ERMA New Zealand

Evaluation and Review Report

Application for Approval to Import or Manufacture NTNCS2 for Release

Application Number: ERMA200030

Executive Summary

Background information

- Bayer New Zealand Limited is seeking approval to import or manufacture NTNCS2 for release.
- NTNCS2 is a veterinary medicine for the control of ectoparasites on sheep.
- NTNCS2 will be sold as a ready-to-use pour-on formulation with a dedicated applicator to allow effective product application by the user.
- NTNCS2 will be applied at the recommended maximum dose rate of 14 mls per 10 kg live weight.
- The active ingredients present in NCNTS2 are present in other products available in New Zealand.

Classification

- The Agency has classified NTNCS2 based on the composition of NTNCS2 and the effects of its components.

Hazardous Property	**Assessment**
Flammable Liquid	3.1D
Skin Irritancy/Corrosivity	6.3A
Eye Irritancy/Corrosivity	6.4A
Reproductive/developmental toxicity	6.8A
Reproductive/developmental toxicity via lactation	6.8C
Target Organ Toxicity	6.9B
Aquatic Ecotoxicity	9.1A
Soil Ecotoxicity	9.2B
Ecotoxicity to terrestrial vertebrates	9.3B
Ecotoxicity to terrestrial invertebrates	9.4A

Risk Assessment

- The Agency's assessment of the risks posed by NTNCS2 to the environment and to human health, during the substance's lifecycle, is based on qualitative assessment.
- The Agency considers that the risk assessments indicate that the risks associated with the use of NTNCS2 are ***negligible*** with the proposed controls in place.
- The Agency has evaluated information supplied by the applicant about the benefits of NTNCS2 and considers that benefits are likely to be realised through the release of this substance.

Controls

- The Agency has proposed that the default controls for NTNCS2 be modified, such that:
  - no Tolerable Exposure Limits (TELs) are set at this present time;
  - Workplace Exposure Standards (WESs) have been proposed based on Department of Labour values for components D, E and F.
  - no Environmental Exposure Limits (EELs) are set at the present time and any default values are deleted;
  - further controls regarding stationary containment systems are added.
- 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 this E&R Report and further in Appendix 3.

Conclusion

- The Agency considers that there are ***negligible*** risks to human health and to the environment and potentially significant benefits associated with the release of NTNCS2. Therefore, the Agency considers that it is evident that the benefits of releasing NTNCS2 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.

Table 1 Details of the application

Application Code	ERMA200030
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	Bayer New Zealand Ltd
Date Application Received	20 July 2009
Submission Period	31 July 2009 –11 September 2009
Consideration	Due to delays in completing this E&R Report the Authority postponed the consideration until 13 November 2009.
Purpose of the Application	To import or manufacture NTNCS2 as a veterinary medicine to control ectoparasites on sheep after external application.
Parties Notified	On 31 July 2009 the following were notified • the Minister for the Environment, the Department of Labour and the New Zealand Food Safety Authority (ACVM Group), • interested parties listed in Appendix 5, • the public[1].
Submissions received	None
ERMA staff involved in the assessment	Haydn Murdoch – Advisor (Hazardous Substances) Sekove Tinalevu – Advisor (Hazardous Substances) Cora Drijver – 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.
- Decision pathway used in the decision process.

[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.

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. The substance, its lifecycle and its hazardous properties

The substance and its lifecycle

2.1. NTNCS2 is an ectoparasiticide that is used as a pour on for the control of parasites (biting lice and blowfly strike) on sheep.

2.2. The applicant has provided the following details about the lifecycle of NTNCS2.

2.2.1. **Manufacture and Packaging** NTNCS2 will be manufactured under conditions of Good Manufacturing Practice (GMP), at an ACVM approved manufacturing facility in Auckland. The product will be shipped from this facility to a Bayer warehouse, pre-packed into labelled 1 L, 5 L and 20 L HDPE screw top containers. 1 and 5 L containers are placed in cardboard cartons and the 20 L containers are shrink-wrapped on standard shipping pallets.

2.2.2. **Transport** Production, packaging and transportation of NTNCS2 will conform to domestic requirements for transportation and will occur by road and sea.

2.2.3. **Storage** NTNCS2 will be stored in Bayer's standard warehouse facilities prior to distribution. From there NTNCS2 will be distributed to mercantile and veterinary premises for sale to farmers. Several containers of NTNCS2 could be stored on farming premises prior to use.

2.2.4. **Use.** NTNCS2 will be used by farmers, dipping contractors, veterinarians and farm workers to control parasites (sheep biting lice and sheep blowfly strike) on sheep. The product will be decanted into the application equipment through a decanting tap supplied with the product. NTNCS2 will be applied through a closed applicator system applicator allowing the product to be placed accurately on the sheep's back.

2.2.5. **Disposal.** The preferable route of disposal is by use. Unused product and used packaging may be disposed of in approved landfills. Cleaned, used packaging may also be recycled via the DrumMuster program.

