Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

6 July 2011

1. Summary of application

Application Code	ERMA200913
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	Section 28A(2)(b) – least degree of hazard – based on the substances being formulated so that they have one or more hazardous properties and each hazardous property has the least degree of hazard for that property
Applicant	Global Air and Water Limited
Date Application Received	10 June 2011
Consideration Date	Consideration Date – 6 July 2011 Further information was requested from the applicant during the assessment of the application in accordance with section 52 and consequently the consideration was postponed for 9 working days
Purpose of the Application	To import or manufacture Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix, containing naringin, as a pesticide for use in air, water and plants.
Parties Notified	On 10 June 2011the following were notified: The Department of Labour, The Ministry of Health, The Department of Conservation; and The New Zealand Food Safety Authority (ACVM Group)
EPA staff involved in the assessment	Sian Robertson– Advisor (Hazardous Substances) Margaret Keane– Advisor (Hazardous Substances)
EPA staff responsible for review	Matthew Allen – Advisor (Hazardous Substances) Jim Waters– Senior Advisor (Hazardous Substances)
Considered by	Rob Forlong (Chief Executive, EPA)

2. Decision

2.1. The import or manufacture of Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix for release is approved with controls as set out in Appendix A.

2.2. In making this decision the Chief Executive of the Environmental Protection Authority ("the EPA") has applied the relevant sections of the Act and clauses of Hazardous Substances and New Organisms (Methodology) Order 1998 ("the Methodology") as detailed in the decision path attached to this decision as **Appendix B.**

2.3. The substances have been given the following unique identifiers for the EPA Hazardous Substances Register:

Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix

Path-Away Anti-Pathogenic Solution 2.5% Mix

2.4. The Chief Executive has given Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix the following classifications:

6.3B (skin irritant), 6.4A (eye irritant) and 9.1D (biocidal ecotoxicant)

2.5. The Chief Executive has given Path-Away Anti-Pathogenic Solution 2.5% Mix the following classifications:

9.1D (biocidal ecotoxicant)

3. Consideration

Information review

3.1. The staff of the EPA ("the staff") have reviewed the information supplied by Global Air and Water Limited, and considers that the information constitutes an adequate and appropriate basis for assessing the application (clause 8). They also consider that there are no significant uncertainties (ie sufficient to influence decision making) in the scientific and technical information relating to the risks of Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix.

Identification and use of the substances

3.2. Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix is a liquid, used.as a component to make Path-Away Anti-Pathogenic Solution 2.5% Mix. Path-Away Anti-Pathogenic Solution 2.5% Mix is also a liquid, but will be used as an aerosol. Both contain naringen as the active ingredient(s), and other

components. Path-Away Anti-Pathogenic Solution 2.5% Mix is for use to control fungi, bacteria and yeasts in air, surfaces and plants.

Hazardous properties of Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix

3.3. The staff have determined the hazard profile of Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix based on the information provided by the applicant and other available information. The hazard classifications for Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix are set out in Table 1.

Table 1: Hazard profiles of the substances

Hazard Endpoint	Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix	Path-Away Anti-Pathogenic Solution 2.5% Mix
Skin irritancy/corrosivity	6.3B	
Eye irritancy/corrosivity	6.4A	
Ecotoxicity (biocidal)	9.1D	9.1D

Meeting the criteria for rapid assessment under section 28A(2)(b)

3.4. Based on the information presented in Table 1, the staff consider that Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix have been formulated with each hazardous property having the least degree of hazard for that property, and that the criteria for rapid assessment under section 28A(2)(b) have been met.

4. Controls and Risk Assessment

Default controls

4.1. Based on the hazard classifications determined for the substances, a set of associated default controls has been identified by the staff as being applicable to each of Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix. These default controls, expressed as control codes[1], are listed in Tables 2 and 3.

4.2. Additional controls under section 77A are available to manage the risks associated with Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix,

[1] 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 EPA User Guide to the Controls Regulations.

which are not addressed by the default controls. These are considered in paragraphs 4.16 and 4.18 below.

