Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

7 July 2011

1. Summary of application

Application Code	ERMA200826
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)(a) – rapid similar – having a similar composition and similar hazardous properties to a substance that has been approved under the Act
Applicant	BASF New Zealand Limited
Date Application Received	18 March 2011
Consideration Date	6 July 2011 Further information was requested from the applicant during the assessment of the application in accordance with section 52and consequently the consideration was postponed for 65 working days.
Purpose of the Application	To import for release TERMIDOR, with the active ingredient fipronil, to control certain insect pests in urban situations.
Parties Notified	On 18 March 2011 the following were notified: The Department of Labour ;and The Department of Conservation; and The Ministry of Health
EPA staff involved in the assessment	Rachael Linklater – Advisor (Hazardous Substances) Margaret Keane – Advisor (Hazardous Substances)
EPA staff responsible for review	Jim Waters – Senior Advisor (Hazardous Substances) Haydn Murdoch – Advisor (Hazardous Substances)
Considered by	Rob Forlong (Chief Executive, EPA)

2. Decision

2.1. The import or manufacture of TERMIDOR for release is approved with controls as set out in Appendix A.

2.2. In making this decision the Chief Executive has applied the relevant sections of the Act and clauses of the 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 substance has been given the following unique identifier for the EPA Hazardous Substances Register:

TERMIDOR

2.4. The Chief Executive has given TERMIDOR the following classifications:

6.1D (acute oral toxicant), 6.1E (acute dermal and inhalation toxicant), 6.9B (target organ toxicant), 9.1A (aquatic ecotoxicant), 9.3B (terrestrial vertebrate toxicant) and 9.4A (terrestrial invertebrate toxicant).

3. Consideration

Information review

3.1. The staff have reviewed the information supplied by BASF New Zealand Limited, and consider that the information constitutes an adequate and appropriate basis for assessing the application (clause 8). They also consider that there are no significant uncertainties (i.e. sufficient to influence decision making) in the scientific and technical information relating to the risks of TERMIDOR.

Identification of the proposed substance

3.2. TERMIDOR is a suspension concentrate containing fipronil as the active ingredient, and other components.

Identification of the reference substance

3.3. The applicant identified a reference substance with which they consider TERMIDOR may be compared. This reference substance was transferred under the generic description "Suspension concentrate containing 200 g/litre fipronil" and given the HSNO Approval code, HSR000831.

3.4. The staff consider this reference substance to be eligible for comparison with TERMIDOR and have used it as such in this document.

Composition of TERMIDOR compared to that of the reference substance

3.5. TERMIDOR and the reference substance are suspension concentrates containing fipronil as the active ingredient, and other components.

3.6. The active ingredient and other components are the major hazardous components conferring the hazard classifications on TERMIDOR. The active ingredient is the major hazardous component conferring the hazard classifications on the reference substance.

3.7. The overall proportion of the major hazardous components and active ingredients is greater in the reference substance than in the proposed substance.

Hazardous properties of TERMIDOR compared to those of the reference substance

3.8. The staff have determined the hazard profile of TERMIDOR based on the information provided by the applicant and other available information. The hazard classifications for TERMIDOR are set out in Table 1 for comparison against the reference substance.

Table 1: Comparison of hazard profiles of proposed substance and reference substance

Hazard Endpoint	Proposed Substance	Reference Substance
Acute Toxicity (oral)	6.1D	6.1D
Acute Toxicity (dermal)	6.1E	6.1D
Acute Toxicity (inhalation)	6.1E	6.1D
Eye irritancy/corrosivity	--	6.4A
Target Organ Toxicity (oral)	6.9B	6.9A
Aquatic ecotoxicity	9.1A	9.1A
Terrestrial vertebrate ecotoxicity	9.3B	9.3B
Terrestrial invertebrate ecotoxicity	9.4A	9.4A

3.9. The staff note that there are some differences in hazard classification between Termidor and the reference substance in that TERMIDOR has reduced acute dermal and inhalation toxicity and target organ/ system toxicity and has not been classified for eye irritancy. The reduction in hazard is because the reference substance contains a higher concentration of the active ingredient than Termidor.

Comparison of the uses of TERMIDOR and the reference substance

3.10. TERMIDOR is proposed for use as a residual insecticide for the protection of structures from subterranean termite damage and for the control of subterranean termites and ants around domestic and commercial structures. The staff note that TERMIDOR is to be applied by commercial contractors and that it will be applied as a dilute, water-based spray using conventional hand-held spraying equipment.