Classification of the substance

2.3. The Agency has classified NTNCS2 based on the composition of NTNCS2 and the effects of its components. The Agency's classifications are the same as the applicant's proposed HSNO classifications (Table 2).

Table 2: Summary of the applicant's and the Agency's classifications of NTNCS2

Hazardous Property	Applicant's Assessment	Agency's Assessment
Flammable Liquid	3.1D	3.1D
Skin Irritancy/Corrosivity	6.3A	6.3A
Eye Irritancy/Corrosivity	6.4A	6.4A
Reproductive/developmental toxicity	6.8A	6.8A
Reproductive/developmental toxicity via lactation	6.8C	6.8C
Target Organ Toxicity	6.9B	6.9B
Aquatic Ecotoxicity	9.1A	9.1A
Soil Ecotoxicity	9.2B	9.2B
Ecotoxicity to terrestrial vertebrates	9.3B	9.3B
Ecotoxicity to terrestrial invertebrates	9.4A	9.4A

Regulatory context

2.4. 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.

2.5. The Agency notes that the importation, manufacture, transport, use and disposal of the substances will 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 (see Supplementary Information, Section 2).

Default controls

2.6. 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 sections 77 and 77A to produce a set of controls relevant to NTNCS2. Variations and additional controls are considered in section 4 of this report.

2.7. The analysis of risk takes into account 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 assumes the controls are in place.

3. Identification and assessment of risks, costs and benefits

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

Risks and costs

Human health

3.2. The Agency has evaluated the potential of NTNCS2 to cause adverse effects to the health and safety of humans during all stages of the substance's lifecycle using qualitative risk assessment methodologies.

3.3. The Agency has classified NTNCS2 as a skin irritant (6.3A), an eye irritant (6.4A), a reproductive/developmental toxicant (6.8A and 6.8C) and a target organ toxicant (6.9B).

3.4. In addition, NTNCS2 is classified as presenting a low flammability hazard (3.1D) and thus has the potential to cause ***minimal*** to ***major*** adverse health effects (ranging from smoke inhalation to burns, for example). However, the Agency considers that adherence to the HSNO controls on flammable substances will ensure that the level of risk to human health associated with its flammable properties is ***negligible***.

3.5. The risks of NTNCS2 to human health and safety (with controls in place) at various stages of the lifecycle are summarised below in Table 3.1 and discussed more fully in Appendix 2.

Table 3.1 Level of risk of NTNCS2 to human health and safety

Lifecycle stage	Potential Adverse Effect	Likelihood of Adverse Effect Occurring	Magnitude of Adverse Effect	Level of Risk
Manufacture/packing	Skin irritancy Eye irritancy	Highly improbable	Minimal	Negligible

Lifecycle stage	Potential Adverse Effect	Likelihood of Adverse Effect Occurring	Magnitude of Adverse Effect	Level of Risk
	Reproductive/ developmental toxicity Target organ toxicity	Highly improbable	Major	Negligible
Importation, transport or storage	Skin irritancy Eye irritancy	Highly improbable	Minimal	Negligible
	Reproductive/ developmental toxicity Target organ toxicity	Highly improbable	Major	Negligible
Use	Skin irritancy Eye irritancy	Highly improbable	Minimal	Negligible
	Reproductive/ developmental toxicity Target organ toxicity	Highly improbable	Major	Negligible
Disposal	Skin irritancy Eye irritancy	Highly improbable	Minimal	Negligible
	Reproductive/ developmental toxicity Target organ toxicity	Highly improbable	Major	Negligible

Environmental

3.6. The Agency has evaluated the potential of NTNCS2 to cause adverse effects to the environment (non-target organisms) during all stages of the substance's lifecycle using qualitative risk assessment methodologies.

3.7. The Agency has classified NTNCS2 as being very toxic in the aquatic environment (9.1A), toxic to the soil environment (9.2B), toxic to terrestrial invertebrates (9.3B) and very toxic to terrestrial vertebrates (9.4A).

3.8. In addition to its ecotoxic properties, NTNCS2 has been classified by the Agency as being flammable (3.1D – low hazard). The Agency considers that there is potential for damage to the environment to occur if NTNCS2 were to be ignited at any stage of its lifecycle. However, the Agency considers that adherence to the HSNO controls on flammable substances will ensure that the level of risk to the environment associated with its flammable properties is ***negligible***.

3.9. The risks of NTNCS2 to the environment (with controls in place) at various stages of its lifecycle are summarised in Table 3.2 and discussed more fully in Appendix 2.

Table 3.2: Level of risk of NTNCS2 to the environment.

Lifecycle Stage	Potential Adverse Effect	Likelihood of Adverse Effect Occurring	Magnitude of Adverse Effect	Level of Risk
Manufacture, importation, transport and storage	Spillage resulting in death or adverse effects to aquatic or terrestrial organisms in the environment.	Highly improbable	Moderate	Negligible
Use	Use resulting in death or adverse effects to aquatic or terrestrial organisms in the environment.	Highly improbable	Moderate	Negligible
Disposal	Disposal resulting in death or adverse effects to aquatic or terrestrial organisms in the environment	Highly improbable	Minor	Negligible

Benefits

3.10. The applicant considers that the availability of NTNCS2 will provide farmers with a cost-efficient environmentally-sustainable approach to controlling ecotparasites on sheep.

