ENVIRONMENTAL RISK MANAGEMENT AUTHORITY DECISION

3 December 2009

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")
Applicant	Bayer New Zealand Limited
Date Application Received	20 July 2009
Submission Period	31 July 2009 – 11 September 2009
Consideration Date	13 November 2009
Considered by	A Committee of the Authority ("the Committee")
Purpose of the Application	To import or manufacture NTNCS2 as a veterinary medicine to control ectoparasites on sheep after external application.

1 Summary of decision

1.1 The import or manufacture of NTNCS2 for release is **approved with controls.**

1.2 In making this decision the Authority has applied the relevant sections of the Act and clauses of the Methodology as detailed in the decision path attached to this decision as Appendix 1.

1.3 The substance has been given the following unique identifier for the ERMA New Zealand Hazardous Substances Register:

NTNCS2

2 Application process

2.1 The application was formally received on 20 July 2009 and was publicly notified on 31 July 2009 with submissions closing on 11 September 2009.

2.1.1 No comments or submissions were received.

2.2 The Agency prepared an Evaluation and Review Report ("the E&R Report") to aid the Committee in its decision making process. The E&R Report consists of the Agency's review of the application and available data regarding the substance and/or its constituent components. In the E&R Report, the Agency proposed a suite of controls considered suitable to manage the risks associated with the release of NTNCS2 and assessed the potential risks the substance may pose to the environment, human health, Māori, society and community and to the market economy.

2.3 The Department of Labour, the New Zealand Food Safety Authority (Agricultural Compounds and Veterinary Medicines (ACVM) Group) and the applicant were given the opportunity to comment on the E&R Report and the controls proposed therein.

2.4 No external experts were used in the consideration of this application.

2.5 The following members of the Authority considered the application: Ms Helen Atkins (chair) and Dr Valerie Orchard.

2.6 The information available to the Committee comprised:

- the application; and
- the E&R Report including a confidential appendix.

3 Consideration

Purpose of the application

3.1 The purpose of the application is to seek approval for the import and manufacture of NTNCS2 for use as a veterinary medicine to control ectoparasites in sheep.

Hazard classification

3.2 The Agency has classified NTNCS2 as follows:

Hazardous Property	Classification
Flammability	3.1D
Skin Irritancy	6.3A
Eye Irritancy	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

Default controls

3.3 In the E&R Report, the Agency assigned default controls for NTNCS2 based on its hazardous properties as set out in the HSNO Regulations. The default controls were used as a reference for evaluation of the application in the E&R Report. The default controls are listed in Appendix 3 of the E&R Report and have not been reproduced here.

Identification of the potentially non-negligible risks, costs and benefits of the substance

3.4 In its evaluation of NTNCS2, the Agency identified potentially significant, and therefore non-negligible, risks, costs and benefits associated with the NTNCS2.

Potentially non-negligible risks

3.5 The Agency considers that the potentially non-negligible risks associated with NTNCS2 relate to the substance's hazardous properties as set out in paragraph 3.2 above. These risks arise during all phases of its lifecycle.

Potentially non-negligible costs

3.6 The costs and risks were assessed together in an integrated fashion in the Agency's assessment.

Potentially non-negligible benefits

3.7 The applicant claims that the import and manufacture of NTNCS2 will provide the following benefits:

- the availability of NTNCS2 will provide farmers with a cost-efficient environmentally-sustainable approach to controlling ectoparasites on sheep; and
- NTNCS2 is not an organophosphate and this may create some benefit for the environment by replacing some of the older organophosphate based products that are currently used for fly strike.

Assessment of the potentially non-negligible risks and costs of the substance

3.8 Taking into account the Agency's assessment of the potentially non-negligible risks and costs associated with NTNCS2 in New Zealand, the Committee considers that:

- the risks to human health and safety arising from the effects associated with NTNCS2 are negligible;
- the risks to the environment arising from the effects associated with NTNCS2 are negligible;
- significant adverse impacts on the social or economic environment with the controlled use of NTNCS2 are not anticipated;
- it is unlikely that NTNCS2 could have a significant impact on Māori culture or traditional relationships with ancestral lands, water, sites, wāhi tapu, valued flora and fauna or other taonga;
- there is no evidence to suggest that the controlled use of NTNCS2 will breach the principles of the Treaty of Waitangi.

4 Variations to default controls and setting of exposure limits

4.1 A number of variations to the default controls for NTNCS2 were proposed in the E&R Report. These variations and the setting of exposure limits and application rates are discussed below.