Table 2: List of default controls for Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix

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.
T4	Requirements for equipment used to handle substances
T7	Restrictions on the carriage of toxic or corrosive substances on passenger service vehicles
Ecotoxicity Controls	
E1	Limiting exposure to ecotoxic substances through the setting of EELs
E2	Restrictions on use of substances in application areas
E6	Requirements for equipment used to handle substances
Identification Controls	
I1	Identification requirements, duties of persons in charge, accessibility, comprehensibility, clarity and durability
I9	Secondary identifiers for all hazardous substances
I11	Secondary identifiers for ecotoxic substances
I16	Secondary identifiers for toxic substances
I19	Additional information requirements, including situations where substances are in multiple packaging
I21	General documentation requirements
I28	Specific documentation requirements for toxic substances
Packaging Controls	
P1	General packaging requirements
P3	Criteria that allow substances to be packaged to a standard not meeting Packing Group I, II or III criteria
P13	Packaging requirements for toxic substances
PS4	Packaging requirements as specified in Schedule 4
Disposal Controls	
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
Emergency Management Controls	
EM1	Level 1 information requirements for suppliers and persons in charge
EM6	Information requirements for toxic substances
EM7	Information requirements for ecotoxic substances
EM8	Level 2 information requirements for suppliers and persons in charge
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
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.	

Table 3: List of default controls for Path-Away Anti-Pathogenic Solution 2.5% Mix

Ecotoxicity Controls	
E1	Limiting exposure to ecotoxic substances through the setting of EELs
E2	Restrictions on use of substances in application areas
E6	Requirements for equipment used to handle substances
Identification Controls	
I1	Identification requirements, duties of persons in charge, accessibility, comprehensibility, clarity and durability
I9	Secondary identifiers for all hazardous substances
I11	Secondary identifiers for ecotoxic substances
I19	Additional information requirements, including situations where substances are in multiple packaging
I21	General documentation requirements
I29	Signage requirements
Packaging Controls	
P1	General packaging requirements
P3	Criteria that allow substances to be packaged to a standard not meeting Packing Group I, II or III criteria

PS4	Packaging requirements as specified in Schedule 4
Disposal Controls	
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
Emergency Management Controls	
EM1	Level 1 information requirements for suppliers and persons in charge
EM7	Information requirements for ecotoxic substances
EM8	Level 2 information requirements for suppliers and persons in charge
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
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.	

Assessment of the adverse effects

4.3. The staff have evaluated the potential of Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix to cause adverse effects to human health and the environment (non-target organisms) during all stages of these substance's lifecycles. A qualitative risk assessment was carried out to assess these risks (refer to Appendix C for qualitative descriptors of risk).

Assessment of risks to human health

4.4. With respect to human toxicity, Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix has been classified as a skin irritant (6.3B) and an eye irritant (6.4A).

4.5. The staff consider that Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix presents a skin and eye irritancy hazard (6.3B and 6.4A) to which people can be exposed during any phase of the product lifecycle through product spillage during transport or a flaw in packaging, for example; however it is considered that the magnitude of adverse effect would be minimal.

4.6. With default controls in place, such as personal protective equipment requirements, hazard identification through labelling and adequate packaging, the staff consider the likelihood of unintended

exposure to Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix to be highly improbable, giving an overall qualitative assessment of risk of toxic effect as negligible.

Assessment of risks to the environment

4.7. The staff note that Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix does not trigger any ecotoxicity classifications and considers the risk of adverse effects to the environment during manufacturing, importation, transport, storage, use and disposal of Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix as being negligible. However, given the biocidal nature of the substances and their intended uses, the staff has classified these substances as 9.1D accordingly.

Relationship of Māori to the Environment

4.8. The staff note that Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix trigger a number of hazardous properties giving rise to the potential for cultural risk including the general health and well-being of individuals and the community.