3.11. The applicant notes that, while this substance does not have any particular benefits that are peculiar to this substance, NTNCS2 is not an organophosphate and may create some benefit for the environment by replacing some of the older organophosphate based products that are currently used for fly strike.

3.12. The Agency notes that benefits may be derived for New Zealand by allowing the use of NTNCS2.

Likely effects of the substance being unavailable

3.13. The Agency notes that the likely effects of NTNCS2 being unavailable would be a reduction in consumer choice for end-users.

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 below. A full description of the rationale for these variations is documented in Appendix 3.

Table 4 Variations to the default controls for NTNCS2.

Control Code	Subject matter	Variation	Comment
T1	Limiting exposure to toxic substances through the setting of TELs	No TEL values are set at this time.	The Agency is intending to review the setting of ADEs, PDEs and TELs under s77B of the Act. Until this review is complete, the Agency proposes not to set any ADEs, PDEs or TELs for any components of NTNCS2.
T2	Controlling exposure to in places of work through the setting of WESs	WES are proposed as determined by the Department of Labour for Components D, E and F.	The Agency notes that WES values have been set by the Department of Labour for Components D, E and F.
E1	Limiting exposure to ecotoxic substances though the setting of EELs	No EEL values are set at this time and the default EELs are deleted.	Until the Agency has developed formal policy on the implementation of section 77B, it proposes not to set any EEL values for components of NTNCS2 and the default EEL water and soil values are deleted.
E2	Restriction on the use of substances in application areas	Deleted.	As the substance is not intended for application to an area of land and no EEL has been set, this control may be deleted.
E3	Protection of terrestrial invertebrates e.g. beneficial insects	Deleted.	As the substance is intended for use as a pour-on for animals, the risks to bees are considered minimal and therefore this control may be deleted.
E7	Approved handler requirements for ecotoxic substances	Deleted.	It is considered that, based on the use pattern of the substance, the risks to the environment will be lower than for substances which are widely dispersed. The reduced environmental risks will be managed by other controls and therefore the approved handler control can be deleted.
I16	Secondary identifiers for toxic substances	The concentration cut-offs that apply to a component with a hazard classification of 6.5, 6.6, 6.7, 6.8 or 6.9are varied to the following:	The Agency, consistent with the guidance provided by the Global Harmonised System (GHS), considers that regulation 25(e) should be varied.

		HSNO Classification of Component / **Concentration Cut-off for Label (%)** 6.5A, 6.5B / 0.1[2] 6.6A, 6.7A / 0.1 6.6B, 6.7B / 1 6.8A, 6.8C / 0.3 6.8B / 3 6.9A, 6.9B / 10	
TR1	Tracking requirement during use of the substance	Deleted.	It is considered that the risks that may arise during the substance's lifecycle will adequately be managed by other controls such as packaging, labelling and emergency management requirements and therefore the tracking requirements can be deleted.
D2/D4/ D5	Disposal requirements for flammable, toxic, corrosive and ecotoxic substances	Combined	These controls can be combined because they relate to the same requirements.
T3/E5	Requirements for keeping records of use.		
T4/E6	Requirements for equipment used to handle substances		
P13/P15	Requirements for packaging of hazardous substances		
F2/T7	Requirements for the carriage of hazardous substances on passenger vehicles.		

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

Proposed additional controls

4.3. The Agency notes that its risk assessment has been undertaken on the basis that the substance is administered as a veterinary medicine. Accordingly, the Agency considers that the approval should be restricted to the use of the substance as a veterinary medicine.

[2] Identification of sensitising components may be required below the 0.1% level if a lower value has been used for classification.

4.4. The Agency notes that the specified controls do not address the risks associated with stationary container systems, nor do they allow for dispensation where it is unnecessary for any associated pipework to have secondary containment. They also do not address all the risks associated with the unintended ignition of flammable substances. Accordingly, the Agency considers that the application of controls addressing these risks will be more effective than the specified (default) controls in terms of their effect on the management, use and risks of the substance[3]. The proposed controls are shown in Table A4.1 of Appendix 4.

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 NTNCS2. Therefore, the Agency considers that it is evident that the benefits of releasing NTNCS2 outweigh the costs and the application may be approved in accordance with clause 26, with the controls documented in Appendix 4.

[3] section 77A(4)(a)

Appendix 1: Classification of NTNCS2

Classification of NTNCS2

Data from effects testing of the formulation were not provided for all endpoints of NTNCS2. Where no data were available, classification was estimated using mixture rules based on information on the components. A summary of the physical, toxicity and ecotoxicity hazard classification associated with NTNCS2 and its components is provided in Table A2.1 to A2.3. Formulation test data are detailed in these tables where applicable. 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 A2.4.

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 NTNCS2are 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). Where additional data has been provided by the applicant, the Agency has assigned Klimisch data reliability scores to that information and these are included in tables XX and YY. Generally these data are high quality by current international standards.

