation measures are taken into account at member state level to address this risk.

2.9.4. A low long term risk to aquatic organisms from exposure to triclopyr but a high long term exposure to fish from exposure to triclopyr butoxyethyl ether was observed.

2.9.5. The risk to non target plants can be considered as low if risk mitigation measures such as a buffer zone of 5 metres are taken into account.

2.10. The Agency notes that aminopyralid inclusion in EC 91/414 is still pending. However, this component has been recently reviewed by the US EPA (2005). This report highlighted the following environmental concerns:

2.10.1. The proposed uses of aminopyralid pose a risk to non-target terrestrial plants. Risk quotients (RQs) were highest for pasture and rangeland uses, due to the higher proposed application rate. However, even at the much lower rate for wheat, LOCs are still exceeded in some circumstances. The greatest risk is to dicotyledonous plants, although RQs for wetland monocots also exceeded the level of concern (LOC).

3. Identification and assessment of risks, costs and benefits

3.1. The Agency's identification and assessment risks and costs (adverse effects) and benefits (positive effects) is set out in this section and supported by information in Appendix 2 and Supplementary Information (sections 3 and 4).

Risks and costs

Human health

3.2. GF-2574 has been classified as an acute oral toxicant (6.1E), an eye corrosive (8.3A), a contact sensitiser (6.5B) and a target organ toxicant (6.9B).

3.3. In addition to these toxicity classifications, GF-2574 has also been classified as a metal corrosive (8.1A). However, the Agency considers that adherence to the HSNO controls on metal corrosive substances will ensure that the level of risk to human health associated with its metal corrosive properties is ***negligible.***

3.4. The results of the quantitative and qualitative assessment of the human health risks associated with the lifecycle of GF-2574 (see Appendix 2) are documented in Table 3.1.

Table 3.1: Qualitative assessment of human health risks

Description	Exposure Scenario	Magnitude	Likelihood	Comment	Effect level	
Manufacture and packaging	Acute: oral toxicant eye corrosive	Moderate	Highly improbable	Negligible	Workers handling the substance will be aware of the hazards and the measures that need to be undertaken to ensure their own safety. Manufacturing and packaging facilities They will also be required to meet HSNO requirements for personal protective equipment (PPE), and compliance with HSNO information provisions (e.g. labels, advertising, Safety Data Sheets (SDS). Department of Labour (DoL) health and safety requirements will also apply.	Negligible
	Contact Sensitisation	Moderate	Highly improbable	Negligible	The Agency considers that it is highly improbable that workers will receive sensitisation from the substance, given requirements for PPE and compliance with the HSNO information provisions (e.g labels, advertising and SDS)	
	Chronic: Target organ toxicant	Major	Highly improbable	Low	While the qualitative descriptors indicate a low level of risk driven by the major chronic effects, the Agency notes that these processes will be required to meet the HSNO requirements for equipment, emergency management and provision of information as well as good manufacturing practice and Health and Safety regulations. The Agency considers that these requirements, and the voluntary risk being sufficiently managed by workers involved in the manufacture of the substance, will make the likelihood of exposure that would lead to a chronic effect so highly improbable that the level of risk for the chronic toxic adverse effects is ***negligible***.	
Importation, Transport, Storage	Acute: oral toxicant eye corrosive	The Agency considers the risk of effects from GF-2574 during importation, transport or storage to be sufficiently remote that it is not necessary to address, it given that exposure could only occur in isolated spillage incidents.				
	Contact sensitisation					
	Chronic: Target organ toxicant					
Use (Operators and Bystanders)	Acute: oral toxicant eye corrosive	Moderate	Highly improbable	Negligible	Given the requirements for personal protective equipment (PPE) and compliance with HSNO information provisions (e.g. labels, advertising, Safety Data Sheets (SDS), and Department of Labour (DoL) health and safety requirements, it is highly improbable that operators would be exposed to sufficient quantity of GF-2574 to result in a moderate adverse health effect.	Negligible
	Contact	Moderate	Highly	Negligible		

Description	Exposure Scenario	Magnitude	Likelihood	Comment	Effect level	
	sensitisation		improbable			
Use (Operators)	Chronic: Target organ toxicant	Quantitative assessment indicates that the only exposure situations in which risks to operators is considered to be acceptable is when full PPE is worn during mixing, loading and applying the substance, either with or without a respirator. This indicates full PPE should be worn by operators when mixing, loading and/or applying GF-2574. The Agency notes that PPE is triggered as a default control as a result of its 6.1E, 8.3A, 6.5B and 6.9B classifications.				
Use (Bystanders)	Chronic: Target organ toxicant	Quantitative assessment indicates that the chronic risks to bystander health and safety are acceptable and the level of risk is considered to be negligible.				
Disposal	Acute: oral toxicant eye corrosive	Moderate	Highly improbable	Negligible	The applicant indicates that the best method of disposal is to apply the product according to label directions. The applicant states containers should be triple rinsed and may be disposed of in a suitable landfill, burned if conditions are suitable or recycled via the Agrecovery programme. In all cases of disposal, this will be in accordance with the requirements of the Hazardous Substances (Disposal) Regulations 2001 and the Resource Management Act 1991and will reduce the opportunity for individuals to be exposed.	Negligible
	Contact sensititsation	Moderate	Highly improbable	Negligible		
	Chronic: Target organ toxicant	Major	Highly improbable	Low	It is highly improbable that users or bystanders could be repeatedly exposed to GF-2574 during disposal to result in target organ toxic effects, given that the people disposing of GF-2574 will have the necessary skills and knowledge (e.g. via information provided on SDS) to reduce the risk to human health for the disposal of the substance to ***negligible***.	

Environmental

3.5. GF-2574 has been classified as an aquatic ecotoxicant (9.1A), a soil ecotoxicant (9.2A) and a terrestrial vertebrate ecotoxicant (9.3C).

3.6. GF-2574 has been classified by the Agency as being corrosive to metals (8.1A). The Agency considers that adherence to the HSNO controls on metal corrosive substances will ensure that the level of risk to the environment associated with the metal corrosive properties is ***negligible.***

3.7. The Agency notes the potential risks to turf from aminopyralid and as such is proposing additional controls to mitigate these risks (Section 4).

3.8. Table 3.2 documents the results of both the qualitative and quantitative assessments undertaken and identifies the impact of potential risks at each stage of the substance's lifecycle. In conclusion, the Agency considers the risk to the environment is ***negligible.***

Table 3.2: Qualitative assessment of potential environmental risks

Description	Exposure Scenario	Magnitude	Likelihood	Matrix	Comment	Effect level
Manufacture, Importation, transport, storage	Death or adverse effects to aquatic or terrestrial organisms or to the soil environment.	Moderate	Highly improbable	Negligible	Given adherence to the HSNO controls (and the Land Transport Rule 45001, Civil Aviation Act 1990 and Maritime Transport Act 1994 (as applicable) the Agency considers a spill to be highly improbable. Furthermore, a spill is likely to lead to localised effects only involving small quantities of the substance.	Negligible
Use	Death or adverse effects to aquatic or terrestrial organisms or to the soil environment.	Based on the quantitative risk assessment for the aquatic and terrestrial environment, risks to non-target plants have been identified as high. Therefore, the Agency considers it is appropriate to retain the approved handler controls for GF-2574 when it is used in a wide dispersive manner, or by a commercial contractor. Further, the Agency considers that the application rate proposed by the applicant and used in the modelling should be set as a maximum application rate. The Agency notes that there is a risk to non-target plants from spray drift and thus the Agency recommends product users are made aware of this.				
Disposal	Death or adverse effects to aquatic or terrestrial organisms or to the soil environment.	Moderate	Highly improbable	Negligible	Users will in most cases use all of the substance as intended. If GF-2574 is disposed of by means other than use, this will be in accordance with the requirements of the Hazardous Substances (Disposal) Regulations 2001 and the Resource Management Act 1991.	Negligible

Benefits

3.9. The applicant considers that the availability of GF-2574 will have a number of benefits:

- This substance will control economically troublesome weeds in pastures.
- The benefits of using the active ingredients in GF-2574 for weed control are already well established.
- The benefit of GF-2574 is that these active constituents are formulated together in an optimum combination to provide a broad spectrum of weed control. It provides an alternative product to farmers for the control of important pasture weeds.

3.10. The Agency considers that the economic and related benefits to be derived from the use of GF-2574 as a pesticide in New Zealand are potentially significant.

Likely effects of the substance being unavailable.

3.11. If the substance is not available, it will reduce the range of products available to farmers for the control of important pasture weeds.

4. Setting controls

Variations to Default Controls

4.1. As a result of the risk assessment, the Agency considers that the following variations should be made to the default controls. These variations are summarised in Table 4.1 below. A full description of the rationale for these variations is documented in Appendix 4.

4.2. The Agency notes that similar variations were made to pesticides on their transfer to the HSNO regime.

Table 4.1 Variations to the default controls for GF-2574.

Control Code	Subject matter	Variation	Comment
T1	Setting of TELs	No TELs set for GF-2574 at this time.	The Agency is intending to review the setting of ADEs, PDEs and TELs under section 77B of the Act. Until this review is complete, the Agency proposes not to set ADEs, PDEs or TELS for any components of GF-2574 at this time.
T2	Setting of WES	A WES is set for Component C.	This control relates to controlling exposure in places of work through the setting of WESs. The Agency typically adopts WES values listed in the Workplace Exposure Standards (Effective from 2002) document (refer to the following link): http://www.osh.govt.nz/order/catalogu

Control Code	Subject matter	Variation	Comment
			e/pdf/wes2002.pdf.
T7	Carriage of hazardous substances on passenger service vehicles	The trigger quantity is increased to 1.0 L.	The Agency considers that Regulation 10 should apply as if the maximum quantity per package of a 6.5B substance is 1.0 L, rather than 0.1 L.
E1	Setting of TELs and EELs	No EELs set for GF-2574 at this time and the default controls are deleted.	Until the Agency has developed formal policy on the implementation of s77B, it proposes not to set EELs for any components of GF-2574 at this time.
E2	Setting of application rates	set under s77A.	Although no EEL has been set for GF-2574, the Agency proposes setting the maximum application rate of 2 L/ha and one application to the target weed per season as the application rate for GF-2574. This rate was used in the ecological risk assessment.
E7/AH1	Approved handler requirements	Varied to apply for use in wide dispersive manner or used by a commercial contractor.	The outcome of the ecological risk assessment (refer Appendix 3) indicates that there is potential for acute adverse environmental effects on terrestrial plants if the substance moves off-target. The Agency considers it is therefore appropriate to retain the approved handler control.
TR1	Tracking requirements	Deleted.	For a substance where the tracking control has been triggered solely as a result of ecotoxicity, it is considered that any risk that may arise during its lifecycle are adequately managed by other controls such as approved handler, packaging, labeling and emergency management requirements. The Agency therefore considers the tracking control can be deleted as provided by section 77(4)(b).
T4/E6	Requirements for equipment used to handle hazardous substances	Combined.	These controls can be combined as provided for under section 77(5).
D4/D5	Disposal requirements		
P13/P14/P15	Packaging requirements		

Proposed additional controls

4.3. Control EM12 relates to the requirements for secondary containment of pooling substances2. The EM12 secondary containment requirements have been triggered for GF-2574 as a result of its ecotoxicity classification. The Agency considers that the risks associated with the containment of substances which are not class 1 to 5 substances (i.e. do not ignite or explode) are different to those associated with class 1 to 5 substances. Consequently the Agency considers that the secondary containment requirements can be reduced. The Agency considers that these reduced secondary containment measures are adequate to manage the risks of a spillage of GF-2574. Therefore, the proposed additional control, which varies the EM12 control, is more cost-effective in terms of managing the risks of the substance. The proposed controls are shown in Table A4.1 of Appendix 4.