4.9. In addition, the introduction and use of these substances has the potential to inhibit the ability of iwi/Māori to fulfil their role as kaitiaki, particularly given the potential risks to the mauri ora of human health under prolonged exposure to these substances.

4.10. On considering the information outlined here and elsewhere in this report, the staff consider a minimal impact from Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix 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 and the probability of impact to be highly improbable. In addition there is no evidence to suggest that the controlled use of Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix will breach the principles of the Treaty of Waitangi.

4.11. The overall level of risk is therefore considered to be negligible for Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix given that the substance will be handled, stored, transported, used, and disposed of, in accordance with the explicitly stated default and additional controls detailed in this report, and any other controls required by other legislation.

4.12. However, the staff note 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.

Modification of controls and setting of exposure limits

4.13. The staff have reviewed the effectiveness of the default controls for Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix in managing the identified risks and costs associated with the substances. Consequently a number of additional controls are considered appropriate. The additions and the setting of exposure limits and applications rates are discussed below.

Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix

4.14. The following controls were triggered by the intrinsic hazards of Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix but are not considered relevant based on the substance's use as a component in the manufacture of Path-Away Anti-Pathogenic Solution 2.5% Mix, and have therefore not been applied:

Class	Control
Toxicity	T1
Ecotoxicity	E1, E2

Controls relating to the setting of exposure limits and application rates

4.15. The following controls relating to the setting of exposure limits can be varied as provided for under section 77(4):

Control	Comment
T2	This control relates to the requirement to control exposure in places of work through the setting of WESs. The staff typically adopt WES values listed in the Workplace Exposure Standards document (Effective from December 2010): http://www.osh.govt.nz/publications/booklets/wes-dec-2010/wes-dec-2010.pdf The staff note that a Department of Labour WES values have been set for component B in Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and is adopted.

Controls added under section 77A

4.16. The following controls are added under section 77A(3)(a) on the basis that they will mitigate adverse effects not addressed by the default controls and thus will be more effective in terms of their effect on the risks of the substance:

Control	Comment
Use Control	As the assessment of the substance's risk has been based on its use as a component in manufacture only, the following use restriction control is added: *Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix shall only be used as a component or ingredient in the manufacture of Path-Away Anti-Pathogenic Solution 2.5% Mix.*

Schedule 8	The controls relating to stationary containment, 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 of that schedule.
EM12	The following subclauses are added after subclause (3) of regulation 36[2] (control EM12) to allow for dispensation where it is unnecessary for any associated pipework to have secondary containment[3]: *(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.*
EM12	The following subclauses are added after subclause (3) of regulation 37[4] (control EM12) to take into account any risk of adverse effects posed by pooling hazardous substances: *(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.*
EM12	The following subclauses are added after subclause (3) of regulation 38[5] (control EM12) to take into account any risk of adverse effects posed by pooling hazardous substances:

[2] Hazardous Substances (Emergency Management) Regulations 2001
3 Hazardous Substances (Emergency Management) Regulations 2001
4 Hazardous Substances (Emergency Management) Regulations 2001
5 Hazardous Substances (Emergency Management) Regulations 2001

	(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.*

Path-Away Anti-Pathogenic Solution 2.5% Mix

Controls relating to the setting of exposure limits and application rates

4.17. The following controls relating to the setting of exposure limits can be varied as provided for under section 77(4):

Control	Comment
E1	Control E1 relates to the requirements to limit exposure of non-target organisms in the environment through the setting of Environmental Exposure Limits (EELs). No EELs are set at this time. The default EELs, set under regulation 32 of the Hazardous Substances (Classes 6, 8 and 9 controls) Regulations, are deleted.
E2	Control E2 relates to the restrictions on use of substances in application areas. As no EEL value has been set, no application rate is required to be set at this time.

Controls added under section 77A

4.18. The following controls are added under section 77A(3)(a) on the basis that they will mitigate adverse effects not addressed by the default controls and thus will be more effective in terms of their effect on the risks of the substance:

Control	Comment
Use Control	The following use restriction control is added: *Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix shall not be added onto or into water.*
Schedule 8	The controls relating to stationary containment, 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 of that schedule.