3.11. The staff note that the use of the reference substance is somewhat different in that it is used for the control of diamondback moth and white butterfly in vegetable brassica, Kelly's citrus thrip in citrus, mushroom flies (sciarids, cecids and phorids) in mushrooms and thrips in onions. The reference substance is applied as a high volume spray.

3.12. The staff consider that the risks to the environment will be somewhat less due to the less widely dispersive use of TERMIDOR; however, the exposure to people is somewhat increased due to the substance's use in commercial and domestic settings. The staff note the precautions on the label indicating that residents and pets should not be present when a room is being treated and considers this label warning should be added as a control and would be sufficient to mitigate any health risks from exposure to the substance. Therefore, the staff do not consider that the risks from use of TERMIDOR would not be increased compared to the risks from use of the reference substance.

3.13. The staff consider that there are no other substantial differences in the lifecycles, uses, purposes and presentations between TERMIDOR and the reference substance.

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

3.14. Based on the comparison and assessment detailed above, the staff consider that the criteria for rapid assessment under section 28A(2)(a) have been met through TERMIDOR having a similar composition and similar hazardous properties to a substance that has been approved under the Act.

Comparison of the adverse effects of TERMIDOR and the reference substance

3.15. Given the similarities in lifecycle and use of TERMIDOR and the reference substance, the staff do not expect an increase in potential exposure to occur.

3.16. The staff consider that there are no other matters which would prevent this application for TERMIDOR from being approved under section 28A.

4. Controls

4.1. A set of controls was applied to the reference substance when it was approved under the Act. It is noted that changes that have been made in legislation subsequent to the approval of the reference substance now also apply to it (section 77(2)(a)).

4.2. The staff note that the proposed and reference substances have similar use patterns, therefore most of the controls assigned to the reference substance will be applicable to the proposed substance. However, as TERMIDOR has a slightly reduced hazard profile relative to the reference substance, the project team notes that the following controls assigned to the reference substance are not triggered for TERMIDOR:

Class/Lifecycle Stage	Control
Toxicity	T3

4.3. The staff also note that the following controls have been triggered for TERMIDOR on the basis of its intrinsic hazards. However, these controls are not considered relevant as the substance is will not be used as vertebrate toxic agent, and have therefore not been listed:

Class/Lifecycle Stage	Control
Toxicity	T8
Ecotoxicity	E4

4.4. The following modifications, additions and combinations applied to the reference substance, as provided for under section 77 and section 77A, and are equally applicable to TERMIDOR:

4.4.1. The setting of exposure limits:

Control	Comment
T1	This control relates to the setting of tolerable exposure limits (TELs) to control hazardous substances entering the environment in quantities sufficient to present a risk to people. No ADEs, PDEs or TELs are set for any component of TERMIDOR at this time.
T2	This control relates to the requirement to control exposure in places of work through the setting of WESs. The EPA typically adopts WES values listed in the Department of Labour's 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 Department of Labour WES values have been set for component B in the reference substance and it is considered that these values are applicable to TERMIDOR.

E1	This control relates to the setting of environmental exposure limits (EELs) to control hazardous substances entering the environment in quantities sufficient to present a risk to the environment. No EELs for any component of TERMIDOR are set at this time. The default EEL values are deleted.
E2	This control relates to restrictions on use of substances in application areas. As no EEL has been set for TERMIDOR, no application rate is required to be set at this time.

4.4.2. Control modifications:

Control	Comment
E7/AH1	These controls relate to approved handler/security requirements. The staff note the approved handler/ security requirements placed on the reference substance were triggered by the 9.1A and 9.4A ecotoxicity classifications; however it is considered that Regulation 9(1) should be varied to reduce the approved handler requirements based on the substance's use as a pesticide applied in a wide and dispersive manner. This variation has also been carried out for other similar substances approved under the Act: *(1) This hazardous substance must be under the personal control of an approved handler when the substance is:* *(a) applied in a wide dispersive manner; or* *(b) used by a commercial contractor.*

4.4.3. Control deletions:

Control	Comment
TR1	This control relates to Tracking requirements and has been triggered by the 9.1A and 9.4A ecotoxicity classifications of TERMIDOR. It is considered that the control can be deleted under section 77(4)(b) as being unnecessary to manage the risk of adverse effects from the use of TERMIDOR, which are already well-managed under other controls.