4.4. The controls relating to stationary container systems as set out in Schedule 8 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004 (Supplement to the New Zealand Gazette, 26 March 2004, No. 35, page 767), as amended, are set for this substance, notwithstanding clause 1(1). This control has been applied to other similar approved substances.

4.5. As the assessment of the proposed substance's risk has been based on its use as a pesticide at a set application rate and application method, and because of the risks to non-target plant and animal species, the following use restriction controls are added:

- *The application rate for GF-2574 is set at a maximum of 2 L/ha, applied once per season to the same target plant.*
- *GF-2574 is to be applied via ground based methods only.*
- *GF-2574 is not to be applied onto or into water.*

4.6. The Agency notes that previously approved substances containing aminopyralid have an additional control restricting their use to agricultural/commercial horticultural use (excluding turf management). The Agency considers this control is equally applicable to GF-2574 and is applied under section 77A. The Agency requires that the following statements appear on the label:

4.6.1. *The product must not be used on turf*

*DO NOT use hay or other plant material harvested within 10 weeks of treatment with (*tradename of substance*) for making compost or mulching susceptible crops.*

*DO NOT use plant material that has been treated with (*tradename of substance) *within the previous 10 weeks to make mushroom substrate.*

*DO NOT use manure, paunch grass or dairy effluent from animals grazing areas treated with (*tradename of substance*) within the previous 10 weeks for making compost unless the clean feed withholding period has been observed.*

[2] Regulations 35 – 41 of the Hazardous Substances (Emergency Management) Regulations 2001

5. Overall evaluation and recommendation

5.1. The Agency considers that there are negligible risks to human health and to the environment and no potentially significant costs associated with the release of GF-2574. Therefore. The Agency considers that it is evident that the benefits of releasing GF-2574 outweigh the costs and the application may be approved in accordance with clause 26, with the controls documented in Appendix 4.

Appendix 1: Hazard classification of GF-2574

Classification of GF-2574

Data from effects testing of the formulation were not provided for any hazard endpoint for GF-2574, so classification was estimated using information on the effects of the components and mixture rules. The relevant sections of the User Guide to Thresholds and Classifications under the HSNO Act (ERMA 2008a) that describe the mixture rules are listed in Table A1.1. Classifications of the formulation are shown in Table A1.2.

Data quality – overall evaluation

The Agency has adopted the Klimisch et al (1997) data reliability scoring system for evaluating data used in the hazard classification and risk assessment of chemicals (section 1.2.4 in ERMA 2008a). The data used by the Agency to classify GF-2574 are predominantly the classifications which have been officially gazetted during the transfer process and are publicly available through the HSNO Chemical Classification Information Database (CCID) (ERMA 2008b). Generally these data are high quality by current international standards.

The Agency acknowledges that frequently, there are data gaps in the hazard classification for chemicals which have been in use internationally for a long time. International programmes such as the OECD High Production Volume programme (OECD 1990) and REACH (EU 2006) are progressively working towards filling these data gaps. As new information becomes available, and resources permit, the Agency will endeavour to update the HSNO classifications for those substances.

Table A1.1: Location of mixture rules within the HSNO Thresholds and Classifications User Guide (V2.0. March 2008).

Hazard	User Guide to HSNO Thresholds and Classifications Reference
Subclass 6.1 Acute Toxicity	Part V, Chapter 10, Page 12
Subclass 6.3/8.2 Skin Irritancy/Corrosivity	Part V, Chapter 11, Page 7
Subclass 6.4/8.3 Eye Irritancy/Corrosivity	Part V, Chapter 12, Page 9
Subclass 6.5 Contact and Respiratory Sensitisation	Part V, Chapter 13, Page 8
Subclass 6.6 Mutagenicity	Part V, Chapter 14, Page 5
Subclass 6.7 Carcinogenicity	Part V, Chapter 15, Page 8
Subclass 6.8 Reproductive Developmental Toxicity	Part V, Chapter 16, Page 11
Subclass 6.9 Target Organ Systemic Toxicity	Part V, Chapter 17, Page 10
Subclass 9.1 Aquatic Ecotoxicity	Part VI, Chapter 19, Page 18
Subclass 9.2 Soil Ecotoxicity	Part VI, Chapter 20, Page 8
Subclass 9.3 Terrestrial Vertebrate Ecotoxicity	Part VI, Chapter 21, Page 7
Subclass 9.4 Terrestrial Invertebrate Ecotoxicity	Part VI, Chapter 22, Page 5

Table A1.2: Summary of the toxicity and ecotoxicity hazard classifications of GF-2574

Hazardous Property	Agency Classification	Component driving classification
Metallic corrosive	8.1A	Component A
Acute Toxicity (Oral)	6.1E	Component A
Eye Irritation/Corrosion	8.3A	Component A
Contact Sensitisation	6.5B	Component A
Target Organ Toxicity	6.9B	Component A
Aquatic Ecotoxicity	9.1A	Component A
Soil Ecotoxicity	9.2A	Component A
Ecotoxic to terrestrial vertebrates	9.3C	Component A

Appendix 2: Risk assessment

The methodology involved in assessing risk is outlined in the Supplementary Information section.

Quantitative risk assessments have been undertaken for the use phase of the substance's lifecycle using the GENEEC2 and German BBA models.

Qualitative assessments have been undertaken for all other stages of the lifecycle. In these cases, the level of risk has been evaluated on the basis of the magnitude and likelihood of adverse effects occurring to people or the environment.

The Agency did not identify any risks associated with society and the community, the market economy or New Zealand's international obligations.

Relationship of Māori to the environment

ERMA New Zealand has considered this application in accordance with the clauses 9(b) (i) and 9(c) (iv) and sections 6(d) and 8. In addition, the framework contained in the ERMA New Zealand user guide "Working with Māori under the HSNO Act 1996" has been used to assess the effects of this application on the relationship of Māori to the environment.

The Agency notes that GF-2574 triggers a number of hazardous properties giving rise to the potential for cultural risk including the deterioration of the mauri of taonga flora and fauna species, the environment and the general health and well-being of individuals and the community.

In addition, the introduction and use of this substance has the potential to inhibit the ability of iwi/Māori to fulfil their role as kaitiaki, particularly in relation to the guardianship of waterways given the highly ecotoxic nature of the substance to aquatic species, and potential risks to the mauri ora of human health under prolonged exposure to this substance.

On considering the information outlined here and elsewhere in this report, the Agency considers a minimal impact from Falcon and a minimal impact from Falcon on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna and other taonga to be improbable. In addition there is no evidence to suggest that the controlled use of GF-2574 will breach the principles of the Treaty of Waitangi.

The overall level of risk is therefore considered to be negligible for GF-2574 assuming that the substance will be handled, stored, transported, used, and disposed of, in accordance with the explicitly stated default and additional controls proposed in this report, and any other controls required by other legislation.

However, the Agency notes that should inappropriate use, or accident, result in the contamination of waterways or the environment generally, that users notify the appropriate authorities including the relevant iwi authorities in that region. This action should include advising them of the contamination and the measures taken to contain and remediate.

Operator exposure assessment

The Agency has undertaken an assessment of risks to operator health using the United Kingdom Pesticide Safety Directorate's interpretation of the German BBA Model to estimate operator exposure to aminopyralid tri-isopropanolamine and triclopyr triethylamine salt during the use of GF-2574. This model estimates the exposure of workers to a pesticide during mixing, loading and during spray application, in mg/kg person/day (http://www.pesticides.gov.uk/index.htm). The derived values consider both dermal and inhalation exposure routes.

The BBA model can use either the geometric mean or the 95th percentile model - the geometric mean was used for assessing GF-2574. The BBA model provides for a range of different spray applications (tractor-mounted/trailed sprayers and hand-held sprayers) and formulation types (liquid, wettable powder and wettable granule). Additionally, the BBA model also allows flexibility to vary protective clothing (hands, head and body). Five different scenarios were modeled for GF-2574 as shown in Table A3.1.

The Agency notes that aminopyralid tri-isopropanolamine and triclopyr triethylamine salts rapidly dissociates in water to their equivalent acids. Therefore the exposure assessment was based on the acids instead of the salts.

The applicant states that the maximum application rate of GF-2574 is as follows:

- 2 L GF-2574 /ha which is equivalent to:
    - 0.0588 kg aminopyralid/ha;
    - 0.3886 kg triclopyr/ha

Calculation of Acceptable Operator Exposure Level (AOEL)

The toxicological endpoint used for assessment of occupational (worker) and re-entry worker risks is the AOEL (Acceptable Operator Exposure Level). The AOEL is the maximum amount of active substance to which the operator/re-entry worker may be exposed with a low probability of adverse health effects amongst the healthy worker sub-population, allowing for some margin of safety. AOELs describe the internal (absorbed) dose available for systemic distribution from any route of absorption and are expressed as internal (systemic) levels (mg/kg bw/day). They are derived by dividing the most appropriate NOAEL from relevant studies by one or more uncertainty (safety) factors selected on the basis of the extent and quality of the available data, the species for which data are available and the nature of the effects observed. An absorption factor may be applied to take into account the absorbed dose in the study where this is known (this is a percentage expressed as a factor).

$$\text{AOEL} = \frac{\text{NOAEL}}{\text{Uncertainty Factors}} \text{ x Absorption Factor} = \text{mg/kg bw/day}$$

Selection of NOAELs, Absorption Factor and Uncertainty Factors:
With respect to assigning an appropriate NOA(E)L to calculate the AOEL, the Agency has taken the likely duration and frequency of worker exposure into consideration. The agency has determined that the 90 day repeat-daily exposure is the most appropriate duration and frequency of exposure.

For aminopyralid:

- The Agency considers it is appropriate to use the NOAEL of 26 mg/kg bw/day obtained in the 90 day rabbit study was used. This was based on in-co-ordinated gait in pregnant rabbits at the next higher dose.
- No correction for oral absorption in rabbits is necessary as aminopyralid is extensively absorbed following gavage dosing of pregnant rabbits (EFSA DAR, 2008).
- In the absence of specific data, the Agency has used a combined safety factor of 100 to account for intra- and interspecies variation.

$$\text{AOEL} = \frac{26\,\text{mg/kg bw/day}}{10\,\text{x}\,10}\,\text{x}\,1 = 0.26\,\text{mg/kg bw/day}$$

For triclopyr:

- The Agency considers it is appropriate to use the NOAEL of 5 mg/kg bw/day obtained in the sub-chronic rat study was used. This was determined on the basis of evidence of degeneration of the descending proximal tubules of the kidney at the next higher dose.
- The Agency notes that from the EFSA Report, it indicates that triclopyr is rapidly and extensively absorbed. It is mainly excreted as unchanged in urine (>80%). Therefore, the Agency has assumed 100% absorption.
- In the absence of specific data, the Agency has used a combined safety factor of 100 to account for intra- and interspecies variation.

$$\text{AOEL} = \frac{5\,\text{mg/kg bw/day}}{10\,\text{x}\,10}\,\text{x}\,1 = 0.05\,\text{mg/kg bw/day}$$

Calculation of Risk Quotients and operator risk assessment

To assess the risks to operators the Agency has divided the estimated exposure values as calculated from the exposure modeling by the AOEL to derive a risk quotient (RQ) for each exposure scenario modeled (Table A3.1).

$$\text{RQ} = \frac{\text{Estimated Operator Exposure}}{\text{AOEL}}$$

An RQ > 1 indicates the likelihood of a risk to the operator.