Setting of exposure limits and application rates

4.2 Control **T1** relates to the requirement to limit public exposure to toxic substances by the setting of Tolerable Exposure Limits (TELs), which are derived from Acceptable Daily Exposure (ADE) values. **No ADE, PDE or TEL values are set** for NTNCS2 at this time.

4.3 Control **T2** relates to the requirement to limit worker exposure to toxic substances by the setting of Workplace Exposure Standards (WESs). **WES values are set** for components D, E and F of NTNCS2.

4.4 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 EEL values are set** at this time for NTNCS2 and the default values are **deleted.**

4.5 Control **E2** relates to the requirement to set an application rate for a class 9 substance that is to be sprayed on an area of land (or air or water) and for which an EEL has been set. As the substance is not intended for application to an area of land and no EEL has been set, this control has been **deleted**.

Additions and modifications to controls

4.6 The Committee notes that the risk assessment has been undertaken on the basis that the substance is administered as a veterinary medicine. Accordingly, the Committee considers that the approval should be restricted to the use of the substance as a veterinary medicine. An additional control which adds this restriction is shown in Table 2.1 of Appendix 2.

4.7 The Committee 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 Committee 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. The revised controls are shown in Table 2.1 of Appendix 2.

4.8 Control **I16**[1] includes a requirement to identify certain toxic components on product labels. The Committee, consistent with the guidance provided by the Global Harmonised System (GHS), considers that regulation 25(e) should be varied such that the concentration cut-offs that apply to a component with a hazard classification of 6.5, 6.6, 6.7, 6.8 or 6.9, for the purpose of triggering this requirement, are as follows:

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

4.9 Control **E3** relates to the requirement to protect bees. As the substance is intended for use as a pour-on for animals, the Committee considers that the risks to bees are minimal. Thus, this control is **deleted**.

4.10 Controls **E7** and **AH1** relate to requirements for ecotoxic substances to be under the control of an approved handler. The Committee considers that these controls are not relevant for NTNCS2, given that the substance is not used in a wide dispersive manner and is consequently of a lesser risk to the environment. Thus, these controls are **deleted**.

4.11 Control **TR1** relates to the requirements for a substance to be tracked and is triggered for NTNCS2 only by virtue of its ecotoxicity. Consequently, the Committee considers that tracking the substance would be unduly onerous, as the key risks can be managed through other controls such as packaging, labelling and emergency management requirements. Thus, this control is **deleted**.

4.12 The Committee has combined the following controls as they relate to the same requirements:

4.12.1 Controls **F2** and **T7** which relate to restrictions on carriage of hazardous substances on passenger service vehicles.

4.12.2 Controls **T3** and **E5** which relate to requirements to keep records of use.

[1] Regulation 25 of the Hazardous Substances (Identification) Regulations 2001

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

4.12.3 Controls **T4** and **E6** which relate to requirements for equipment used to handle hazardous substances.

4.12.4 Controls **P13** and **P15** which relate to requirements for packaging hazardous substances.

4.12.5 Controls **D2**, **D4** and **D5** which relate to requirements for disposal of NTNCS2.

5 Overall evaluation of risks and costs

5.1 On the basis of the assessment of risks and costs and taking into account the controls imposed, including the additional controls, the Committee considers that NTNCS2 poses negligible risks and costs to the environment and to human health.

6 Review of controls for cost-effectiveness

6.1 The Committee considers that the proposed controls are the most cost-effective means of managing the identified potential risks and costs associated with this application.

6.2 The applicant was given an opportunity to comment on the proposed controls as set out in the E&R Report. The applicant made no comments on the proposed controls.

7 Comparison of risks, cost and benefits

7.1 As the Committee considers that the risks to the environment and human health are negligible with the controls in place, the Committee may approve the manufacture or import for release of NTNCS2 if it is evident that the benefits associated with the substances outweigh the costs.

7.2 As no costs not associated with risks have been identified, the Committee is satisfied that the potential benefits associated with the substance outweigh the costs.

8 Recommendations

8.1 The Committee recommends that, should inappropriate or accidental use, transport or disposal of NTNCS2 result in the contamination of waterways, the appropriate authorities, including the relevant iwi authorities in the region, should be notified. This action should include advising them of the contamination and the measures taken in response.

9 Environmental user charges

9.1 The Committee considers that the application of controls to NTNCS2 will provide an effective means of managing risks associated with this substance. At this time no consideration has been given to whether or not environmental charges should be applied to this substance as an alternative or additional means of achieving effective risk management.