The Agency acknowledges that there are frequently 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.

The effect of the lower quality data on the overall evaluation of the effects of NTNCS2 was not significant because the individual components making up this substance are not new in New Zealand.

Table A2.1: Summary of the physical hazard classifications of NTNCS2

Endpoint Component	2.1.1	2.1.2	3.1	3.2	4.1.1	4.2	4.3	5.1.1	5.1.2	8.1	1.1	1.2	1.3	1.4	1.5	1.6
NTNCS2	**ND**	**ND**	**3.1D***	**ND**	**ND**	**ND**	**ND**	**ND**	**ND**	**ND**	**ND**	**ND**	**ND**	**ND**	**ND**	**ND**
A	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
B	NA	NA	NA	NA	ND	ND	ND	ND	NA	ND	No	No	No	No	No	No
C	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	NA	NA	NA	NA	NA	NA
D	NA	NA	3.1D	NA	NA	NA	NA	ND	NA	ND	ND	ND	ND	ND	ND	ND
E	NA	NA	No	NA	ND	ND	ND	ND	NA	ND	NA	NA	NA	NA	NA	NA
F	NA	NA	3.1D	No	ND	ND	NA	No	NA	ND	No	No	No	No	No	No

ND = no data/insufficient data/inconclusive data
NA = not applicable
* Flashpoint of the product is 88 ^{o}C

Table A2.2: Summary of the toxicity hazard classifications of NTNCS2

Endpoint Component	6.1 Oral	6.1 Dermal	6.1 Inhalation	6.3/8.2	6.4/8.3	6.5A	6.5B	6.6	6.7	6.8AB	6.8C	6.9
NTNCS2	**No***	**ND**	**ND**	**6.3A#**	**6.4A#**	**ND**	**No***	**ND**	**ND**	**6.8A**	**6.8C#**	**6.9B#**
A	No	No	ND	No	No	ND	No	No	No	No	No	6.9B
B	6.1C	No	No	No	No	ND	No	No	No	No	ND	6.9B
C	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
D	No	No	ND	No	No	ND	No	ND	ND	No	ND	No
E	6.1D	ND	ND	No	No	ND	6.5B	No	ND	No	6.8C	6.9B
F	6.1E	No	No	6.3A	6.4A	ND	ND	No	ND	6.8A	ND	No

ND = no data/insufficient data/inconclusive data
#Classification based on data from components / mixture rules
*Classification based on formulation data

Formulation data

Acute Oral Toxicity
SPECIES: Rats
STRAIN: Wistar
TEST SUBSTANCE: imdacloprid+triflumuron pour-on formulation
DOSE LEVELS: 2000 mg/kg bw
NO/SEX/GROUP: 3 female rats
ENDPOINT: LD_{50}
VALUE: > 5000 mg/kg bw
GLP: Yes
TEST GUIDELINES: OECD 423
REFERENCE SOURCE: Gillissen U, 2009. Acute toxicity in the rat after oral administration, Bayer Schering Pharma AF, Germany.
RELIABILITY (KLIMISCH SCORE): 1

Acute Dermal Toxicity
SPECIES: Rats
STRAIN: Wistar
TEST SUBSTANCE: imdacloprid+triflumuron pour-on formulation
DOSE LEVELS: 2000 mg/kg bw
NO/SEX/GROUP: 5 male and 5 female rats
ENDPOINT: LD50
VALUE: > 2000 mg/kg bw
GLP: Yes
TEST GUIDELINES: OECD 434
REFERENCE SOURCE: Gillissen U, 2009. Acute toxicity in the rat after dermal administration, Bayer Schering Pharma AF, Germany.
RELIABILITY (KLIMISCH SCORE): 1

Contact sensitization
SPECIES: Guinea pigs
TEST SUBSTANCE: imdacloprid+triflumuron pour-on formulation
NO./SEX/GROUP: 30 female guinea pigs
RESULT: No positive response 24 and 48 hours following the challenge dose.
GLP: Yes
TEST GUIDELINES: OECD 406
REFERENCE SOURCE: Vohr HW, 2009. Study For The Skin Sensitisation Effect In Guinea Pigs, Bayer Schering Pharma AF, Germany.
RELIABILITY (KLIMISCH SCORE): 1

Table A2.3: Summary of the ecotoxicity hazard classifications of NTNCS2

Endpoint Component	9.1 Fish	9.1 Crustacean	9.1 Algal	Bio accumulative +$	Rapidly Degradable +^	9.2	Soil DT50>30 Days +^	9.3	9.4
NTNCS2#	**No**	**9.1A**	**No**	**No**	**No**	**9.2B**	**No**	**9.3B**	**9.4A**
A	No	9.1A	ND	Yes	ND	No	no	No	9.4A
B	9.1C	9.1A	No	No	No	9.2A	yes	9.3A	9.4A
C	9.1A	9.1A	9.1A	No	No	ND	ND	ND	ND
D	No	No	ND	No	Yes	ND	no	No	ND
E	ND	9.1D	9.1D	Yes	No	ND	no	9.3C	ND
F	No	ND	No	No	Yes	ND	no	No	ND