4.19. The additions to the default controls, as above, have been incorporated into the list of controls for Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix detailed in Appendix A.

5. Environmental user charges

5.1. The staff consider that use of controls on Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix is an effective means of managing risks associated with these substances. At this time, no consideration has been given to whether or not environmental user charges should be applied to these substances as an alternative or additional means of achieving effective risk management. Accordingly, no report has been made to the Minister for the Environment.

6. Decision

6.1. Pursuant to section 28A, I have considered this application to import or manufacture Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix for release made under section 28.

6.2. Having considered the composition, hazardous properties and proposed uses of Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix, I am satisfied that the criteria for rapid assessment under section 28A(2)(b) are met, in that the substances each have one or more hazardous properties and each hazardous property has the least degree of hazard for that property.

6.3. I am satisfied with the hazard classifications identified by the staff in Table 1 and confer them accordingly on Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix.

6.4. As the risks posed by Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix are negligible, I consider that applying the HSNO default controls to Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix, with the additions and amendments detailed in paragraphs 4.14 to 4.18 (inclusive), will ensure adequate management of any adverse effects of Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix.

6.5. In this consideration, I have also applied the following criteria in the Methodology:

- clause 9 – equivalent of sections 5, 6 and 8;
- clause 12 – risk assessment;

- clause 21 – the decision accords with the requirements of the Act and regulations;
- clause 24 – the use of recognised risk identification, assessment, evaluation and management techniques;
- clause 25 – the evaluation of risks; and
- clause 35 – the costs and benefits of varying the default controls.

6.6. The application to import or manufacture the hazardous substances Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix (for use as a component in the manufacture of a pesticide) and Path-Away Anti-Pathogenic Solution 2.5% Mix (for use as pesticide) is thus approved with controls as detailed in **Appendix A**.

Rob Forlong	Date: 6 July 2011
Chief Executive, Environmental Protection Authority	

Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix	
HSNO Approval Code:	**HSR100548**

Path-Away Anti-Pathogenic Solution 2.5% Mix	
HSNO Approval Code:	**HSR100549**

APPENDIX A

Controls applying to Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix

The controls imposed on Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix and Path-Away Anti-Pathogenic Solution 2.5% Mix are detailed in Table A1 and A2 respectively. The regulations cited should be referred to for definitions and exemptions. The EPA publication *User Guide to Control Regulations* provides useful guidance on the controls.

Table A1: Controls for Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix – codes, regulations and variations

Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001

Code	Regulation	Description	Variation
T2	Regs 29, 30	Controlling exposure in places of work through the setting of WESs.	DoL WES value is set for component B of Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix.
T4	Reg 7	Requirements for equipment used to handle substances	
T7	Reg 10	Restrictions on the carriage of toxic or corrosive substances on passenger service vehicles	

Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001

Code	Regulation	Description	Variation
E6	Reg 7	Requirements for equipment used to handle substances	

Hazardous Substances (Identification) Regulations 2001

Code	Regulation	Description	Variation
I1	Regs 6, 7, 32 – 35, 36(1) – (7)	Identification requirements, duties of persons in charge, accessibility, comprehensibility, clarity and durability	
I9	Reg 18	Secondary identifiers for all hazardous substances	
I11	Reg 20	Secondary identifiers for ecotoxic substances	
I16	Reg 25	Secondary identifiers for toxic substances	
I19	Regs 29 – 31	Additional information requirements, including situations where substances	

		are in multiple packaging	
I21	Regs 37 – 39, 47 – 50	General documentation requirements	
I28	Reg 46	Specific documentation requirements for toxic substances	
I29	Regs 51, 52	Signage requirements	