4.4.4. Additional controls:

Control	Comment
Water	The staff note that for pesticides transferred to the HSNO Act on 1 July 2004, a use restriction control was applied. This is considered to be equally applicable to TERMIDOR: *TERMIDOR shall not be applied onto or into water[1].*

1 where 'water' means water in all its physical forms, whether flowing or not, and whether over or under ground, but does not include water in any form while in a pipe, tank or cistern.

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[3] (control EM12) to allow for dispensation where it is unnecessary for any associated pipework to have secondary containment: *(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	For addition at the end of regulation 37[2] as the risks associated with the containment of substances which are not class 1 to 5 substances are less than those associated with class 1 to 5 substances, consequently the secondary containment requirements with respect to pooling hazardous substances can be reduced as follows: *(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.*

[2] Hazardous Substances (Emergency Management) Regulations 2001

EM12	For addition at the end of regulation 38[5] as the risks associated with the containment of substances which are not class 1 to 5 substances are less than those associated with class 1 to 5 substances, consequently the secondary containment requirements with respect to pooling hazardous substances can be reduced as follows: *(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.*

4.5. Taking into account the control modifications referred to above, the proposed controls for TERMIDOR are detailed in Appendix A.

5. Environmental user charges

5.1. The staff consider that use of controls on TERMIDOR is an effective means of managing risks associated with this substance. At this time, no consideration has been given to whether or not environmental user charges should be applied to this substance 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 a hazardous substance for release made under section 28.

6.2. Having considered the composition, hazardous properties and proposed use of TERMIDOR, I am satisfied that it meets the criteria for rapid assessment under section 28A(2)(a) in that they have a similar composition and similar hazardous properties to a substance that has been approved under the Act.

6.3. I am satisfied with the hazard classifications identified by the staff in Table 1 and confer them accordingly on TERMIDOR.

6.4. As the risks posed by TERMIDOR are similar to those of the reference substance, I consider that applying the same suite of controls to TERMIDOR, with the variations proposed in paragraphs 4.3.1 to 4.3.4, will ensure adequate management of the adverse effects of TERMIDOR.

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 the hazardous substance, TERMIDOR, for use as an insecticide is thus approved with controls as detailed in Appendix A. I am also satisfied that, as the manufacture of TERMIDOR would not impose any additional risks over the importation of the substance, this approval should apply to both importation and manufacture of TERMIDOR.

Rob Forlong	Date: 7 July 2011
Chief Executive, EPA	

TERMIDOR	
HSNO Approval Code:	**HSR100550**

APPENDIX A

Controls applying to TERMIDOR

The controls imposed on TERMIDOR are as follows. 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 TERMIDOR – codes, regulations and variations

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

Code	Regulation	Description	Variation
T1	Regs 11-27	Limiting exposure to toxic substances through the setting of TELs	No TELs are set for this substance at this time.
T2	Regs 29, 30	Controlling exposure in places of work through the setting of WESs	DoL WES values are set for component B of TERMIDOR.
T4	Reg 7	Requirements for equipment used to handle substances	
T5	Reg 8	Requirements for protective clothing and equipment	
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
E1	Regs 32-45	Limiting exposure to toxic substances through the setting of EELs	No EELs are set for this substance at this time and the default EEL values are deleted.
E2	Regs 46-48	Restrictions on use of substances in application areas	As no EELs have been set for this substance, no application rate is required to be set under this control at this time.
E3	Reg 49	Controls relating to protection of terrestrial invertebrates eg beneficial insects	
E5	Regs 5(2), 6	Requirements for keeping records of use	
E6	Reg 7	Requirements for equipment used to handle substances	

E7	Reg 9	Approved handler/security requirements for certain ecotoxic substances	The following control is substituted for Regulation 9(1) of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001: *(1) The substance must be under the personal control of an approved handler when the substance is -* *(a) applied in a wide dispersive manner; or* *(b) used by a commercial contractor*

Hazardous Substances (Identification) Regulations 2001

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	
I3	Reg 9	Priority identifiers for ecotoxic substances	
I8	Reg 14	Priority identifiers for toxic substances	
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	
I17	Reg 26	Use of generic names	
I18	Reg 27	Requirements for using concentration ranges	
I19	Regs 29 – 31	Additional information requirements, including situations where substances are in multiple packaging	
I20	Reg 36(8)	Durability of information for class 6.1 substances	
I21	Regs 37 – 39, 47 – 50	General documentation requirements	
I23	Reg 41	Specific documentation requirements for ecotoxic substances	
I28	Reg 46	Specific documentation requirements for toxic substances	