ND = no data/insufficient data/inconclusive data

[#]Classification based on data from components / mixture rules

[+] in the case of ND the Agency default is bioaccumulation and not rapidly degradable

[$] in the case of the weighted sum of components that are bioaccumulative being >25%, then it can be said that the mixture contains toxic components that are bioaccumulative

^ in the case of the weighted sum of components that are not rapidly degradable being >25%, then it can be said that the mixture contains toxic components that are not rapidly degradable

Table A2.4: Location of mixture rules within the User Guide to the Thresholds and Classifications in the HSNO Act (V2.0. March 2008) (ERMA 2008a).

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

Appendix 2: Risk Assessment

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

Qualitative assessments have been undertaken for all 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

The Agency notes that the substance triggers a number of hazardous properties giving rise to the potential for cultural risk. However, based on the information provided, the Agency considers that the risks will be ***negligible*.** The rationale for this approach is outlined in the Supplementary Information (section 3).

Human health risk assessment

Assessment of risks to human health – manufacture and packaging

The Agency has qualitatively assessed the risks of NTNCS2 to human health and safety during manufacture and packaging and considers the risks to be ***negligible***.

This assessment is based on the following considerations:

- Manufacturing and packaging facilities for NTNCS2 will be required to meet the HSNO requirements for equipment, emergency management and provision of information (e.g. Safety Data Sheets (SDS)) as well as the requirements of Good Manufacturing Practice (GMP) and the Health and Safety in Employment Act (H&SE Act).

- The Agency considers that it is ***highly improbable*** that workers will suffer skin or eye irritancy from NTNCS2, given requirements for personal protective equipment (PPE), and compliance with HSNO information provisions (e.g. labels, advertising, SDS). Furthermore, the magnitude of skin and eye irritancy is considered ***minimal***, given the temporary nature of effects.

- The Agency considers that it is ***highly improbable*** that workers will receive repeated exposure to NTNCS2 at levels required to cause reproductive/developmental toxicity or target organ toxicity, given requirements for PPE compliance with HSNO information provisions (e.g. labels, advertising, SDS). While reproductive/developmental toxicity and target organ toxicity effects are considered ***major***, the Agency considers that the voluntary risk will be sufficiently managed by workers involved in the manufacture and packing of the substance to reduce the level of risk to human health during manufacture and packing to ***negligible***.

- The Agency considers the risk of repeated exposure to bystanders during manufacture and packing is sufficiently remote that it is not necessary to address, given that the general public are normally excluded from manufacturing facilities.

Assessment of risks to human health – importation, storage and transport

The Agency has qualitatively assessed the risk of NTNCS2 to human health and safety during importation, transportation and storage and considers the risks to be ***negligible***.

This assessment is based on the following considerations:

- Workers and bystanders could only be exposed to the substance during transport and storage in isolated incidents where spillage occurs.

- The Agency considers that it is ***highly improbable*** that a spillage of NTNCS2 will occur during importation, transport or storage and workers or bystanders will suffer skin or eye irritancy, given adherence to the HSNO controls (e.g. packaging, identification and emergency management) and the Land Transport Rule 45001, Civil Aviation Act 1990 and Maritime Transport Act 1994 (as applicable). Furthermore, the magnitude of skin and eye irritancy is considered ***minimal***, given the temporary nature of effects.

- The Agency considers the risk of reproductive/developmental toxicity or target organ toxicity effects from NTNCS2 during importation, transport or storage to be sufficiently remote that it is not necessary to address, given that exposure could only occur in isolated spillage incidents.

Assessment of risks to human health - use

The Agency has qualitatively and quantitatively assessed the risks of NTNCS2 to human health and safety during use and considers the risks to be ***negligible***.

This assessment is based on the following considerations:

- The Agency notes that there will be a wool withholding time stated on the label for NTNCS2. The Agency considers that the withholding time will reduce any potential risks associated with exposure of shearers and wool handlers to residues the substances on treated wool.

- The Agency considers that it is ***highly improbable*** that users will suffer skin or eye irritancy from NTNCS2, given the HSNO requirements for PPE and provision of hazard and precautionary information on the product label. Furthermore, the magnitude of skin and eye irritancy is considered ***minimal***, given the temporary nature of the effects.

- The Agency considers that it is ***highly improbable*** that users will receive repeated exposure to NTNCS2 at levels required to cause reproductive/developmental toxicity or target organ toxicity, given requirements for PPE compliance with HSNO information provisions (e.g. labels, advertising, SDS). While reproductive/developmental toxicity and target organ toxicity effects are considered ***major***, the Agency considers that the voluntary risk will be sufficiently managed by users of the substance to reduce the level of risk to human health during use to ***negligible***.

Assessment of risks to human health - disposal

The Agency has qualitatively assessed the risk to human health and safety during disposal of NTNCS2, and considers the risks to the health and safety of people to be ***negligible***.