Hazardous Substances (Packaging) Regulations 2004

Code	Regulation	Description	Variation
P1	Regs 5,6, 7(1), 8	General packaging requirements	
P3	Reg 9	Criteria that allows substances to be packaged to a standard not meeting Packing Group I, II or III criteria.	
P13	Reg 19	Packaging requirements for toxic substances.	
PS4	Schedule 4	Packaging requirements as specified in Schedule 4	

Hazardous Substances (Disposal) Regulations 2001

Code	Regulation	Description	Variation
D4	Reg 8	Disposal requirements for toxic and corrosive substances	
D5	Reg 9	Disposal requirements for ecotoxic substances	
D6	Reg 10	Disposal requirements for packages	
D7	Regs 11, 12	Information requirements for manufacturers, importers and suppliers, and persons in charge	
D8	Regs 13, 14	Documentation requirements for manufacturers, importers and suppliers, and persons in charge	

Hazardous Substances (Emergency Management) Regulations 2001

Code	Regulation	Description	Variation
EM1	Regs 6, 7, 9 – 11	Level 1 information requirements for suppliers and persons in charge	
EM6	Reg 8(e)	Information requirements for toxic substances	
EM7	Reg 8(f)	Information requirements for ecotoxic substances	
EM8	Regs 12 – 16,	Level 2 information requirements for	

	18 – 20	suppliers and persons in charge	
EM11	Regs 25 – 34	Level 3 emergency management requirements: duties of person in charge, emergency response plans	
EM12	Regs 35-41	Level 3 emergency management requirements: secondary containment	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 syst em; 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.* The following subclauses are added 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.* The following subclauses are added 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	Reg 42	Level 3 emergency management requirements: signage	

Hazardous Substances (Tank Wagon and Transportable Containers) Regulations 2004

Code	Regulation	Description	Variation
Tank	Regs 4 to 43	Controls relating to tank wagons and	

Wagon	as applicable	transportable containers.	

Schedule 8 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004

Code	Regulation	Description
Sch 8	Schedule 8	This schedule prescribes the controls for stationary container systems. The requirements of this schedule are detailed in the consolidated version of the Hazardous Substances (Dangerous Goods and Schedule Toxic Substances) Transfer Notice 2004

Additional controls

Code	Regulation	Description
Use	77A	Path-Away Anti-Pathogenic Solution Concentrate Pre-Mix shall only be used as a component or ingredient in the manufacture of Path-Away Anti-Pathogenic Solution 2.5% Mix.

Table A2: Controls for Path-Away Anti-Pathogenic Solution 2.5% Mix – codes, regulations and variations

Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001

Code	Regulation	Description	Variation
E1	Regs 32-45	Limiting exposure to ecotoxic substances through the setting of EELs	No EELs are set at this time and the default EELS are deleted.
E2	Regs 46-48	Restrictions on use of substances in application areas	No application rate is set at this time.
E6	Reg 7	Requirements for equipment used to handle substances	

Hazardous Substances (Identification) Regulations 2001

Code	Regulation	Description	Variation
I1	Regs 6, 7, 32 – 35, 36(1) – (7)	Identification requirements, duties of persons in charge, accessibility, comprehensibility, clarity and durability	
I9	Reg 18	Secondary identifiers for all hazardous substances	
I11	Reg 20	Secondary identifiers for ecotoxic substances	
I19	Regs 29 – 31	Additional information requirements, including situations where substances are in multiple packaging	
I21	Regs 37 – 39, 47 – 50	General documentation requirements	
I29	Regs 51, 52	Signage requirements	

Hazardous Substances (Compressed Gases) Regulations 2004

Code	Regulation	Description	Variation
CG		The Hazardous Substances (Compressed Gases) Regulations 2004 prescribe a number of controls relating to compressed gases including aerosols and gas cylinders.	