I29	Regs 51, 52	Signage requirements	
I30	Reg 53	Advertising corrosive and toxic substances	

Hazardous Substances (Packaging) Regulations 2001

Code	Regulation	Description	Variation
P1	Regs 5,6,7(1), 8	General Packaging Requirements	
P3	Reg 9	Criteria that allow substances to be packaged to a standard not meeting Packing Group I, II or III criteria	
P13	Reg 19	Packaging requirements for toxic substances	
P15	Reg 21	Packaging requirements for ecotoxic substances	
PG3	Schedule 3	Packaging requirements equivalent to UN Packing Group III	
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, 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	
EM12	Regs 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.* 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 (Personal Qualifications) Regulations 2001

Code	Regulation	Description	Variation
AH1	4 -6	Approved Handler requirements (including test certificate and qualification requirements)	

Additional controls

Code	Regulation	Description
Water	77A	The substance shall not be applied onto or into water.

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

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 similar substances**. These applications are made and determined under section 28A(2)(a) 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 Methodology.

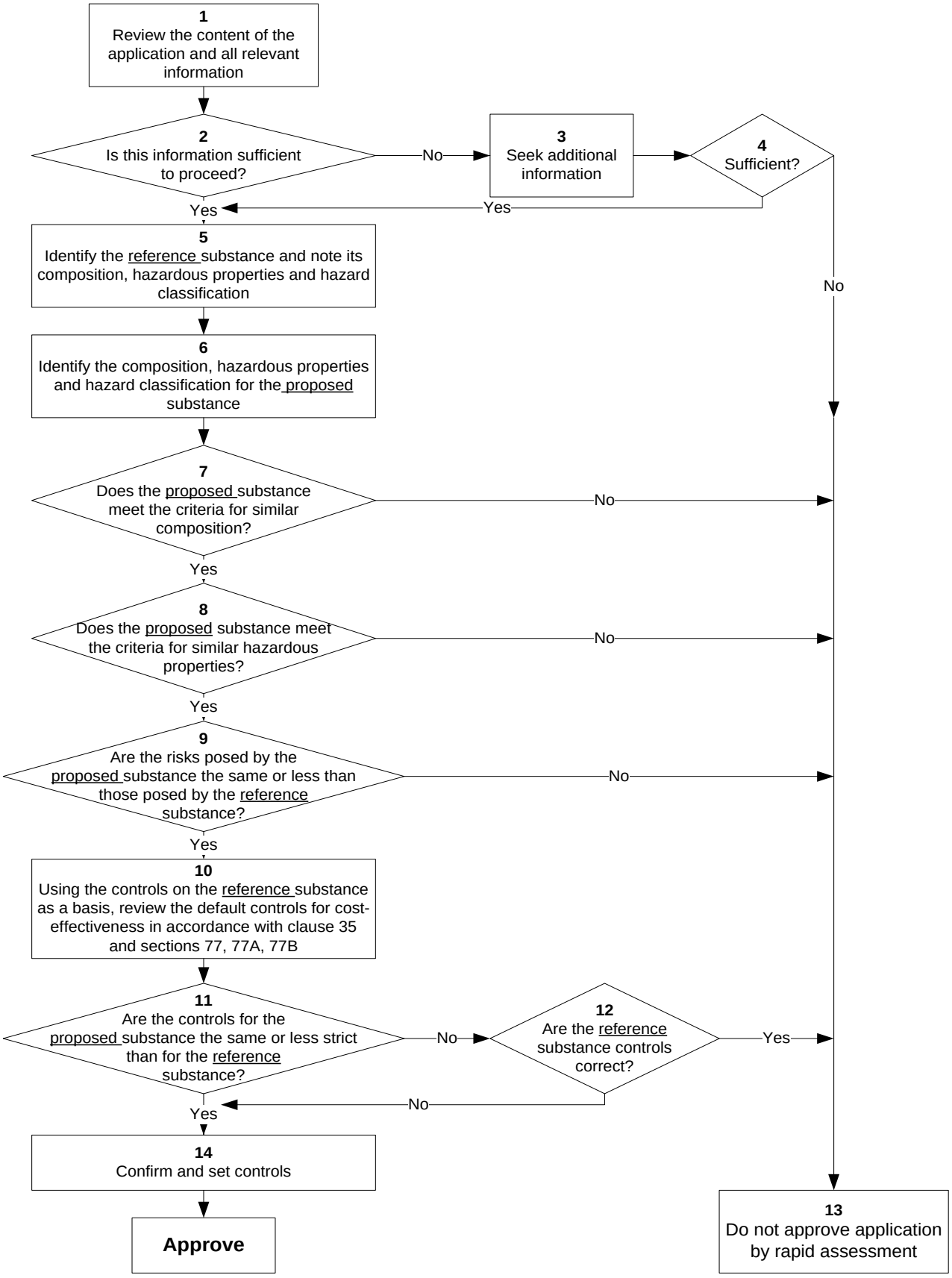
The decision path has two parts –

- **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 reference substance and note its composition, hazardous properties and hazard classification
6
Identify the composition, hazardous properties and hazard classification for the proposed substance
No
7
Does the proposed substance meet the criteria for similar composition?
No
Yes
8
Does the proposed substance meet the criteria for similar hazardous properties?
No
Yes
9
Are the risks posed by the proposed substance the same or less than those posed by the reference substance?
No
Yes
10
Using the controls on the reference substance as a basis, review the default controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A, 77B
11
Are the controls for the proposed substance the same or less strict than for the reference substance?
No
12
Are the reference substance controls correct?
Yes
No
Yes
14
Confirm and set controls
Approve
13
Do not approve application by rapid assessment

EXPLANATORY NOTES

Item 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 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 Authority in 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 reference substance, and note its composition, hazardous properties and hazard classification**