Exposure Calculations

- The Agency has used the maximum application rate for conducting an operator exposure assessment for GF-2574 which is equivalent to:
    - 0.0588 kg aminopyralid/ha;

- 0.3886 kg triclopyr/ha

Table A2.1a to A2.1d details the estimated exposure for each scenario modeled. The following points have been taken into account for the purposes of calculating the estimated exposure. **(Note that the German BBA model does not provide for estimation of operator exposure from aerial application)**. For each model only the conservative scenario as described below, has been addressed:

- an application rate of 0.0588 kg aminopyralid/ha and 0.3886 kg triclopyr/ha;
- the substance is sprayed using a tractor mounted/ boom sprayer with hydraulic nozzles;
- a work rate of 20 hectares per day (the default value for boom sprayers used in the German BBA model) is used in the absence of specific work rate data in the New Zealand context;
- a 25% percutaneous absorption value was used for aminopyralid which was calculated using the Durkin equation and;
- 18% for the dilution and 10% for the concentrate were used for triclopyr based on the in vitro study with human skin (EFSA Report, 2005);
- the bodyweight for operators is set at 70 kg.

Table A2.1a and A2.1d give the estimate RQ values for each exposure scenario based on the AOEL.

Table A2.1a: Estimated exposure to aminopyralid for 70 kg operator applied by ground boom under five different exposure scenarios as predicted from the UK PSDs interpretation of the BBA Model and associated RQ estimates from use of GF-2574

Exposure scenario	Estimated operator exposure (mg/kg bw/day)	RQ
No PPE during mixing, loading and application	0.0187	0.07
Gloves only during mixing and loading	0.0087	0.03
Gloves only during application	0.0171	0.07
Full PPE during mixing, loading and application (excluding respirator)	0.0005	0.00
Full PPE during mixing, loading and application (including respirator)	0.0005	0.00

"Full" PPE includes: gloves, hood/visor, coveralls, and heavy boots during application. The model only provides for use of gloves at mixing loading.

The Agency notes that in all exposure situations modelled, risks to operators are considered to be at acceptable levels (RQ < 1). The Agency considers that, while the 'no PPE' exposure model leads to an acceptable level of risk, it is appropriate to retain requirements for PPE since the use of PPE when handling agrichemicals is good practice. The Agency notes that the HSNO PPE requirements are not prescriptive allowing users to select an appropriate level of PPE.

Table A2.1b: Estimated exposure to triclopyr for 70 kg operator applied by ground boom under five different exposure scenarios as predicted from the UK PSDs interpretation of the BBA Model and associated RQ estimates from use of GF-2574

Exposure scenario	Estimated operator exposure (mg/kg bw/day)	RQ
No PPE during mixing, loading and application	0.0676	1.35
Gloves only during mixing and loading	0.0412	0.82
Gloves only during application	0.0601	1.20
Full PPE during mixing, loading and application (excluding respirator)	0.0022	0.04
Full PPE during mixing, loading and application (including respirator)	0.0020	0.04

"Full" PPE includes: gloves, hood/visor, coveralls, and heavy boots during application. The model only provides for use of gloves at mixing loading.

The only exposure situations in which risks to operators is considered to be acceptable (RQ < 1) is when full PPE is worn during mixing, loading and applying the substance, either with or without a respirator. This indicates full PPE should be worn by operators when mixing, loading and/or applying GF-2574. The Agency notes that PPE is triggered as a default control for GF-2574 as a result of its 6.1E, 8.3A, 6.5B and 6.9B classifications.

Table A2.1c: Estimated exposure to aminopyralid for 70 kg operator applied by knapsack under five different exposure scenarios as predicted from the UK PSDs interpretation of the BBA Model and associated RQ estimates from use of GF-2574

Exposure scenario	Estimated operator exposure (mg/kg bw/day)	RQ
No PPE during mixing, loading and application	0.0518	0.20
Gloves only during mixing and loading	0.0092	0.04
Gloves only during application	0.0496	0.19
Full PPE during mixing, loading and application (excluding respirator)	0.0011	0.00
Full PPE during mixing, loading and application (including respirator)	0.000761	0.00

"Full" PPE includes: gloves, hood/visor, coveralls, and heavy boots during application. The model only provides for use of gloves at mixing loading.

The Agency notes that in all exposure situations modelled, risks to operators are considered to be at acceptable levels (RQ < 1). The Agency considers that, while the 'no PPE' exposure model leads to an acceptable level of risk, it is appropriate to retain requirements for PPE since the use of PPE when handling agrichemicals is good practice. The Agency notes that the HSNO PPE requirements are not prescriptive allowing users to select an appropriate level of PPE.

Table A2.1d: Estimated exposure to triclopyr for 70 kg operator applied by knapsack under five different exposure scenarios as predicted from the UK PSDs interpretation of the BBA Model and associated RQ estimates from use of GF-2574

Exposure scenario	Estimated operator exposure (mg/kg bw/day)	RQ
No PPE during mixing, loading and application	0.1561	3.12
Gloves only during mixing and loading	0.0435	0.87
Gloves only during application	0.1456	2.91
Full PPE during mixing, loading and application (excluding respirator)	0.0047	0.09
Full PPE during mixing, loading and application (including respirator)	0.002724	0.05

"Full" PPE includes: gloves, hood/visor, coveralls, and heavy boots during application. The model only provides for use of gloves at mixing loading.

The only exposure situations in which risks to operators is considered to be acceptable (RQ < 1) is when full PPE is worn during mixing, loading and applying the substance, either with or without a respirator. This indicates full PPE should be worn by operators when mixing, loading and/or applying GF-2574. The Agency notes that PPE is already stated on the label and is also triggered as a default control for GF-2574 as a result of its 6.1E, 8.3A, 6.5B and 6.9B classifications.

Re-entry worker exposures
The Agency assessed the re-entry worker exposures to aminopyralid and triclopyr from the use of GF-2574, using the guidance provided by the Chemicals Regulation Directorate: Pesticides (CRD) on the following web site:
http://www.pesticides.gov.uk/applicant_guide.asp?id=1246&link=%2Fuploadedfiles%2FWeb%5FAssets%2FPSD%2FRe%2Dentry%2520worker%2520guidance%5Ffinal%2520version%2Epdf

The criteria used in the re-entry exposure assessment were:

- Dermal absorption for aminopyralid of 25% (as above);
- Dermal absorption for triclopyr of 18% (as above);
- AOELs for the actives as stated above;
- The default dislodgeable foliar residue of 3 µg of a.i./square cm of foliage/kg a.i per hectare (Chemical Regulation Directorate) and 8 µg of a.i./square cm of foliage/kg a.i per hectare (EU Draft Assessment Report, Triclopyr, 2005) were used for aminopyralid and triclopyr respectively;
- A transfer coefficient of 5000 cm^2/hr (EU Draft Assessment Report, Aminopyralid, 2008) and 500 cm^2/hr (EU Draft Assessment Report, Triclopyr, 2005) were used for aminopyralid and triclopyr respectively;
- A work rate of 8 hours per day;
- Application rates for the actives as described above;
- A protection factor of 1 (for use of clothing) [A value of 1 is used assuming no clothing such as a long sleeved shirt is worn to protect the skin from exposure];
- No protective equipment is worn;

- The assessment assumes that by 28 days (the specified minimum re-application period) there is no residual active ingredient remaining on the treated turf i.e. the initial and re-applications are acting as toxicologically independent exposures.

The results of the re-entry exposure assessment are shown in Table A2.1e.

Table A2.1e: Re-entry exposure assessment for GF-2574 and associated RQ estimates

Active Ingredient	Internal (absorbed) dose available for systemic distribution mg/kg bw/8 hours	AOEL mg/kg bw/day	RQ
Aminopyralid	0.025 mg/kg bw/8 hr	0.26 mg/kg bw/day	0.096
Triclopyr	0.03mg/kg bw/8 hr	0.05 mg/kg bw/day	0.6

The Agency notes that the RQ for re-entry exposure for aminopyralid and triclopyr are below the acceptable intake level thus the re-entry risk is acceptable in the absence of PPE.

Public health exposure and risk assessment

The main potential source of exposure to the general public from GF-2574 (other than via food residues which will be considered as part of the registration of this substance under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997) is via spray drift.

In terms of bystander exposure, toddlers are regarded as the most sensitive sub-population and are regarded as having the greatest exposures. For these reasons, the risk of bystander exposure to GF-2574 was assessed in this sub-population. The oral chronic reference dose (CRfD) was selected because it is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. Thus, the bystander exposure risk assessment estimates the life-time risk associated with repeated daily exposure of the most sensitive human sub-population over their lifespan. The CRfD is calculated by:

$$\text{CRfD} = \frac{\text{NOAEL (most relevant study)}}{\text{Safety Factors}}$$

For aminopyralid:

- *Selection of NOAEL*: The Agency considers it is appropriate to use the NOAEL of 26 mg/kg bw/day obtained in the 90 day rabbit study was used. This was based on in-co-ordinated gait in pregnant rabbits at the next higher dose.
- *Selection of Uncertainty Factors*: The Agency has adopted a combined safety factor of 100 to account for interspecies extrapolation and intraspecies variation. i.e. 10x10.
- *Aminopyralid CRfD calculation:*

$$\text{CRfD} = \frac{26}{100} = 0.26\,\text{mg/kg bw/day}$$

For triclopyr:

- *Selection of NOAEL*: The NOAEL of 3 mg/kg/day is used. This is based on the occurrence of kidney effects on a two-year oral study in rats.
- *Selection of Uncertainty Factors*: The Agency has adopted a combined safety factor of 100 to account for interspecies extrapolation and intraspecies variation. i.e. 10x10.
- *Triclopyr triethylamine CRfD calculation:*

$$\text{CRfD} = \frac{3}{100} = 0.03\,\text{mg/kg bw/day}$$

Table A3.1f: Estimated exposure to aminopyralid applied by ground boom for a 15 kg toddler under four different exposure scenarios as predicted from modified versions of the UK CRD and US EPA toddler exposure equations and associated RQ estimates from use of GF-2574

Exposure scenario	Estimated exposure of 15 kg toddler exposed through contact to surfaces 8 m from an application area (µg/kg bw/day)	Risk Quotient (8 m from an application area)
High boom, fine droplets	0.59	0.0023
High boom, coarse droplets	0.09	0.0004
Low boom, fine droplets	0.20	0.0008
Low boom, coarse droplets	0.05	0.0002

Note: Refer to the Confidential Appendix 10 for more information on the results of the exposure assessment

Table A3.1g: Estimated exposure to triclopyr applied by ground boom for a 15 kg toddler under four different exposure scenarios as predicted from modified versions of the UK CRD and US EPA toddler exposure equations and associated RQ estimates from use of GF-2574

Exposure scenario	Estimated exposure of 15 kg toddler exposed through contact to surfaces 8 m from an application area (µg/kg bw/day)	Risk Quotient (8 m from an application area)
High boom, fine droplets	2.99	0.0998
High boom, coarse droplets	0.48	0.0158
Low boom, fine droplets	1.01	0.0337
Low boom, coarse droplets	0.24	0.0080

Note: Refer to the Confidential Appendix 10 for more information on the results of the exposure assessment

Table A3.1h: Estimated exposure to aminopyralid applied aerially for a 15 kg toddler under four different exposure scenarios as predicted from modified versions of the UK CRD and US EPA toddler exposure equations and associated RQ estimates from use of GF-2574

Exposure scenario	Estimated exposure of 15 kg toddler exposed through contact to surfaces 8 m from an application area (ug/kg bw/day)	RQ
Swath width 20 m, Med-coarse droplet size	0.80	0.0031
Swath width 20 m, coarse- v. coarse droplets	0.59	0.0023
Swath width 20 m, extremely coarse droplets	0.40	0.0015
Swath width 24 m, v. fine-fine droplets	2.21	0.0085

Exposure scenario	Estimated exposure of 15 kg toddler exposed through contact to surfaces 8 m from an application area (ug/kg bw/day)	RQ
Swath width 24 m, fine-med. droplets	1.14	0.0044
Swath width 24 m, med.-coarse droplets	0.78	0.0030

Note: Refer to the Confidential Appendix 10 for more information on the results of the exposure assessment

The Agency acknowledges that the label recommends that pasture will be treated using coarse droplets. A low boom and swath width 20 m, coarse droplets sprayers for boom application is assumed. Therefore, for boom application the Agency is using the worst exposure scenarios in the bystander exposure assessment which is high boom fine droplets.