This assessment is based on the following considerations:

- If NTNCS2 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.

- The Agency considers that it is ***highly improbable*** that workers will suffer skin or eye irritancy from NTNCS2 during disposal, given that NTNCS2 will generally be disposed of by use. Furthermore, the magnitude of skin and eye irritancy is considered ***minimal***, given the temporary nature of effects.

- The Agency considers it ***highly improbable*** that users or bystanders could be repeatedly exposed to NTNCS2 during disposal to such an extent that reproductive/developmental toxicity or target organ toxicity effects occur. While the effects of reproductive/developmental toxicity and target organ toxicity are considered ***major***, the Agency considers that people disposing of the substance will have the necessary skills and knowledge (e.g. via information provided on the label) to reduce the risk to human health from the disposal of the substance to ***negligible.***

Environmental exposure and risk assessment

Assessment of environmental risks - manufacture, importation, transport and storage

The Agency has qualitatively assessed the risks to the environment of NTNCS2 during manufacture, importation, transportation and storage and considers the risks to be ***negligible.***

This assessment is based on the following considerations:

- The magnitude of adverse effects on the environment from a spillage during manufacture, importation, transport or storage are considered by the Agency to be ***moderate***, as although the substance is very toxic to the aquatic environment, toxic to soil organisms, toxic to terrestrial vertebrates and very

toxic to terrestrial invertebrates, any spill would involve small quantities which would lead to localised effects only.

- The Agency also considers such an event to be ***highly improbable*** given adherence to the HSNO controls (e.g. packaging, identification and emergency management) and the Land Transport Rule 45001, Civil Aviation Act 1990 and Maritime Transport Act 1994 (as applicable).

Assessment of environmental risks – use

The Agency has qualitatively assessed the risks to the environment during use of NTNCS2 and considers the risks to be ***negligible***.

This assessment is based on the following considerations:

- NTNCS2 will be administered to animals as a pour-on drench. Based on this use pattern, the Agency considers it ***highly improbable*** that exposure to the environment will occur.

- Should exposure occur, the magnitude of any adverse effects on the aquatic or terrestrial environment is considered to be ***moderate***, based on the toxicity of NTNCS2 to aquatic and terrestrial organisms and the small amount of the substance likely to be involved.

Assessment of environmental risks – disposal

The Agency has qualitatively assessed the risks to the environment of disposal of NTNCS2 and considers the risks to be ***negligible***.

This assessment is based on the following considerations:

- NTNCS2 will generally be disposed of by normal use as a veterinary medicine.

- If NTNCS2 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. The Agency considers the likelihood of adverse effects to the environment arising from disposal to be ***highly improbable*** and the magnitude of such effects ***minor***.

Appendix 3: Default controls for NTNCS2 and their variations.

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[4], are listed in Table A3.1.

Table A3.1: List of default controls for NTNCS2

HSNO Classification	HSNO Controls
3.1D 6.3A 6.4A 6.8A 6.8C 6.9B 9.1A 9.2B 9.3B 9.4A	**Flammability** F2, F6, F11 **Toxic** T1, T2, T3, T4, T5, T7 **Ecotoxic** E1, E2, E3, E5, E6, E7 **Identification** I1, I3, I5, I9, I11, I13, I16, I17, I18, I19, I21, I23, I25, I28, I29 **Packaging** P1, P3, P13, P15, PG3, PS4 **Disposal** D2, D4, D5, D6, D7, D8 **Emergency Management** EM1, EM6, EM7, EM8, EM9, EM10, EM11, EM12, EM13 **Approved Handler** AH1 **Tracking** TR1

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. Those controls which require calculations, derivations or extended discussion are considered in the following sections.

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.

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

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.

Human exposure may also occur through food or drinking water. Exposure through food is managed via the establishment of Maximum Residue Limits (MRLs) as set by the Minister of Food Safety on the advice of the New Zealand Food Safety Authority (NZFSA). Exposure through drinking water is managed via the establishment of Maximum Acceptable Values (MAVs) as set by the Ministry of Health. MRLs and MAVs are also established from ADE values.

Setting of PDEs

If an ADE or RFD value is set for a substance, or component of a substance, a PDE value for each relevant exposure route must also be set. A PDE is an amount of substance (mg/kg bodyweight/day), calculated in accordance with Regulation 23 that estimates the relative likelihood of particular exposures. A PDE for any single exposure route is a fraction of the ADE or RFD, and the sum of all PDE values from all possible exposures must be less than or equal to the ADE or RFD.

The main routes of exposure considered are ingestion (food, water, air, and soil), inhalation (air) and skin contact (surface deposition, water, soil).

Setting of ADEs

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 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 NTNCS2 that trigger the need to consider setting a TEL are 6.3A, 6.4A, 6.8A, 6.8C and 6.9B.

For NTNCS2, the Agency consider that Components A, B, E and F fulfil the requirements of Reg 11 (1)(a) and (b), and potentially Reg 11 (1)(c). Given the specific use of NTNCS2, the Agency considers that the principal source of exposure of the general public to this substance is via food residues, an exposure route managed by NZFSA through the setting of MRLs. The Agency notes that MRLs have been set for Components A and B.