Identify and confirm the composition of the reference substance (i.e. the substance with similar composition and hazardous properties that has previously been approved either in an earlier Part V5HSNO approval, or through a deemed approval under the transfer process). The reference substance should have a similar life cycle and use to that of the proposed substance.

Confirm the hazard classifications for the reference substance[3].

Item 6: **Identify the composition, hazardous properties and hazard classification for the proposed substance**

Identify the composition of the proposed substance (ie. the substance that is the subject of the application), and establish the hazard classifications for the proposed substance.

Using this information, determine the default controls for the proposed substance using the regulations 'toolbox'.

Item 7: **Does the proposed substance meet the criteria for similar composition?**

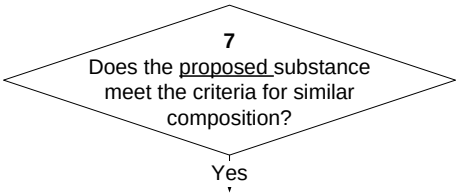
Consider whether the proposed substance meets the criteria for similar composition (to the reference substance), as detailed in the Interpretation and Explanation of Key Concepts Document (Policy Document "Rapid Assessment for Importation or Manufacture of Hazardous Substances for Release -

[3] If the hazard classification for the reference substance are found to be incorrect then the reference substance should be flagged as requiring reassessment or a section 67A amendment.

Criteria for Determining Eligibility"[4]).

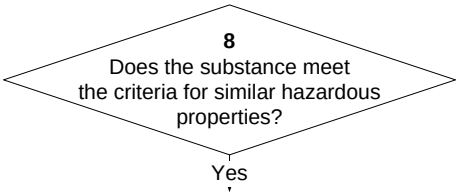
Item 8: **(if 'yes' from item 7) Does the substance meet the criteria for similar hazardous properties?**

Consider whether the proposed substance meets the criteria for similar hazardous properties (to the reference substance), as detailed in the Interpretation and Explanation of Key Concepts Document (Policy Document "Rapid Assessment for Importation or Manufacture of Hazardous Substances for Release - Criteria for Determining Eligibility" 2)



Item 9: **(if 'yes' from item 8) Are the risks posed by the proposed substance the same or less than those posed by the reference substance?**

Consider whether the risks posed by the proposed substance are the same as or less than those posed by the reference substance.



This requires that the risks associated with the proposed substance should be identified and assessed 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, 13, 22, 24, 25 and 29-32 of the Methodology.