Hazardous Substances (Disposal) Regulations 2001

Code	Regulation	Description	Variation
D5	Reg 9	Disposal requirements for ecotoxic substances	
D6	Reg 10	Disposal requirements for packages	
D7	Regs 11, 12	Information requirements for	

		manufacturers, importers and suppliers, and persons in charge	
D8	Regs 13, 14	Documentation requirements for manufacturers, importers and suppliers, and persons in charge	

Hazardous Substances (Emergency Management) Regulations 2001

Code	Regulation	Description	Variation
EM1	Regs 6, 7, 9 – 11	Level 1 information requirements for suppliers and persons in charge	
EM7	Reg 8(f)	Information requirements for ecotoxic substances	
EM8	Regs 12 – 16, 18 – 20	Level 2 information requirements for suppliers and persons in charge	
EM11	Regs 25 – 34	Level 3 emergency management requirements: duties of person in charge, emergency response plans	
EM13	Reg 42	Level 3 emergency management requirements: signage	

Hazardous Substances (Tank Wagon and Transportable Containers) Regulations 2004

Code	Regulation	Description	Variation
Tank Wagon	Regs 4 to 43 as applicable	Controls relating to tank wagons and transportable containers.	

Schedule 8 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004

Code	Regulation	Description
Sch 8	Schedule 8	This schedule prescribes the controls for stationary container systems. The requirements of this schedule are detailed in the consolidated version of the Hazardous Substances (Dangerous Goods and Schedule Toxic Substances) Transfer Notice 2004

Additional controls

Code	Regulation	Description
Use	77A	Path-Away Anti-Pathogenic Solution 2.5% Mix shall not be applied onto or into water.

APPENDIX B

Decision path for rapid assessment applications to import or manufacture a hazardous substance

1. Context

This decision path describes the decision-making process for applications to **import or manufacture a hazardous substance under the rapid assessment route for least degrees of hazard**. These applications are made and determined under section 28A(2)(b) of the HSNO Act. If the application is 'not approved' then the Authority **may** proceed to consider the application under Section 29 of the Act.

2. Introduction

The purpose of the decision path is to provide the Authority with guidance so that **all relevant matters** in the HSNO Act and the Methodology have been addressed. It does not attempt to direct the weighting that the Authority may decide to make on individual aspects of an application.

In this document 'section' refers to sections of the HSNO Act, and 'clause' refers to clauses of the ERMA New Zealand Methodology.