With respect to setting TELs for other exposure routes, the Agency is intending to review the setting of ADEs, PDEs and TELs under s77B of the Act. Until this review is complete, the Agency proposes not to set ADEs, PDEs or TELs for any components of NTNCS2 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/m^3 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 2001.

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 Department of Labour WES values have been set for components D, E and F in NTNCS2. These Department of Labour WES values are considered relevant to NTNCS2 and it is proposed that these are adopted as HSNO WES.

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 NTNCS2 at this time. It is also proposed that the default EEL water and soil values be deleted until the policy has been established.

Approved Handler Controls- Highly ecotoxic substances (AH1, E7)

Approved handler requirements have been triggered for NTNCS2 as a result of its 9.1A and 9.4A classifications. The outcome of the ecological risk assessment (refer

Appendix 3) indicates that it is unlikely there will be any adverse environmental effects from the proposed use of this substance. The Agency therefore considers that the approved handler controls 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).

Tracking control- Highly ecotoxic substances (TR1)

Tracking requirements have been triggered for NTNCS2 as a result of its 9.1A and 9.4A classifications. However, for 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 life-cycle are adequately managed by other controls such as 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).

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.

This product is not designed to be used in this manner, nor have any EELs been set. Consequently, the Agency considers this control is not relevant to NTNCS2.

Identification controls

Identification of Toxic Components on Labels/Documentation (SDS)

The Hazardous Substances (Identification) Regulations 2001 specify that certain toxic 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 toxic components on SDS

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

Regulations 39(5) states:

"The requirements of 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

NTNCS2 - 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
Components F	Components A, B, E, F

Appendix 4: Proposed controls for NTNCS2

Table A4.1: Proposed controls for NTNCS2 codes, regulations and variations.

Control Code[5]	Regulation[6]	Topic	Variations
Flammable substances (Classes 1 to 5) Regulations 2001			
F2	8	General public transportation restrictions and requirements for all class 1 to 5 substances	Controls F2 and T7 are combined
F6	60-72	Requirements to prevent unintended ignition of class 2.1.1, 2.1.2 and 3.1 substances	
F11	76	Segregation of incompatible substances	
Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001			
T1	11-27	Limiting exposure to toxic substances	No ADE, PDE or TEL values are set at this time
T2	29, 30	Controlling exposure in places of work	WES values are set for Components D, F and H
T3, E5	5, 6	Requirements for keeping records of use	Controls T3 and E5 are combined
T4, E6	7	Requirements for equipment used to handle hazardous 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	
E1	32-45	Limiting exposure to ecotoxic substances through the setting of EELs	No EEL values are set at this time and the default EELs are deleted.
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	

[5] 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.

[6] These Regulations form the controls applicable to this substance. Refer to the cited Regulations for the formal specification, and for definitions and exemptions.

<table>
<tr><th>Control Code[5]</th><th>Regulation[6]</th><th>Topic</th><th>Variations</th></tr>
<tr><td>I3</td><td>9</td><td>Priority identifiers for ecotoxic substances</td><td></td></tr>
<tr><td>I5</td><td>11</td><td>Priority identifiers for flammable substances</td><td></td></tr>
<tr><td>I9</td><td>18</td><td>Secondary identifiers for all hazardous substances</td><td></td></tr>
<tr><td>I11</td><td>20</td><td>Secondary identifiers for ecotoxic substances</td><td></td></tr>
<tr><td>I13</td><td>22</td><td>Secondary identifiers for flammable substances</td><td></td></tr>
<tr><td>I16</td><td>25</td><td>Secondary identifiers for toxic substances</td><td rowspan="3">Revised cut-offs for component labelling required by Regulation 25(e)
<table><tr><th>HSNO Classification of Component</th><th>Concentration Cut-off for Label (%)</th></tr><tr><td>6.5A, 6.5B</td><td>0.1[7]</td></tr><tr><td>6.6A, 6.7A</td><td>0.1</td></tr><tr><td>6.6B, 6.7B</td><td>1</td></tr><tr><td>6.8A, 6.8C</td><td>0.3</td></tr><tr><td>6.8B</td><td>3</td></tr><tr><td>6.9A, 6.9B</td><td>10</td></tr></table></td></tr>
<tr><td>I17</td><td>26</td><td>Use of Generic Names</td></tr>
<tr><td>I18</td><td>27</td><td>Use of Concentration Ranges</td></tr>
<tr><td>I19</td><td>29-31</td><td>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</td><td></td></tr>
<tr><td>I21</td><td>37-39, 47-50</td><td>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</td><td></td></tr>
</table>

[7] Identification of sensitising components may be required below the 0.1% level if a lower value has been used for classification.