10 Confirmation and setting of controls

10.1 The controls listed in Appendix 2 will apply to NTNCS2.

11 Decision

11.1 The Committee determines that:

11.1.1 NTNCS2 has the following hazard classifications:

Hazardous Property	Classification
Flammability	3.1D
Skin Irritancy	6.3A
Eye Irritancy	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

11.1.2 The positive effects of NTNCS2 outweigh the adverse effects.

11.1.3 The importation or manufacture and release of the hazardous substance, NTNCS2, is thus **approved** with controls as listed in Appendix 2.

Ms Helen Atkins Date: 3 December 2009

Chair

ERMA New Zealand Approval Code: HSR100103

Appendix 1: Decision Path

Context

This decision path describes the decision-making process for applications to **import or manufacture a hazardous substance**. These applications are made under section 28 of the HSNO Act, and determined under section 29 of the Act.

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 HSNO (Methodology) Order 1998 "(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 more 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.

Figure 1 FLOWCHART

Decision path for applications to import or manufacture a hazardous substance, application made under section 28 of the Act and determined under section 29.

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

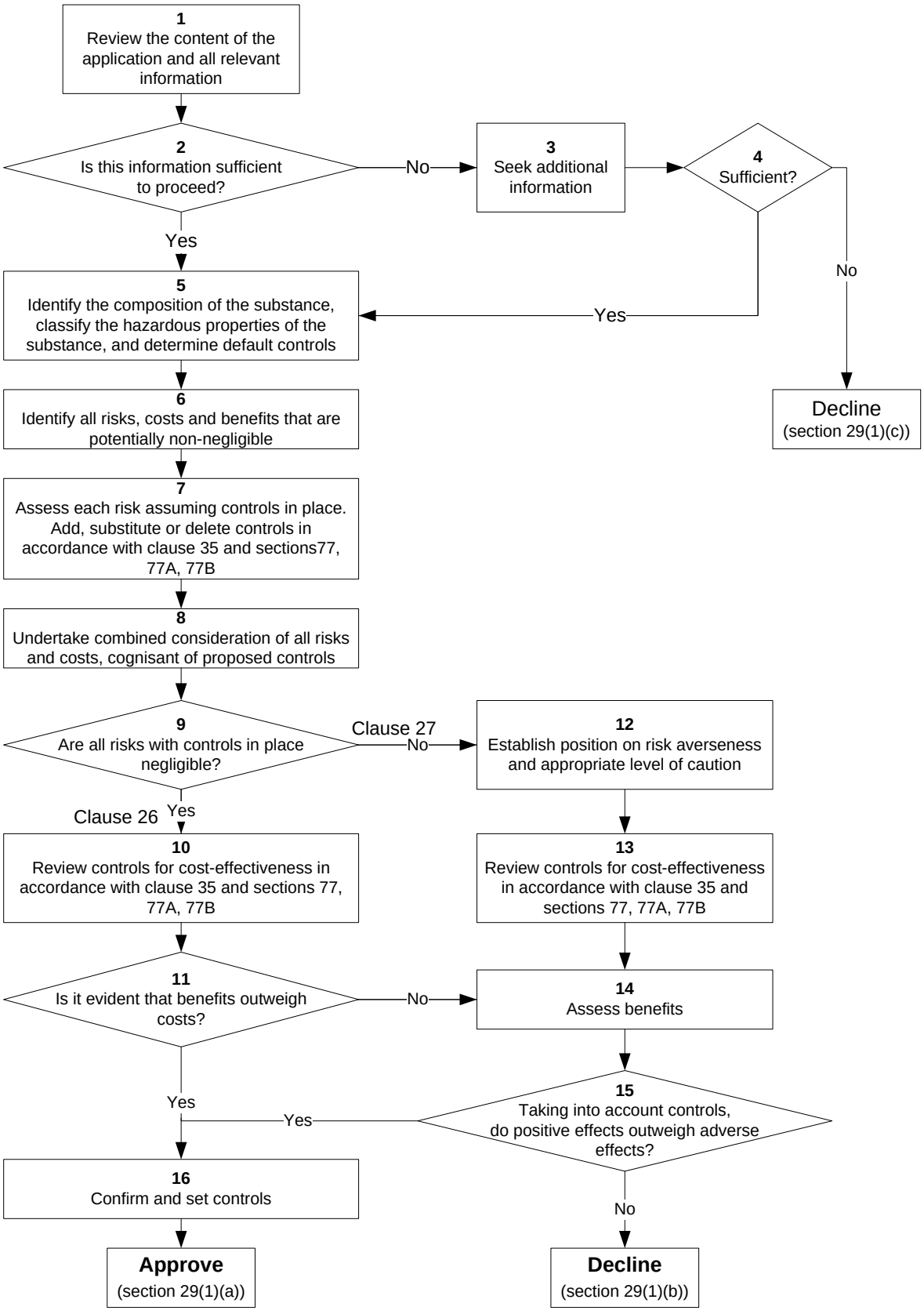


Figure 1 EXPLANATORY NOTES

Item 1: Review the content of the application and all relevant information

Review the application, the E&R Report, and information received from experts and that provided in submissions (where relevant) in terms of section 28(2) of the Act and clauses 8, 15, 16 and 20 of the Methodology.

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 Agency 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?

If the Authority is not satisfied that it has sufficient information for consideration, then the application must be declined under section 29(1)(c).

Item 5: (If 'yes' from item 2 or from item 4) Identify the composition of the substance, classify the hazardous properties, and determine default controls

Identify the composition of the substance, and establish the hazard classifications for the identified substance.

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

Item 6: Identify all risks, costs and benefits that are potentially non-negligible[3]

[3] Relevant effects are **marginal effects**, or the changes that will occur as a result of the substance being available. Financial costs associated with preparing and submitting an application are not marginal effects and are not effects of the substance(s) and are therefore not taken into account in weighing up adverse and positive effects. These latter types of costs are sometimes called 'sunk' costs since they are incurred whether or not the application is successful.

Costs and benefits are defined in the Methodology as the value of particular effects (clause 2). However, in most cases these 'values' are not certain and have a likelihood attached to them. Thus costs and risks are generally linked and may be addressed together. If not, they will be addressed separately. Examples of costs that might not be obviously linked to risks are direct financial costs that cannot be considered as 'sunk' costs (see footnote 1). Where such costs arise and they have a market economic effect they will be assessed in the same way as risks, but their likelihood of occurrence will be more certain (see also item 11).