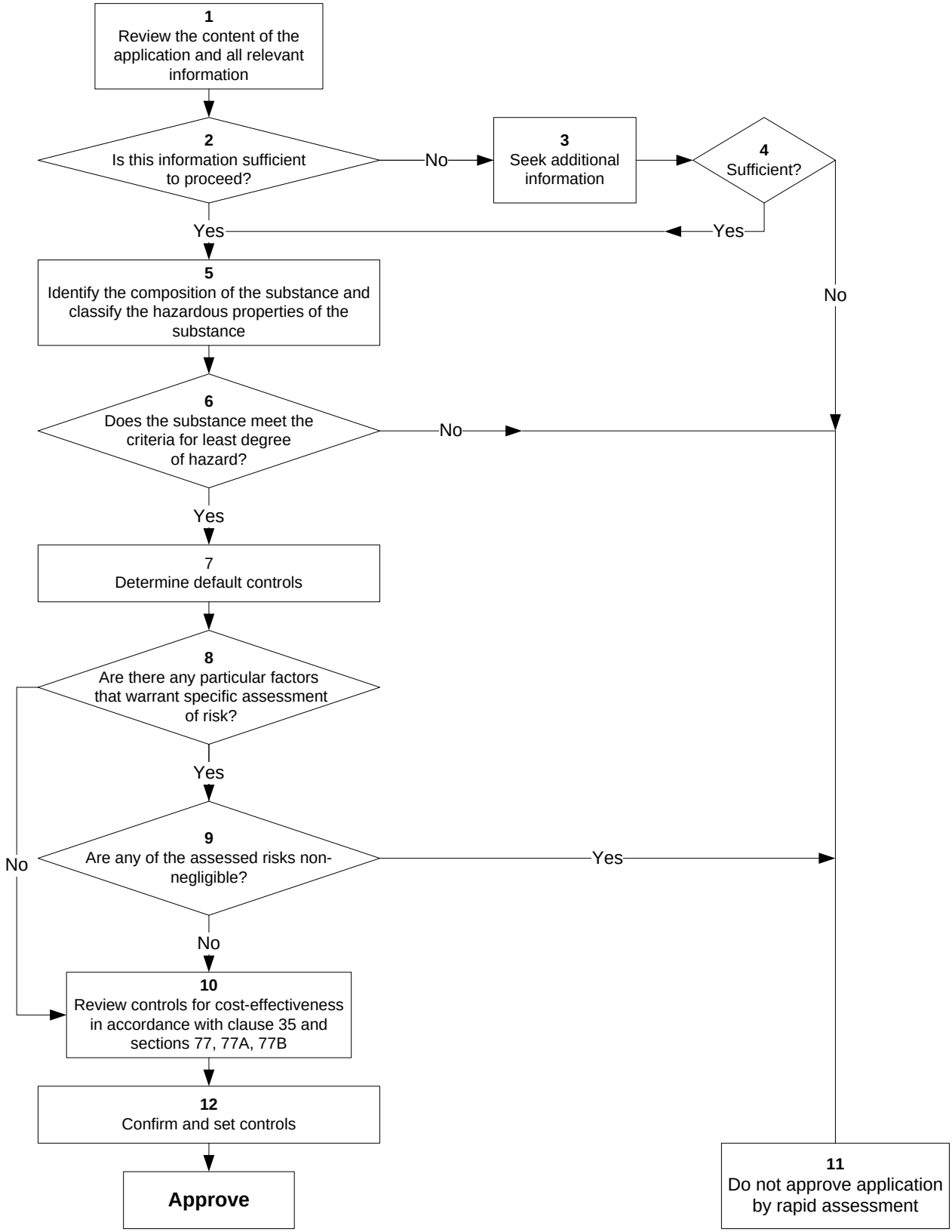
The decision path has two parts –

- **Flowchart** (a logic diagram showing the process prescribed in the Methodology and the HSNO Act to be followed in making a decision), and
- **Explanatory notes** (discussion of each step of the process).

Of necessity the words in the boxes in the flowchart are brief, and key words are used to summarise the activity required. The explanatory notes provide a comprehensive description of each of the numbered items in the flowchart, and describe the processes that should be followed to achieve the described outcome.

For proper interpretation of the decision path it is important to work through the flowchart in conjunction with the explanatory notes.

FLOWCHART


1
Review the content of the application and all relevant information
2
Is this information sufficient to proceed?
No
3
Seek additional information
4
Sufficient?
Yes
Yes
5
Identify the composition of the substance and classify the hazardous properties of the substance
No
6
Does the substance meet the criteria for least degree of hazard?
No
Yes
7
Determine default controls
8
Are there any particular factors that warrant specific assessment of risk?
Yes
9
Are any of the assessed risks non-negligible?
Yes
No
No
10
Review controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A, 77B
12
Confirm and set controls
Approve
11
Do not approve application by rapid assessment

EXPLANATORY NOTES

Items 1: **Review the content of the application and all relevant information**

Review the application, the staff advice in the form of an E&R Report or Draft Decision and information received from experts (where relevant) in terms of section 28(2) of the Act and clauses 8, 15, 16 and 20 of the Methodology.

Applications for rapid assessment require that the applicant verify the information contained in the application by statutory declaration (section 28A(1)).

Item 2: **Is this information sufficient to proceed?**

Review the information and determine whether or not there is sufficient information available to make a decision.

The Methodology (clause 8) states that the information used by the Authorityin evaluating applications shall be that which is appropriate and relevant to the application. While the Authority will consider all relevant information, its principal interest is in information which is significant to the proper consideration of the application; ie information which is "necessary and sufficient" for decision-making.