For aminopyralid:

- The total exposure from high boom, fine droplets at 8 metres from the application area is 0.59 µg/kg bw/day (0.00059 mg/kg bw/day). This is below the CRfD, indicating that the risk to young children from dermal, hand to mouth, object to mouth, soil ingestion and aerial exposure to aminopyralid is acceptable.

For triclopyr:

- The total exposure from high boom, fine droplets at 8 metres from the application area is 3.89 µg/kg bw/day (0.00389 mg/kg bw/day). This is below the CRfD, indicating that the risk to young children from dermal, hand to mouth, object to mouth, soil ingestion and aerial exposure to triclopyr is acceptable.

Summary and conclusions of the human risk assessment

The outcome of the quantitative assessment of risks from the use of GF-2574 indicates that operators (without full PPE) are considered to be at risk as the some of the RQs calculated from all the different scenarios are greater than 1.

The outcome of the quantitative assessment for re-entry workers and bystanders indicates that risk to re-entry workers and bystanders from the use of GF-2574 are considered acceptable.

Environmental exposure and risk assessment

For Class 9 substances, irrespective of the intrinsic hazard classification, the ecological risk can be assessed for a substance by calculating a risk quotient based on an estimated exposure concentration. Such calculations incorporate toxicity values, exposure scenarios (including spray drift, application rates and frequencies), and the half lives of the component(s) in soil and water. The calculations provide an Estimated Environmental Concentration (EEC) which, when divided by the LC_{50} or EC_{50}, gives a risk quotient (RQ).

$$\text{Acute RQ} = \frac{EEC_{\text{short term}}}{LC_{50} \text{ or } EC_{50}} \qquad \text{Chronic RQ} = \frac{EEC_{\text{long term}}}{NOEC}$$

If the RQ exceeds a predefined level of concern, this suggests that it may be appropriate to refine the assessment or to apply the approved handler (AH) control and/or other controls to ensure that appropriate matters are taken into account to minimize off-site movement of the substance. Conversely, if a worst-case scenario is used, and the level of concern is not exceeded, then in terms of the environment, there is a presumption of low risk which is able to be adequately managed by such things as label statements (warnings, disposal). The AH control can then be removed on a selective basis.

Levels of concern (LOC) developed by the USEPA (Urban and Cook 1986) and adopted by the Agency, to determine whether a substance poses an environmental risk are provided in Table A2.1.

Table A2.1: Levels of concern as adopted by the Agency.

Endpoint	LOC	Presumption
Aquatic (fish, invertebrates)		
Acute RQ≥	0.5	High acute risk
Acute RQ	0.1-0.5	Risk can be mitigated through restricted use
Acute RQ<	0.1	Low risk
Chronic RQ≥	1.0	High chronic risk
Plants (aquatic and terrestrial)		
Acute RQ≥	1.0	High acute risk
Mammals and birds		
Acute dietary RQ≥	0.5	High acute risk
Acute oral dose [granular products] RQ≥	0.5	High acute risk
Chronic RQ≥	1.0	High chronic risk

Aquatic risk

Assessment of Expected Environmental Concentration

The Agency has used the Generic Estimated Environmental Concentration Model v2 (GENEEC2) surface water exposure model (USEPA 2001) to estimate the EEC of in surface water which may potentially arise as a result of spray drift and surface runoff from the applicant's proposed New Zealand use pattern.

The parameters used in the GENEEC2 modeling are listed in Table A2.2 and represent the recommended use on pasture (highest rate) a conservative estimate.

The active ingredient triclopyr triethylamine salt dissociates very rapidly in the aquatic environment to triclopyr acid; moreover all degradation data and aquatic ecotox data available refer to triclopyr acid. Therefore the aquatic risk was assessed on triclopyr acid basis. This has been done previously in the assessment of the active ingredient concentrate HSR05048 (Garlon 360).

Table A2.2: Input parameters for GENEEC2 analysis.

Active ingredient	Triclopyr acid	Aminopyralid	Reference
Application rate	562.3 g triclopyr triethylamine/ha that equals to **388.612** triclopyr/ha	113.1 g aminopyralid triisopropanolamine salt/ha that equals to **58.8** aminopyralid/ha	Applicant
Application frequency	1	1	
Application interval	NA	NA	
Sorption	K_d: 40.54 mL/g	K_{oc}: 1.72 mL/g*	
Aerobic soil DT_{50}	56.9 days	72 days **	
Pesticide wetted in?	No	No	
Methods of application	Aerial	Aerial	
'No spray' zone	0	0	
Water solubility	440 mg/L	2480 mg/L	
Aerobic aquatic DT_{50}	142 days	999 days ***	
Aqueous photolysis DT_{50}	0.38 days	0.6 days	

* *According to GENEEC2 user guide: The lowest of measured values on non-sand texture soil.*

** *As there are values available from 4 different studies the upper 90% confidence limit has been calculated according to GENEEC2 user guide.*

*** *The longest value of three available calculated aerobic aquatic half-lifes (water-sediment system) was selected as recommend by the GENEEC2 user guide.*

Output from the GENEEC2 model-Triclopyr

```
RUN No.   1 FOR triclopyr        ON   pasture       * INPUT VALUES *
-----------------------------------------------------------------------
RATE (#/AC)    No.APPS &    SOIL  SOLUBIL    APPL TYPE  NO-SPRAY INCORP
 ONE(MULT)     INTERVAL      Kd    (PPM)     (%DRIFT)    ZONE(FT)   (IN)
-----------------------------------------------------------------------
.346 (.346)     1   1       .5     440.0   AERL_B (13.0)    .0      .0


FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)
-----------------------------------------------------------------------
METABOLIC  DAYS UNTIL  HYDROLYSIS    PHOTOLYSIS    METABOLIC  COMBINED
 (FIELD)   RAIN/RUNOFF   (POND)      (POND-EFF)     (POND)     (POND)
-----------------------------------------------------------------------
  56.90        2          N/A        .38-   47.12   142.00     35.38
```

```
GENERIC EECs (IN MICROGRAMS/LITER (PPB))     Version 2.0 Aug 1, 2001
-----------------------------------------------------------------
    PEAK      MAX 4 DAY     MAX 21 DAY    MAX 60 DAY    MAX 90 DAY
    GEEC      AVG GEEC       AVG GEEC      AVG GEEC      AVG GEEC
-----------------------------------------------------------------
    19.27       18.97         17.33         14.22         12.34
```

The Estimated Environmental Concentration (EEC) for triclopyr as estimated by GENEEC2 are:

Peak EEC 0.01927 mg/L

Output from the GENEEC2 model-Aminopyralid

```
 RUN No.   1 FOR aminopyralid     ON   pasture       * INPUT VALUES *
-----------------------------------------------------------------------
 RATE (#/AC)   No.APPS &   SOIL  SOLUBIL   APPL TYPE NO-SPRAY INCORP
  ONE(MULT)     INTERVAL    Koc   (PPM )    (%DRIFT)    (FT)      (IN)
-----------------------------------------------------------------------
.052(   .052)   1   1       1.7 2480.0   AERL_B( 13.0)     .0    .0


FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)
-----------------------------------------------------------------------
METABOLIC  DAYS UNTIL  HYDROLYSIS   PHOTOLYSIS   METABOLIC  COMBINED
 (FIELD)   RAIN/RUNOFF   (POND)     (POND-EFF)    (POND)     (POND)
-----------------------------------------------------------------------
  72.00        2          N/A       .60-   74.40   999.00     69.24


GENERIC EECs (IN MICROGRAMS/LITER (PPB))     Version 2.0 Aug 1, 2001
-----------------------------------------------------------------
    PEAK      MAX 4 DAY     MAX 21 DAY    MAX 60 DAY    MAX 90 DAY
    GEEC      AVG GEEC       AVG GEEC      AVG GEEC      AVG GEEC
-----------------------------------------------------------------
     3.11        3.08          2.94          2.65          2.46
```

The Estimated Environmental Concentration (EEC) for triclopyr as estimated by GENEEC2 are:

Peak EEC 0.00311 mg/L

Assessment of acute risk-Triclopyr

Table A2.3: Aquatic Ecotoxicity endpoints to be used in risk assessment.

Acute risk		**Chronic risk**	
Species	**LC/EC_{50} (mg/L)**	**Species**	**NOEC (mg/L)**
Fish	117	Fish	ND
Crustacea	132.9	Crustacea	ND
Algae	0.56		

Table A2.4: Acute risk quotients derived from the GENEEC2 model and toxicity data.

	Peak EEC from GENEEC2 (mg/L)	**LC_{50} or EC_{50} (mg/L)**	**RQ (Acute) EEC/ LC_{50} or EC_{50}**

Fish	0.0193	117	0.000165
Crustacea		132.9	0.000145
Algae		0.56	0.0344

When compared against the relevant acute levels of concern (Table A2.3), the acute RQs derived from the GENEEC2 modeling for triclopyr indicate the following:

For fish and crustacean: the acute risk is low
For algae: the acute risk is low

As no chronic ecotoxicity data was available for triclopyr, no estimation of chronic risk was able to be made.

Assessment of acute risk-Aminopyralid

Table A2.5: Aquatic Ecotoxicity endpoints to be used in risk assessment.

Acute risk		**Chronic risk**	
Species	**LC/EC$_{50}$ (mg/L)**	**Species**	**NOEC (mg/L)**
Fish	100	Fish	ND
Crustacea	98.6	Crustacea	ND
Algae	15		

Table A2.6: Acute risk quotients derived from the GENEEC2 model and toxicity data.

	Peak EEC from GENEEC2 (mg/L)	**LC$_{50}$ or EC$_{50}$ (mg/L)**	**RQ (Acute) EEC/ LC$_{50}$ or EC$_{50}$**
Fish	0.00311	100	0.00003
Crustacea		98.6	0.00003
Algae		15	0.0002

When compared against the relevant acute levels of concern (Table A2.6), the acute RQs derived from the GENEEC2 modeling for aminopyralid indicate the following:

For fish and crustacean: the acute risk is low
For algae: the acute risk is low

As no chronic ecotoxicity data was available for aminopyralid, no estimation of chronic risk was able to be made.

Terrestrial risk

Spray Drift Modelling – Phytotoxicity

Triclopyr triethylamine

Triclopyr triethylamine is sprayed at a maximum application rate of 0.5623 kg a.i./ha or 0.5623 x 100 = 56.23 mg a.i./m^2.

Soil-based exposure

If it assumed that the triclopyr triethylamine is dispersed to a depth of 0.05 m and the density of soil is 1500 kg/m^3, then the 56.23 mg a.i./m^2 triclopyr triethylamine will be dispersed within 75 kg of soil/m^2 giving 56.23/75 = 0.75 mg/kg.