Control Code[5]	Regulation[6]	Topic	Variations
		Regulation 48 – Location and presentation requirements for documentation Regulation 49 – Documentation requirements for vehicles Regulation 50 – Documentation to be supplied on request	
I23	41	Specific documentation requirements for ecotoxic substances	
I25	43	Specific documentation requirements for flammable substances	
I28	46	Specific documentation requirements for toxic substances	
I29	51, 52	Signage requirements	
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, P15	19, 21	Packaging requirements for toxic and ecotoxic substances	Controls P13 and P15 combined
PG3	Schedule 3	The tests in Schedule 3 correlate to 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			
D2, D4, D5	6, 8, 9	Disposal requirements for flammable, toxic, corrosive and ecotoxic substances	Controls D2, 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	

Control Code[5]	Regulation[6]	Topic	Variations
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	
EM9	17	Additional information requirements for flammable oxidising substances and organic peroxides	
EM10	21-24	Fire extinguisher 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 shall be 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.* *(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.*
EM13	42	Level 3 emergency management requirements: signage	

Control Code[5]	Regulation[6]	Topic	Variations
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			
The controls relating to stationary container systems, secondary containment and unintended ignition of flammable substances, as set out in schedules 8, 9 and 10 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 Schedules 8 and 9 and clause 1 of Schedule 10.			
Addition of subclauses after subclause (3) of Regulation 36, refer control EM12.			
NTNCS2shall only be used as a veterinary medicine.			

Appendix 5: Parties notified

Aakland Chemicals (1997) Limited
Agcarm Incorporated
AgResearch Limited
Ancare Scientific Limited
ARPPA
BALDWINS
BASF New Zealand Limited
Chancery Green
CSD Consultancy Ltd
Far North District Council
Federated Farmers of New Zealand (Incorporated)
Fort Dodge New Zealand Limited
Grayson Wagner Company Ltd
Green Party of Aotearoa New Zealand
Intervet Limited
Kaipara District Council
Landcorp Farming Limited
Lowndes Associates
Massey University
Merial New Zealand Limited
Ministry of Research Science and Technology (MoRST)
New Zealand Bee Industry Group - Federated Farmers
New Zealand Chemical Industry Council Inc
New Zealand Customs Service
New Zealand Press Association
New Zealand Society of Gunsmiths Inc
Ngati Kahungunu Iwi Incorporated
Northland Regional Council
Pesticide Action Network Aotearoa New Zealand
Pfizer New Zealand Limited
PharmVet Solutions
Reckitt Benckiser
South Taranaki District Council
Syngenta Crop Protection Limited
Taupo District Council
Television New Zealand
University of Auckland
Virbac New Zealand Limited

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/

Klimisch, HJ, Andreae, E, Tillman, U (1997). A systematic approach for evaluating the quality of experimental and ecotoxicological data. *Regulatory Toxicology and Pharmacology* 25: 1–5.

OECD (1990) Manual for Investigation of HPV Chemicals. http://www.oecd.org/document/21/0,3343,en_2649_34379_1939669_1_1_1_1,00.html Retrieved 23 January 2008.

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 used 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 2 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 substance. Variations and additional controls for the substance 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 (Pesticides) 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 (Class 1 to 5 Controls) Regulations 2001* prescribe a number of controls aimed at ensuring hazardous substances handled in a manner appropriate to their flammability.

Flammability Controls	
F1	General test certification requirements for hazardous substance locations
F2	Restrictions on the carriage of flammable substances on passenger service vehicles
F3	General limits on flammable substances
F4	Approved handler/security requirements for certain flammable substances
F5	Requirements regarding hazardous atmosphere zones for class 2.1.1, 2.1.2 and 3.1 substances
F6	Requirements to prevent unintended ignition of class 2.1.1, 2.1.2 and 3.1 substances
F7	Limits on ignition sources and temperature for class 3.2 and 4 substances
F8	Requirements to prevent unintended ignition of class 4.1.1 substances
F9	Requirements to prevent unintended ignition of class 4.1.2 substances
F10	Requirements to prevent unintended ignition of class 3.2 and 4.1.3 substances
F11	Segregation of incompatible substances
F12	Requirement to establish a hazardous substance locations if flammable substances are present
F13	Controls on hazardous substance locations where class 3.2 and 4 substances are present
F14	Test certification requirements for facilities where class 2.1.1, 2.1.2 or 3.1 substances

	are present
F15	Test certification requirements for facilities where class 3.2 or 4 substances are present
F16	Controls on transit depots where flammable substances are present

2.4. 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

2.5. 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

2.6. 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

2.7. 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

2.8. 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

2.9. 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

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

Tracking Controls	
TR1	General tracking requirements

2.11. 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)

2.12. 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

2.13. 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.

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

2.15. 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 be assessed in accordance with sections 5 and 6 and clauses 9 and 12. The assessment must be undertaken with regard 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 substance 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. As in 3.2 above outlining the aspects in which the risk assessment is undertaken in relation with, the Agency assesses each application for any effects associated with the relationship of Māori to the environment. In most cases the substance 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 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.

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 effect8 resulting from that initiating event. It will be a combination of the likelihood of the initiating event and several intermediary likelihoods[9]. 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

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8 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.

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

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

5. Decision Path