Item 3: **(if 'no') Seek additional information**

If there is not sufficient information then additional information may need to be sought from the applicant, the staff or other parties/experts under section 58 of the Act (clause 23 of the Methodology).

Item 4: **Sufficient?**

When additional information has been sought, has this been provided, and is there now sufficient information available to make a decision?

Item 5: **(if 'yes' from item 2 or item 4) Identify the composition and classify the hazardous properties of the substance**

Confirm the composition of the substance and establish its hazard classifications

Item 6: **Does the substance meet the criteria for least degree of hazard?**

Consider whether the substance meets the criteria for the least degree of hazards as detailed in the Policy Document Interpretation and Explanation of Key Concepts Document (Policy Document "Rapid Assessment for Importation or Manufacture of Hazardous Substances for Release - Criteria for Determining Eligibility"[6]), including the criteria for substances containing sensitisers.

Item 7: **Determine the default controls**

Determine the default controls for the specified hazardous properties using the regulations 'toolbox'.

Item 8: **Are there any particular factors that warrant specific assessment of risk?**

Consider whether there are any factors associated with the substance that would warrant a specific assessment of risk.

If so, the assessment of costs and residual risks should be carried out in the same way as for items 6, 7, 8 and 9 of Figure 1 (Decision Paths for Applications to Import or Manufacture a Hazardous Substance (determined under section 29)). This assessment includes reference to clauses 12 to 14, 22, 25, and

[6] http://www.ermanz.govt.nz/resources/publications/pdfs/ER-PR-03-20%2001-08.pdf

29 to 32 of the Methodology. The process of risk assessment includes the estimation of the likelihood and magnitude of each effect. The assessment is carried out with the default controls in place.

Item 9: **Are any of the assessed risks non-negligible?**

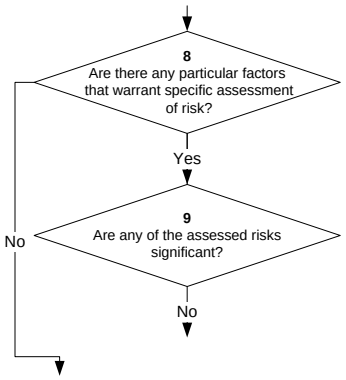
Consider whether any of the assessed risks are deemed to be non-negligible.

If there are any non-negligible risks associated with the substance, then it cannot be approved under rapid assessment (since it would then require the consideration of benefits under clause 27) and may instead be considered as a full assessment.

Item 10: **(if 'no' from items 8 or 9) Review controls in accordance with clause 35 and sections 77, 77A, 77B**

This is effectively a clause 26 approval since all risks are negligible.

In accordance with clause 35, consider varying the controls under sections 77 and 77A of the Act, while ensuring that the residual risks are not increased. If the substance has toxic or ecotoxic properties, consider setting exposure limits under section 77B.



Item 11: **(if 'no' from item 4 or 6 or 'yes' from item 9) Do not approve for rapid assessment**

If the application cannot be approved by rapid assessment, the Authority may choose to consider it as a full assessment under section 29 of the Act.

(from item 4) If the Authority is not satisfied that it has sufficient information for consideration, then the Authority may choose to not approve that application or the application may lapse.

(From item 6) If the substance does not meet the criteria for least degree of hazard then the substance is not approved under rapid assessment.

(From item 9) If any of the identified risks are non-negligible then the substance is not approved under rapid assessment.

Item 12: **Confirm and set controls**

Controls have been considered earlier in the process (items 7 and 11). However, the final step in the decision-making process confirms and sets the controls.

APPENDIX C

Qualitative descriptors for risk/benefit assessment

This section describes how the 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).

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 C1 and C2 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 C1 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 C2 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

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).

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 resulting from that initiating event. It will be a combination of the likelihood of the initiating event and several intermediary likelihoods. The best way to determine the likelihood is to specify and analyse the complete pathway from source to impact.

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 C3 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

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

In the example shown in Table C4, 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.

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 C4 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

APPENDIX D

Confidential information