If it is assumed that 13% (aerial application) of the triclopyr triethylamine will reach directly outside the target area (an assumption based on GENEEC2 modeling), then the concentration of triclopyr triethylamine adjacent to a sprayed field would be 0.75 x 0.13 = 0.0975 mg/kg soil.

Triclopyr triethylamine generates an EC_{25} value of 0.002 mg/kg for soybean. Consequently, triclopyr triethylamine (aerial application) results in a risk quotient of 0.0975/0.002 = **48.75**.

Aminopyralid acid, triisopropanolamine salt

Aminopyralid acid, triisopropanolamine salt is sprayed at a maximum application rate of 0.0588 kg a.i./ha or 0.0588 x 100 = 5.88 mg a.i./m^2.

Soil-based exposure

If it assumed that the aminopyralid acid, triisopropanolamine salt is dispersed to a depth of 0.05 m and the density of soil is 1500 kg/m^3, then the 5.88 mg a.i./m^2 aminopyralid acid, triisopropanolamine salt will be dispersed within 75 kg of soil/m^2 giving 5.88/75 = 0.0784 mg/kg.

If it is assumed that 13% (aerial application) of the aminopyralid acid, triisopropanolamine salt will reach directly outside the target area (an assumption based on GENEEC2 modeling), then the concentration of aminopyralid acid, triisopropanolamine salt adjacent to a sprayed field would be 0.0784 x 0.13 = 0.010192 mg/kg soil.

Aminopyralid acid, triisopropanolamine salt generates an EC_{50} value of 0.00154 mg/kg for soybean. Consequently, aminopyralid acid, triisopropanolamine salt (aerial application) results in a risk quotient of 0.010192/0.00154 = **6.6**.

Summary and conclusions of the ecological risk assessment

Based on the risk assessment for the aquatic and terrestrial environment as set out above, risks to the following species groups have been identified.

For non-target plants: the risk is **high**

Based on the acute RQs for non-target plants, the Agency considers it is appropriate to retain the approved handler controls for GF-2574 when it is used in a wide dispersive manner, or by a commercial contractor. Further, the Agency considers that the application rate proposed by the applicant and used in the modeling should be set as a maximum application rate.

Appendix 3: Default controls for GF-2574 and their variation

Based on the hazard classification as shown in Table A3.1, the set of associated controls has been identified. These default controls, expressed as control codes[3], are listed in Table A3.1.

Table A3.1: List of default controls for GF-2574

HSNO Classification	HSNO Controls
8.1A 6.1E 8.3A 6.5B 6.9B 9.1A 9.2A 9.3C	**Toxic** T1, T2, T4, T5, T7 **Ecotoxic** E1, E2, E5, E6, E7 **Identification** I1, I2, I3, I8, I9, I10, I11, I16, I17, I18, I19, I21, I22, I23, I28, I29, I30 **Packaging** P1, P3, P13, P14, P15, PG3, PS4 **Disposal** D4, D5, D6, D7, D8 **Emergency Management** EM1, EM2, EM6, EM7, EM8, EM11, EM12, EM13 **Approved Handler** AH1 **Tracking** TR1 **Tank Wagons and Transportable Containers**

The Authority is able to vary the default controls and impose controls under sections 77 and 77A to produce a set of controls relevant to substance under assessment. The following discussion reviews the default controls and rationalises their use for these substances.

Toxicity Controls

Setting of TELs (Control Code T1)

Tolerable Exposure Limits (TELs) are designed to limit the extent to which the general public is exposed to hazardous (toxic) substances. A TEL represents the maximum concentration of a substance legally allowable in a particular medium, and can be set as either a guideline value or an action level that should not be exceeded. For the purposes of setting TELs, an environmental medium is defined as air, water, soil or a surface that a hazardous substance may be deposited onto.

TELs are established from PDE (Potential Daily Exposure) values, which are themselves established from ADE (Acceptable Daily Exposure) values or reference doses (RfD) which are similar to ADE but are used to protect against a specific toxic effect of concern.

An ADE is an amount of a hazardous substance (mg/kg bodyweight/day), that, given a lifetime of daily exposure, would be unlikely to result in adverse human health effects. An

[3] Control codes are those assigned by ERMA New Zealand to enable easy cross reference with the regulations. A detailed list of these codes is contained in the Supplementary Information (section 2).

RfD (reference dose) is a similar measure that can be used to protect against a specific toxic effect of concern.

Regulation 11(1) of the Hazardous Substances (Classes 6, 8 and 9) Controls Regulations 2001 determines when an ADE/RfD is required to be set:

> *(1) This regulation applies to a class 6 substance if-*
>
> *(a) it is likely to be present in-*
>
> *(i) 1 or more environmental media; or*
>
> *(ii) food; or*
>
> *(iii) other matter that might be ingested; AND*
>
> *(b) it is a substance to which a person is likely to be exposed on 1 or more occasions during the lifetime of the person; AND*
>
> *(c) exposure to the substance is likely to result in an appreciable toxic effect.*

If all three requirements of regulation 11(1) are met, then an ADE/RfD should be set for the relevant component(s), and PDE and TEL values subsequently established for each relevant exposure route.

The toxicity (Class 6) classifications of GF-2574 that trigger the need to consider setting a TEL are 6.1E, 6.5B and 6.9B classifications.

For GF-2574, the Agency considers that triclopyr triethylamine salt fulfills the requirements of Regulation 11(1)(a), (b) and (c), and therefore notes that an ADE is required to be set for this component. Given the specific use of GF-2574, the Agency considers that the principal source of exposure of the general public to the substance is via food residues, an exposure route managed by the NZFSA through the setting of MRLs. The Agency notes that MRLs have been set for triclopyr acid and its salt and are applicable to GF-2574.

With respect to setting TELs for other exposure routes, the Agency is intending to review the setting of ADEs, PDEs and TELs under section 77B of the Act. Until this review is complete, the Agency proposes not to set ADEs, PDEs or TELS for any components of GF-2574 at this time.

Setting of WES (Control Code T2)

Workplace Exposure Standards (WES) are designed to protect persons in the workplace from the adverse effects of toxic substances. A WES is an airborne concentration of a substance (expressed as mg substance/m3 of air, or ppm in air), which must not be exceeded in a workplace and only applies to places of work (Regulation 29(2), Hazardous substances (Classes 6, 8 and 9 Controls) Regulations 2001).

Regulation 29(1) of the Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 determines when a WES is required to be set. If all three of the requirements of this regulation are met then a WES is required to be set.

Regulation 29 states:

(*1*) *This regulation and regulation 30 apply to a **class 6** substance if,-*

(a) under the temperature and pressure the substance is to be used in, it can become airborne and disperse in air in the form of inspirable or respirable dust, mists, fumes, gases or vapours; AND

(b) human exposure to the substance is primarily through the inhalation or dermal exposure routes; AND

(c) the toxicological and industrial hygiene data available for the substance is sufficient to enable a standard to be set.

When setting WES, the Authority must either adopt a value already proposed by the Department of Labour or already set under HSNO or derive a value by taking into account the matters described in Regulation 30(2) of the Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations.

The Agency typically adopts WES values listed in the Workplace Exposure Standards (Effective from 2002) document (refer to the link below):
http://www.osh.govt.nz/order/catalogue/pdf/wes2002.pdf

The Agency notes that at this time a Department of Labour WES value has been set for component C in GF-2574; however, no values have been found to have been set for any other component by any relevant overseas body that the Agency monitors. This Department of Labour WES value is considered relevant to GF-2574 and it is proposed that it be adopted as HSNO WES.

Approved Handler Controls - Highly Toxic Substances (AH1, T6)

Approve Handler controls are not triggered by the toxicity classification.

Tracking Control - Highly Toxic Substances (TR1)

The tracking control is not triggered by the toxicity classification.

Ecotoxicity Controls

Setting of EELs (Control code E1)

Regulation 33 of the Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 specify that an environmental exposure limit (EEL) may be set for a class 9 substance for one or more environmental media if organisms that live in that environment may be exposed to the substance. An EEL is the (maximum) concentration of a substance in an environmental medium that will present a negligible risk of adverse environmental effects to organisms (excluding humans) in non-target areas.

As specified by regulation 32, a default EEL of 0.1 µg/L water is set for any class 9.1 substance, and 1 µg/kg soil (dry weight) for any class 9.2 substance.

For the purposes of setting EELs, an environmental medium is defined as water, soil or sediment where these are in the natural environment, or a surface onto which a hazardous substance may be deposited.

An EEL can be established by one of three means:

- Applying the default EELs specified in regulation 32
- Adopting an established EEL as provided by regulation 35(a)
- Calculating an EEL from an assessment of available ecotoxicological data as provided by regulation 35(b).

The Hazardous Substances and New Organisms (Approvals and Enforcement) Act 2005 added a new section (s77B) to the HSNO Act, which, amongst other things provided the Authority with the ability to set EELs as guideline values, rather than the previous pass/fail values.

However, until the Agency has developed formal policy on the implementation of s77B, it proposes not to set EELs for any components of GF-2574 at this time. It is also proposed that the default EEL water and soil values be deleted until the policy has been established.

Setting of Application Rate (Control Code E2)

These regulations relate to the requirement to set an application rate for a class 9 substance that is to be sprayed or applied to an area of land (or air or water) and for which an EEL has been set.

Although no EEL has been set for GF-2574, the Agency proposes setting the application rate of 2 L/ha maximum and once only to the target weed per season as the application rate for GF-2574. This rate was used in the ecological risk assessment.

Approved Handler Controls - Highly Toxic Substances (AH1, T6)

Approved handler requirements have been triggered for GF-2574 as a result of its 9.1A and 9.2A classification. The outcome of the ecological risk assessment (refer Appendix 3) indicates that there is potential for acute adverse environmental effects on terrestrial plants if the substance moves off-target. The Agency considers it is therefore appropriate to retain the approved handler control.

This approach is consistent with the Authority's policy on approved handler and tracking controls for class 9 substances (November 2003).

Tracking Control - Highly Toxic Substances (TR1)

Tracking requirements have been triggered for GF-2574 as a result of its 9.1A and 9.2A classifications. However, for substances where the tracking control has been triggered solely as a result of ecotoxicity, it is considered that any risk that may arise during its life-cycle are adequately managed by other controls such as approved handler, packaging, labeling and emergence management requirements. The Agency therefore considers the tracking control can be deleted as provided by section 77(4)(b).

This approach is consistent with the Authority's policy on approved handler and tracking controls for class 9 substances (November 2003).

Other controls required as a result of the ecological risk assessment.

- This substance is to be applied via ground based methods only.

- This substance is not to be applied onto or into water.

Controls to manage physical hazards

Approved Handler Controls

GF-2574 is classified as a physical hazard (8.1A); however, the Approved Handler controls are not triggered.

Tracking control (TR1)

GF-2574 is classified as a physical hazard (8.1A); however the Tracking control is not triggered.

Identification controls

Identification of Toxic and/or Corrosive Components on Labels/Documentation (SDS)

The Hazardous Substances (Identification) Regulations 2001 specify that certain toxic and/or corrosive components are required to be specified on the product label and on SDS documentation.

Identification of toxic components on labels

Regulations 25(e) and 25(f) require that certain toxic components are required to be specified on the product label.

Regulation 25(e) states:

...a toxic substance must be identified by...

'information identifying, by its common or chemical name, every ingredient, that would, independently of any other ingredient, give the substance a hazard classification of 6.1A, 6.1B, 6.1C, 6.5, 6.6, 6.7, 6.8 or 6.9, and the concentration of that ingredient in the substance."

Regulation 25(f) states:

...a toxic substance must be identified by...

"information identifying (other than an ingredient referred to in paragraph (E)) that would, independently of any other ingredient, give the substance a hazard classification of 6.1D, and the concentration of the ingredient that would contribute the most to that classification."