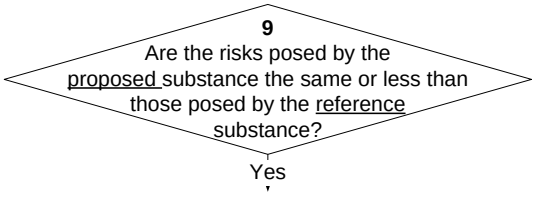
However, since the non-negligible risks for the reference substance are known, the risk identification and assessment in this case concentrates on identifying any additional non-negligible risks associated with the proposed substance, and any use patterns that mean that the risks associated with proposed substance may be greater than those associated with the reference substance.

If there are any additional non-negligible risks associated with the proposed 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.

Clause 25(b) requires the Authority to consider the values associated with the relationship of Maori culture and traditions with their ancestral lands and taonga. If Maori consultation was not undertaken for the reference substance, consider whether Maori consultation is required[5]. If Maori consultation is required then it must occur before the application is considered further for rapid assessment. If consultation indicates that there are no concerns then consideration under rapid assessment can proceed. If consultation indicates that there are non-negligible risks for Maori, then the proposed substance cannot be approved by rapid assessment and may instead be considered as a full assessment.

Item 10: **(if 'yes' from item 9) Using the controls on the reference substance as a basis, review the default controls for cost-effectiveness in accordance with clause 35 and section 77, 77A, 77B?**

This is effectively a clause 26 approval since all additional risks are negligible and all non-negligible



[4] http://www.ermanz.govt.nz/resources/publications/pdfs/ER-PR-03-20%2001-08.pdf
[5] See http://www.ermanz.govt.nz/resources/publications/policy/consultationwithmaori.html

risks have been considered at the time of the original approval of the reference substance.

Consider modifying the controls to be applied to the proposed substance in accordance with sections 77 and 77A of the Act to maximise the cost effectiveness of the controls. If the substance has toxic or ecotoxic properties, consider setting exposure limits under section 77B.

Item 11: **Are the controls for the proposed substance the same or less strict than for the reference substance?**

Compare the controls applied to the reference substance and the controls that have been specified for the proposed substance and consider whether the proposed controls are the same or less stringent than those applied to the reference substance.

Item 12: **(if 'no' from item 11) Are the reference substance controls correct?**

Check whether the controls on the reference substance are correct, or if there has been a technical error in setting the controls for the reference substance.

If the controls on the proposed substance are more stringent than the reference substance, and the controls on the reference substance are technically correct, then this indicates that the proposed substance is not sufficiently similar to the reference substance to be approved by rapid assessment.

If however the difference is due simply to a technical error (in which case the reference substance may require reassessment or consideration under section 67A), then the previous checks in items 7, 8 and 9 are adequate to allow approval by rapid assessment under the similar substance criteria.

Item 13: **(If 'no' from items 4,7, 8 or 9 or 'yes' from item 12) Do not approve application by 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 (reference).

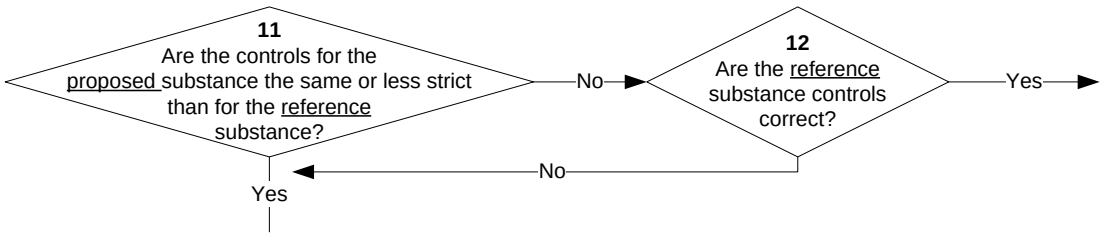
(from item 7) If the substance does not meet the criteria for similar composition then the application should not be approved by rapid assessment.

(from item 8) If the substance does not meet the criteria for similar properties then the application should not be approved by rapid assessment.

(from item 9) If the risks posed are greater than the risks posed by the reference substance then the application should not be approved by rapid assessment.

(from item 12) If the controls for the reference substance are stricter than for the proposed substance then the application should not be approved by rapid assessment.

Item 14:



(if 'yes' from item 11 or 'no' from item 12) Confirm and set controls

Controls have been considered earlier in the process (items 6, 11 and 12). However, the final step in the decision-making process confirms and sets the controls.

APPENDIX C

Confidential information