Identification of corrosive components on labels

Regulation 19(f) requires that certain corrosive components are required to be specified on the product label.

Regulation 19(f) states:

...a corrosive substance must be identified by...

"If the substance contains any ingredient in such a concentration that the ingredient would, independently of any other ingredient, cause the substance to be classified as class 8.2 or class 8.3, in respect of each such ingredient,-
(i) its common or chemical name; and
(ii) a statement of its concentration in the substance."

Identification of toxic and/or corrosive components on SDS

Regulation 39(5) of the Hazardous Substances (Identification) Regulations 2001, states that certain corrosive and toxic components are required to be specified on documentation.

Regulations 39(5) states:

"The requirements of regulation 19(f) or (as the case requires) regulation 25(e) apply to all documentation; but any ingredient required by that provision to be identified (other than an ingredient to which regulation 26 applies) must also be identified by any Chemical Abstract Services number allocated to it."

Concentration cut-offs for component identification

Consistent with the guidance provided by GHS, the Hazardous Substances Standing Committee (HSSC) agreed that the concentration cut-offs triggering the requirement for identification of components on labels and documentation are:

HSNO Classification	Cut-off for label (% w/w)	Cut-off for SDS (% w/w)
6.5A, 6.5B, 6.6A, 6.7A	0.1	0.1
6.6B	1	1
6.7B	1	0.1
6.8A, 6.8C	0.3	0.1
6.8B	3	0.1
6.9A, 6.9B	10	1

GF-2574 - Components requiring identification

Under these regulations, as determined by the HSSC (March 2006), the name and concentration of the following components need to be specified on the label and documentation:

Label	Documentation
Triclopyr triethylamine	Triclopyr triethylamine

Appendix 4: Proposed controls for GF-2574

Table A4.1: Proposed controls for GF-2574 – codes, regulations and variations.

Control Code[4]	Regulation [5]	Topic	Variations
Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001 - Toxicity			
T1	11 – 27	Limiting exposure to toxic substances through the setting of TELs	No TELs are set for GF-2574 at this time.
T2	29, 30	Controlling exposure in places of work through the setting of WESs.	A WES is set for Component C.
T4, E6	7	Requirements for equipment used to handle substances	Controls T4 and E6 are combined.
T5	8	Requirements for protective clothing and equipment	
T7	10	Restrictions on the carriage of toxic or corrosive substances on passenger service vehicles	Regulation 10 applies as if the maximum quantity per package of a 6.5 substance is 1.0 L.
Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001 - Ecotoxicity			
E1	32 – 45	Limiting exposure to ecotoxic substances through the setting of EELs	No EELs are set for GF-2574 at this time.
E2	46 – 48	Restrictions on use of substances in application areas	An application rate is set for GF-2574 under section 77A: *2 L/ha once a season*
E5	5(2), 6	Requirements for keeping records of use	
E7	9	Approved handler/security requirements for certain ecotoxic substances	This substance must be under the personal control of an approved handler when the substance is: a) applied in a wide dispersive manner; or b) used by a commercial contractor.
Hazardous Substances (Identification) Regulations 2001			
I1	6, 7, 32-35, 36 (1)-(7)	General identification requirements Regulation 6 – Identification duties of suppliers Regulation 7 – Identification duties of persons in charge Regulations 32 and 33 – Accessibility of information Regulations 34, 35, 36(1)-(7) – Comprehensibility, Clarity and Durability of information	
I2	8	Priority identifiers for corrosive	

[4] Note: The numbering system used in this column relates to the coding system used in the ERMA New Zealand Controls Matrix. This links the hazard classification categories to the regulatory controls triggered by each category. It is available from the ERMA New Zealand website www.ermanz.govt.nz/resources and is also contained in the ERMA New Zealand User Guide to the HSNO Control Regulations.

[5] These Regulations form the controls applicable to this substance. Refer to the cited Regulations for the formal specification, and for definitions and exemptions. The accompanying explanation is intended for guidance only.

Control Code[4]	Regulation [5]	Topic	Variations
		substances	
I3	9	Priority identifiers for ecotoxic substances	
I8	14	Priority identifiers for toxic substances	
I9	18	Secondary identifiers for all hazardous substances	
I10	19	Secondary identifiers for corrosive substances	
I11	20	Secondary identifiers for ecotoxic substances	
I16	25	Secondary identifiers for toxic substances	
I17	26	Use of Generic Names	
I18	27	Use of Concentration Ranges	
I19	29-31	Alternative information in certain cases Regulation 29 – Substances in fixed bulk containers or bulk transport containers Regulation 30 – Substances in multiple packaging Regulation 31 – Alternative information when substances are imported	
I21	37-39, 47-50	Documentation required in places of work Regulation 37 – Documentation duties of suppliers Regulation 38 – Documentation duties of persons in charge of places of work Regulation 39 – General content requirements for documentation Regulation 47 – Information not included in approval Regulation 48 – Location and presentation requirements for documentation Regulation 49 – Documentation requirements for vehicles Regulation 50 – Documentation to be supplied on request	
I22	40	Specific documentation requirements for corrosive substances	
I23	41	Specific documentation requirements for ecotoxic substances	
I28	46	Specific documentation requirements for toxic substances	
I29	51, 52	Signage requirements	
I30	53	Advertising corrosive and toxic substances	

Control Code[4]	Regulation [5]	Topic	Variations
Hazardous Substances (Packaging) Regulations 2001			
P1	5, 6, 7 (1), 8	General packaging requirements Regulation 5 – Ability to retain contents Regulation 6 – Packaging markings Regulation 7(1) – Requirements when packing hazardous substance Regulation 8 – Compatibility Regulation 9A and 9B – Large Packaging	
P3	9	Packaging requirements for substances packed in limited quantities	
P13, P14, P15	17, 18, 19	Packaging requirements for toxic substances	Controls P13, P14 and P15 are combined.
PG3	Schedule 3	The tests in Schedule 3 correlate to the packaging requirements of UN Packing Group III (UN PGIII).	
PS4	Schedule 4	This schedule describes the minimum packaging requirements that must be complied with when a substance is packaged in limited quantities	
Hazardous Substances (Disposal) Regulations 2001			
D4, D5	8, 9	Disposal requirements for GF-2574	Controls D4 and D5 are combined.
D6	10	Disposal requirements for packages	
D7	11, 12	Disposal information requirements	
D8	13, 14	Disposal documentation requirements	
Hazardous Substances (Emergency Management) Regulations 2001			
EM1	6, 7, 9-11	Level 1 emergency management information: General requirements	
EM2	8(a)	Information requirements for corrosive substances	
EM6	8(e)	Information requirements for toxic substances	
EM7	8(f)	Information requirements for ecotoxic substances	
EM8	12-16, 18-20	Level 2 emergency management documentation requirements	
EM11	25-34	Level 3 emergency management requirements – emergency response plans	
EM12	35-41	Level 3 emergency management requirements: secondary containment	The following subclauses are added:

After subclause (3) of regulation 36:

(4) For the purposes of this regulation, and regulations 37 to 40, where this substance is contained in pipework that is installed and operated so as to manage any loss of containment in the pipework it—

(a) is not to be taken into account in determining whether a place is required to have a secondary containment system; and

(b) is not required to be located in a secondary containment system.

Control Code[4]	Regulation [5]	Topic	Variations
(5) In this clause, pipework— *(a) means piping that—* *(i) is connected to a stationary container; and* *(ii) is used to transfer a hazardous substance into or out of the stationary container; and* *(b) includes a process pipeline or a transfer line.* At the end of regulation 37: *(2) If pooling substances which do not have class 1 to 5 hazard classifications are held in a place above ground in containers each of which has a capacity of 60 litres or less—* *(a if the place's total pooling potential is less than 20,000 litres, the secondary containment system must have a capacity of at least 25% of that total pooling potential:* *(b) if the place's total pooling potential is 20,000 litres or more, the secondary containment system must have a capacity of the greater of—* *(i) 5% of the total pooling potential; or* *(ii) 5,000 litres.* *(3) Pooling substances to which subclause (2) applies must be segregated where appropriate to ensure that leakage of one substance may not adversely affect the container of another substance.* At the end of regulation 38: *(2) If pooling substances which do not have class 1 to 5 hazard classifications are held in a place above ground in containers 1 or more of which have a capacity of more than 60 litres but none of which have a capacity of more than 450 litres—* *(a) if the place's total pooling potential is less than 20,000 litres, the secondary containment system must have a capacity of either 25% of that total pooling potential or 110% of the capacity of the largest container, whichever is the greater:* *(b) if the place's total pooling potential is 20,000 litres or more, the secondary containment system must have a capacity of the greater of—* *(i) 5% of the total pooling potential; or* *(ii) 5,000 litres* *(3) Pooling substances to which subclause (2) applies must be segregated where appropriate to ensure that the leakage of one substance may not adversely affect the container of another substance.*			
EM13	42	Level 3 emergency management requirements: signage	
Hazardous Substances (Personnel Qualifications) Regulations 2001			
AH1	4 – 6	Approved Handler requirements (including test certificate and qualification requirements)	varied (see Control E7)
Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004			
Regulations 4 to 43 where applicable		The Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004 prescribe a number of controls relating to tank wagons and transportable containers and must be complied with as relevant	

Additional controls set under s77A
GF-2574 not to be applied onto or into water.
The maximum application rate for GF-2574 is set at 2 L/ha, applied once per season to the same plant.
GF-2574 is to be applied via ground based methods only.
The following statements must appear on the label: THE PRODUCT MUST NOT BE USED ON TURF DO NOT use hay or other plant material harvested within 10 weeks of treatment with (tradename of substance) for making compost or mulching susceptible crops. DO NOT use plant material that has been treated with (tradename of substance) within the previous 10 weeks to make mushroom substrate. DO NOT use manure, paunch grass or dairy effluent from animals grazing areas treated with (tradename of substance) within the previous 10 weeks for making compost unless the clean feed withholding period has been observed.
The controls relating to stationary container systems, as set out in Schedule 8 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004 (Supplement to the *New Zealand Gazette*, 26 March 2004, No. 35, page 767), as amended, shall apply to this substance, notwithstanding clause 1(1) of that schedule.
Addition of subclauses after subclause (3) of Regulation 36 of the Hazardous Substances (Emergency Management Controls) Regulations 2001 (control EM12)
Addition of clauses after Regulation 37 of the Hazardous Substances (Emergency Management Controls) Regulations 2001 (control EM12).
Addition of clauses after Regulation 38 of the Hazardous Substances (Emergency Management Controls) Regulations 2001 (control EM12).

Appendix 5: Parties notified

Aakland Chemicals (1997) Limited
AgBio Research Limited
Agcarm Incorporated
AgResearch Limited
Agronica New Zealand Limited
AR and JA Drysdale Limited
ARPPA
Baldwins Intellectual Property
BASF New Zealand Limited
Bayer New Zealand Limited
BOC Limited
Chancery Green
Chemagro New Zealand Limited
Chemsafety Limited
Comunity and Public Health
Dow AgroSciences Australia Limited
DuPont (New Zealand) Limited
Environment Bay of Plenty
Far North District Council
Farmoz Pty Ltd
Federated Farmers of New Zealand (Incorporated)
Fish and Game Eastern Region
Fruitfed Supplies Limited (PGG Wrightson Ltd)
Grayson Wagner Company Ltd
Greater Wellington - The Regional Council
Green Party of Aotearoa New Zealand
Hawkes Bay Regional Council
IMCD New Zealand Limited
Kaipara District Council
Kawerau District Council
Landcorp Farming Limited
Lowndes Associates
Ministry of Agriculture and Fisheries (MAF) Biosecurity New Zealand
Ministry of Research Science and Technology (MoRST)
Napier Health Centre - Public Health Unit
National Beekeepers Association
New Zealand Bee Industry Group - Federated Farmers
New Zealand Chemical Industry Council Inc
New Zealand Customs Service
New Zealand Meatworkers Union
New Zealand Press Association
New Zealand Society of Gunsmiths Inc
Ngāti Kahungunu Iwi Incorporated
Northland District Health Board
Northland Regional Council
Nufarm New Zealand Limited
Pacific Growers Supplies Limited
Pesticide Action Network Aotearoa New Zealand
PharmVet Solutions
Physicians and Scientists for Global Responsibility (PSGR)

Rangitikei District Council
Reckitt Benckiser
Schering Plough Animal Health Limited
Sigma Aldrich
South Taranaki District Council
Sustainability Council of New Zealand
Syngenta Crop Protection Limited
Taranaki Regional Council
Tasman District Council
Taupo District Council
Technical Compliance Consultants Ltd
Television New Zealand
The Eden Park Trust
The National Beekeepers Association of New Zealand
The New Zealand Institute for Plant and Food Research Limited (Auckland)
The New Zealand Society for Risk Management Inc
TMP Consultancy
Zelam Limited

7 Private Individuals

Appendix 6: References

ERMA New Zealand (2008a) *User Guide to HSNO Thresholds and Classifications.* ERMA New Zealand, Wellington.

ERMA New Zealand (2008b) HSNO Chemical Classification Information Database (CCID) http://www.ermanz.govt.nz/hs/compliance/chemicals.html

European Union (2006) *Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC*. http://reach.jrc.it/

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Urban DJ, Cook, NJ (1986) *Hazard Evaluation Division Standard Evaluation Procedure: Ecological Risk Assessment*. EPA 540/9-85-001. United States Environmental Protection Agency Office of Pesticide Programs, Washington DC, USA.

USEPA (2001) Generic Estimated Environmental Concentration Model v2 (GENEEC2). United States Environmental Protection Agency Office of Pesticide Programs, Washington DC, USA http://www.epa.gov/oppefed1/models/water/index.htm#geneec2

Appendix 7: Confidential material

Supplementary Information

This document has been prepared to support the Agency's Hazardous Substances Evaluation and Review reports. It contains background information on five areas and has been divided into the following sections:

1) The regulatory basis for assessing the application.

2) Legislation that will affect the use of hazardous substances within New Zealand. -this section covers the range of default controls available for use by the Agency and lists other legislation that will affect the use of hazardous substances.

3) Risk Assessment- The steps and methodology involved in assessment of effects.

4) Qualitative Descriptors for Risk/Benefit Assessment- the descriptors used to assess the level of each risk or benefit to determine their level of significance.

5) Decision pathway- to be use when assessing an application for the release of hazardous substances.

1. Regulatory basis for assessing the application

1.1. The application was lodged pursuant to section 28 of the Hazardous Substances and New Organisms Act 1996 ("the Act").

1.2. The Evaluation and Review report ("the E&R report") takes into account matters to be considered in section 29; matters specified under Part II of the Act; and the relevant provisions of the Hazardous Substances and New Organisms (Methodology) Order 1998 ("the Methodology"). Unless otherwise stated, references to section numbers in the report refer to sections of the Act and clauses to clauses of the Methodology.

1.3. The Minister for the Environment was advised of the application under section 53(4)(a) and given the opportunity to "call-in" the application under section 68. This action was not initiated

1.4. The Authority is able to vary the default controls and impose controls under sections 77 and 77A to produce a set of controls relevant to the substances. Variations and additional controls for the substances are considered in Section 5 of the E&R report.

1.5. In undertaking this assessment the Agency has considered the Authority's approvals given to substances under Part 5 of the Act as well as those transferred to the Act under the *Hazardous Substances (Chemicals) Transfer Notice 2004*.

1.6. Section 96 provides that the Authority may identify and report to the Minister where it considers that a reduction in the likely occurrence of adverse effects similar to that achieved by the controls attached to any substance could be achieved by any environmental user charge, or a combination of an environmental user charge and controls.

1.7. The Agency considers that use of controls is the most effective means of managing the risks throughout the lifecycle of the substance being assessed. The imposition of an environmental user charge instead of, or in combination with controls, is therefore not recommended under this approval.

2. Legislation that will affect the use of hazardous substances within New Zealand

2.1. The HSNO legislation and other legislation, such as the Resource Management Act 1992 ("the RMA") and the Health and Safety in Employment Act ("the HSE Act") provide for a number of controls that are aimed at preventing exposure to hazardous substances, and/or mitigating any adverse effects caused by such substances in the event of an accident, or a breach of controls. The key controls that relate to the protection of human health and the environment during the various stages of the lifecycle of hazardous substances are outlined in the sections below.

HSNO Legislation

2.2. The controls available to control a substances use under the HSNO legislation are determined by the substances hazard classification and are comprehensively described in ERMA New Zealand's User Guide to the Threshold and Classifications under the Hazardous Substances and New Organisms Act 1996.The following paragraphs describe the sorts of controls available and list those that are available for use.

2.3. The *Hazardous Substances (Identification) Regulations 2001* require that the hazardous properties of substances be clearly identified on the label, as well as described in any documentation (Safety Data Sheet) supplied with the substance. While the substance is being transported (including importation), the regulations provide for bulk transport containers and/or any outer packaging to be labelled or marked in compliance with either the Land Transport Rule 45001, Civil Aviation Act 1990 or the Maritime Safety Act 1994 as relevant (control code I19).

Identification Controls	
I1	Identification requirements, duties of persons in charge, accessibility, comprehensibility, clarity and durability
I2	Priority identifiers for corrosive substances
I3	Priority identifiers for ecotoxic substances
I4	Priority identifiers for explosive substances
I5	Priority identifiers for flammable substances
I6	Priority identifiers for organic peroxides
I7	Priority identifiers for oxidising substances
I8	Priority identifiers for toxic substances
I9	Secondary identifiers for all hazardous substances
I10	Secondary identifiers for corrosive substances
I11	Secondary identifiers for ecotoxic substances
I12	Secondary identifiers for explosive substances
I13	Secondary identifiers for flammable substances
I14	Secondary identifiers for organic peroxides
I15	Secondary identifiers for oxidising substances

I16	Secondary identifiers for toxic substances
I17	Use of generic names
I18	Requirements for using concentration ranges
I19	Additional information requirements, including situations where substances are in multiple packaging
I20	Durability of information for class 6.1 substances
I21	General documentation requirements
I22	Specific documentation requirements for corrosive substances
I23	Specific documentation requirements for ecotoxic substances
I24	Specific documentation requirements for explosive substances
I25	Specific documentation requirements for flammable substances
I26	Specific documentation requirements for organic peroxides
I27	Specific documentation requirements for oxidising substances
I28	Specific documentation requirements for toxic substances
I29	Signage requirements
I30	Advertising corrosive and toxic substances

2.4. The *Hazardous Substances (Emergency Management) Regulations 2001* prescribe controls that must be complied with if the levels of substance held are above the trigger quantities specified. These controls are aimed at mitigating adverse effects in the event of a spill and prescribe specific requirements with respect to emergency management information, emergency response plans, secondary containment facilities and signage.

Emergency Management Controls	
EM1	Level 1 information requirements for suppliers and persons in charge
EM2	Information requirements for corrosive substances
EM3	Information requirements for explosive substances
EM4	Information requirements for flammable substances
EM5	Information requirements for oxidising substances and organic peroxides
EM6	Information requirements for toxic substances
EM7	Information requirements for ecotoxic substances
EM8	Level 2 information requirements for suppliers and persons in charge
EM9	Additional information requirements for flammable and oxidising substances and organic peroxides
EM10	Fire extinguisher requirements
EM11	Level 3 emergency management requirements: duties of person in charge, emergency response plans
EM12	Level 3 emergency management requirements: secondary containment
EM13	Level 3 emergency management requirements: signage

2.5. The *Hazardous Substances (Packaging) Regulations 2001* prescribe a number of controls aimed at ensuring hazardous substances are adequately and appropriately packaged.

Packaging Controls

P1	General packaging requirements
P2	Specific criteria for class 4.1.2 and 5.2 substances
P3	Criteria that allow substances to be packaged to a standard not meeting Packing Group I, II or III criteria
P4	Packaging requirements for explosive substances
P5	Packaging requirements for flammable liquids
P6	Packaging requirements for liquid desensitised explosives
P7	Packaging requirements for flammable solids
P8	Packaging requirements for self-reactive flammable substances
P9	Packaging requirements for substances liable to spontaneous combustion
P10	Packaging requirements for substances that emit flammable gases when in contact with water
P11	Packaging requirements for oxidising substances
P12	Packaging requirements for organic peroxides
P13	Packaging requirements for toxic substances
P14	Packaging requirements for corrosive substances
P15	Packaging requirements for ecotoxic substances
PG1	Packaging requirements equivalent to UN Packing Group I
PG2	Packaging requirements equivalent to UN Packing Group II
PG3	Packaging requirements equivalent to UN Packing Group III
PS4	Packaging requirements as specified in Schedule 4

2.6. The *Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001* prescribe a number of controls aimed at ensuring hazardous substances handled in a manner appropriate to their toxicity.

Toxicity Controls	
T1	Limiting exposure to toxic substances through the setting of TELs
T2	Controlling exposure in places of work through the setting of WESs.
T3	Requirements for keeping records of use
T4	Requirements for equipment used to handle substances
T5	Requirements for protective clothing and equipment
T6	Approved handler/security requirements for certain toxic substances
T7	Restrictions on the carriage of toxic or corrosive substances on passenger service vehicles
T8	Controls for vertebrate poisons

2.7. The *Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001* specify a number of controls primarily aimed at limiting the extent to which the environment are exposed to hazardous substances with ecotoxic properties.

Ecotoxicity Controls	
E1	Limiting exposure to ecotoxic substances through the setting of EELs
E2	Restrictions on use of substances in application areas
E3	Controls relating to protection of terrestrial invertebrates eg beneficial insects
E4	Controls relating to protection of terrestrial vertebrates

E5	Requirements for keeping records of use
E6	Requirements for equipment used to handle substances
E7	Approved handler/security requirements for certain ecotoxic substances

2.8. The *Hazardous Substances (Disposal) Regulations 2001* specify controls on the disposal of substances and their containers.

Disposal Controls	
D1	Disposal requirements for explosive substances
D2	Disposal requirements for flammable substances
D3	Disposal requirements for oxidising substances and organic peroxides
D4	Disposal requirements for toxic and corrosive substances
D5	Disposal requirements for ecotoxic substances
D6	Disposal requirements for packages
D7	Information requirements for manufacturers, importers and suppliers, and persons in charge
D8	Documentation requirements for manufacturers, importers and suppliers, and persons in charge

2.9. The *Hazardous Substances (Tracking) Regulations 2001* specify controls for the tracking of substances.

Tracking Controls	
TR1	General tracking requirements

2.10. The *Hazardous Substances (Personnel Qualifications) Regulations 2001* specify the qualifications required of an approved handler.

Approved handler Controls	
AH1	Approved Handler requirements (including test certificate and qualification requirements)

2.11. The *Hazardous Substances (Tank Wagon and Transportable Container) Regulations 2001* prescribe a number of controls relating to tank wagons and transportable containers.

Tank Wagon and Transportable Containers Controls
The Hazardous Substance (Tank Wagons and Transportable Containers) Regulations 2004 prescribe a number of controls relating to tank wagons and transportable containers.

Other legislation

2.12. For internal land transport within New Zealand, the Land Transport Rule: Dangerous Goods 2005 will govern the type of transport, the qualifications of the driver and carrier, and the information requirements for transportation including packaging. Drivers are required to carry emergency management instructions for the substance they are carrying. For internal sea transport within New Zealand (e.g. across the Cook Strait), packages will have to meet the labelling requirements of the IMDG Code for the transport of dangerous goods by sea.

2.13. Under the HSE Act, employers and workers are required to be aware of all hazards.

2.14. The RMA prohibits discharge of contaminants into the environment unless it has been expressly allowed for in a Regional Plan, resource consent or by regulation. This is relevant to all stages of the substance's lifecycle, with specific relevance to the substance during its manufacturing, storage, use and disposal.

3. Risk assessment

3.1. The process by which the risk assessment of substances should be undertaken is specified in the Methodology. The process requires that the risks and benefits of a substance be identified and then assessed for their level of significance

3.2. Potentially non-negligible risks must first be identified for evaluation following clauses 9 and 11, (which incorporate sections 5, 6 and 8) of the Methodology. These risks must then assess in accordance with sections 5 and 6 and clauses 9 and 12. The assessment must be undertaken with regard to the in terms of risks to

- the environment,
- human health and safety,
- the relationship of Māori to the environment,
- society and the community,
- the market economy, and
- New Zealand's international obligations.

3.3. For the purposes of the assessment the following definitions are made in Regulation 2 of the Methodology.

- A "cost" is "the value of a particular adverse effect expressed in monetary or non-monetary terms". Thus, these should be assessed in an integrated fashion together with the risks of the adverse effects in the following assessment.
- A "benefit" is "the value of a particular positive effect expressed in monetary or non-monetary terms". Benefits that may arise from any of the matters set out in clauses 9 and 11 were considered in terms of clause 13.

3.4. To facilitate the assessment of risks the applicant and the Agency have identified the most common potential sources of risk to the environment and to human health and safety through release, spillage or exposure throughout the lifecycle of the substance. These are tabulated in Table S3.1 and are used as the basis for the risk assessment in the "Identification and assessment of effects" section of the E&R report.

Table S3.1: Potential sources of risks associated with hazardous substances

Lifecycle Activity	Associated Source of Risk
Manufacture / Import	An incident during the manufacture or importation of the substances resulting in spillage and subsequent exposure of people or the environment to the substance.
Packing	An incident during the packing of the substance resulting in spillage and subsequent exposure of people or the environment to the substance.
Transport or storage	An incident during the transport or storage of the substance resulting in spillage and subsequent exposure of people or the environment to the substance.
Use	Application of the substance resulting in exposure of users or bystanders or the

	environment; or an incident during use resulting in spillage and subsequent exposure of users or the environment to the substance.
Disposal	Disposal of the substance or packaging resulting in exposure of people or the environment to the substance.

3.5. In undertaking the assessment the Agency notes that the evidence provided by the applicant and additional evidence found by the Agency, relating to the hazardous properties of the substances is largely scientific in nature (clause 25(1)). However, as some of the evaluation of risks, costs and benefits has been carried out on a qualitative basis, it is recognised that there is a degree of uncertainty in the risk analysis.

3.6. Where qualitative assessment is used at any stages of the lifecycle the level of risk has been evaluated on the basis of the magnitude and likelihood of adverse effects occurring to people or the environment

3.7. In accordance with section 29, consideration is given to the likely effects of the substances being unavailable.

3.8. Along with the 5 other compartments outlined in paragraph 3.2 above, the Agency assesses each application for any effects associated with the Relationship of Māori to the Environment. In most cases the substance(s) will trigger a number of hazardous properties giving rise to the potential for cultural risk including the deterioration of the mauri of taonga flora and fauna species, the environment and the general health and well-being of individuals and the community.

3.9. In addition, the introduction and use of hazardous substances have the potential to inhibit the ability of iwi/Māori to fulfill their role as kaitiaki, particularly in relation to the guardianship of waterways given the highly ecotoxic nature of the substance to aquatic species, and potential risks to the mauri ora of human health under prolonged exposure to this substance.

3.10. Where significant effects on the relationship of Māori to the Environment are identified during the Agency's risk assessment these will be fully discussed in the body of the E&R report. Where effects are identified which will have a negligible impact the following process will be undertaken to ensure that significant effects are not overlooked.

3.11. The Agency will consider the information outlined in the report, to determine that there is a minimal impact from the substance on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna and other taonga to ensure that any impacts are highly improbable.

3.12. If this is determined the overall level of risk will therefore be considered to be negligible assuming that the substance will be handled, stored, transported, used, and disposed of, in accordance with the explicitly stated default and additional controls proposed in the report, and any other controls required by other legislation.

3.13. However, the Agency will propose that should inappropriate use, or accident, result in the contamination of waterways or the environment generally, that users will be required to notify the appropriate authorities including the relevant iwi authorities in

that region. This action should include advising them of the contamination and the measures taken to contain and remediate.

4. Qualitative descriptors for risk/benefit assessment

4.1. This section describes how the Agency staff and the Authority address the qualitative assessment of risks, costs and benefits. Risks and benefits are assessed by estimating the magnitude and nature of the possible effects and the likelihood of their occurrence. For each effect, the combination of these two components determines the level of the risk associated with that effect, which is a two dimensional concept. Because of lack of data, risks are often presented as singular results. In reality, they are better represented by 'families' of data which link probability with different levels of outcome (magnitude).

4.2. The magnitude of effect is described in terms of the element that might be affected. The qualitative descriptors for magnitude of effect are surrogate measures that should be used to gauge the end effect or the 'what if' element. Tables S4.1 and S4.2 contain generic descriptors for magnitude of adverse and beneficial effect. These descriptors are examples only, and their generic nature means that it may be difficult to use them in some particular circumstances. They are included here to illustrate how qualitative tables may be used to represent levels of adverse and beneficial effect.

Table S4.1: Magnitude of adverse effect (risks and costs)

Descriptor	Examples of descriptions – Adverse
Minimal	Mild reversible short term adverse health effects to individuals in highly localised area Highly localised and contained environmental impact, affecting a few (less than ten) individuals members of communities of flora or fauna, no discernible ecosystem impact Local/regional short-term adverse economic effects on small organisations (businesses, individuals), temporary job losses No social disruption
Minor	Mild reversible short term adverse health effects to identified and isolated groups Localised and contained reversible environmental impact, some local plant or animal communities temporarily damaged, no discernible ecosystem impact or species damage Regional adverse economic effects on small organisations (businesses, individuals) lasting less than six months, temporary job losses Potential social disruption (community placed on alert)
Moderate	Minor irreversible health effects to individuals and/or reversible medium term adverse health effects to larger (but surrounding) community (requiring hospitalisation) Measurable long term damage to local plant and animal communities, but no obvious spread beyond defined boundaries, medium term individual ecosystem damage, no species damage Medium term (one to five years) regional adverse economic effects with some national implications, medium term job losses Some social disruption (e.g. people delayed)
Major	Significant irreversible adverse health effects affecting individuals and requiring hospitalisation and/or reversible adverse health effects reaching beyond the immediate community Long term/irreversible damage to localised ecosystem but no species loss Measurable adverse effect on GDP, some long term (more than five years) job losses Social disruption to surrounding community, including some evacuations

Massive	Significant irreversible adverse health effects reaching beyond the immediate community and/or deaths Extensive irreversible ecosystem damage, including species loss Significant on-going adverse effect on GDP, long term job losses on a national basis Major social disruption with entire surrounding area evacuated and impacts on wider community

Table S4.2: Magnitude of beneficial effect (benefits)

Descriptor	Examples of descriptions – Beneficial
Minimal	Mild short term positive health effects to individuals in highly localised area Highly localised and contained environmental impact, affecting a few (less than ten) individuals members of communities of flora or fauna, no discernible ecosystem impact Local/regional short-term beneficial economic effects on small organisations (businesses, individuals), temporary job creation No social effect
Minor	Mild short term beneficial health effects to identified and isolated groups Localised and contained beneficial environmental impact, no discernible ecosystem impact Regional beneficial economic effects on small organisations (businesses, individuals) lasting less than six months, temporary job creation Minor localised community benefit
Moderate	Minor health benefits to individuals and/or medium term health impacts on larger (but surrounding) community and health status groups Measurable benefit to localised plant and animal communities expected to pertain to medium term Medium term (one to five years) regional beneficial economic effects with some national implications, medium term job creation Local community and some individuals beyond immediate community receive social benefit.
Major	Significant beneficial health effects to localised community and specific groups in wider community Long term benefit to localised ecosystem(s) Measurable beneficial effect on GDP, some long term (more than five years) job creation Substantial social benefit to surrounding community, and individuals in wider community.
Massive	Significant long term beneficial health effects to the wider community Long term, wide spread benefits to species and/or ecosystems Significant on-going effect beneficial on GDP, long term job creation on a national basis Major social benefit affecting wider community

4.3. The likelihood applies to the composite likelihood of the end effect, and not either to the initiating event, or any one of the intermediary events. It includes:

- the concept of an initiating event (triggering the hazard), and
- the exposure pathway that links the source (hazard) and the area of impact (public health, environment, economy, or community).

4.4. Thus, the likelihood is not the likelihood of an organism escaping, or the frequency of accidents for trucks containing hazardous substances, but the likelihood of the specified adverse effect[6] resulting from that initiating event. It will be a combination of the likelihood of the initiating event and several intermediary likelihoods[7]. The best way to determine the likelihood is to specify and analyse the complete pathway from source to impact.

4.5. Likelihood may be expressed as a frequency or a probability. While frequency is often expressed as a number of events within a given time period, it may also be expressed as the number of events per head of (exposed) population. As a probability, the likelihood is dimensionless and refers to the number of events of interest divided by the total number of events (range 0-1).

Table S4.3: Likelihood

Descriptor	Description
Highly improbable	Almost certainly not occurring but cannot be totally ruled out
Very unlikely	Considered only to occur in very unusual circumstances
Unlikely (occasional)	Could occur, but is not expected to occur under normal operating conditions
Likely	A good chance that it may occur under normal operating conditions
Highly likely	Almost certain, or expected to occur if all conditions met

4.6. Using the magnitude and likelihood tables a matrix representing a level of risk/benefit can be constructed.

4.7. In the example shown in Table S4.4, four levels of risk/benefit are allocated: A (negligible), B (low), C (medium), and D (high). These terms have been used to avoid confusion with the descriptions used for likelihood and magnitude, and to emphasise that the matrix is a tool to help decide which risks/benefits require further analysis to determine their significance in the decision making process.

4.8. For negative effects, the levels are used to show how risks can be reduced by the application of additional controls. Where the Table is used for positive effects it may also be possible for controls to be applied to ensure that a particular level of benefit is achieved, but this is not a common approach. The purpose of developing the tables for both risk and benefit is so that the risks and benefits can be compared.

Table S4.4: Level of risk

	Magnitude of effect				
Likelihood	**Minimal**	**Minor**	**Moderate**	**Major**	**Massive**
Highly improbable	A	A	A	B	B
Very unlikely	A	A	B	B	C
Unlikely	A	B	B	C	C

[6] The specified effect refers to scenarios established in order to establish the representative risk, and may be as specific as x people suffering adverse health effects, or y% of a bird population being adversely affected. The risks included in the analysis may be those related to a single scenario, or may be defined as a combination of several scenarios.

[7] Qualitative event tree analysis may be a useful way of ensuring that all aspects are included.

Likely	B	B	C	C	D
Highly likely	B	C	C	D	D

5. Decision path