Identification is a two step process that scopes the range of possible effects (risks, costs and benefits).

Step 1: Identify all possible risks and costs (adverse effects) and benefits (positive effects) associated with the approval of the substance(s), and based on the range of areas of impact described in clause 9 of the Methodology and sections 5 and 6 of the Act[4]. Consider the effects of the substance through its lifecycle (clause 11) and include the likely effects of the substance being unavailable (sections 29(1)(a)(iii) and 29(1)(b)(iii)).

Relevant costs and benefits are those that relate to New Zealand and those that would arise as a consequence of approving the application (clause 14).

Consider short term and long term effects.

Identify situations where risks and costs occur in one area of impact or affect one sector and benefits accrue to another area or sector; that is, situations where risks and costs do not have corresponding benefits.

Step 2: Document those risks, costs and benefits that can be readily concluded to be negligible[5], and eliminate them from further consideration.

Note that where there are costs that are not associated with risks some of them may be eliminated at this scoping stage on the basis that the financial cost represented is very small and there is no overall effect on the market economy.

Item 7: Assess each risk assuming controls in place. Add, substitute or delete controls in accordance with clause 35 and sections 77, 77A and 77B of the Act.

The assessment of potentially non-negligible risks and costs should be carried out in accordance with clauses 12, 13, 15, 22, 24, 25, and 29 to 32 of the Methodology. The assessment is carried out with the default controls in place.

[4] Effects on the natural environment, effects on human health and safety, effects on Maori culture and traditions, effects on society and community, effects on the market economy.

[5] Negligible effects are defined in the Annotated Methodology as "Risks which are of such little significance in terms of their likelihood and effect that they do not require active management and/or after the application of risk management can be justified by very small levels of benefits.

Assess each potentially non-negligible risk and cost estimating the magnitude of the effect if it should occur and the likelihood of it occurring. Where there are non-negligible financial costs that are not associated with risks then the probability of occurrence (likelihood) may be close to 1. Relevant information provided in submissions should be taken into account.

The distribution of risks and costs should be considered, including geographical distribution and distribution over groups in the community, as well as distribution over time. This information should be retained with the assessed level of risk/cost.

This assessment includes consideration of how cautious the Authority will be in the face of uncertainty (section 7). Where there is uncertainty, it may be necessary to estimate scenarios for lower and upper bounds for the adverse effect as a means of identifying the range of uncertainty (clause 32). It is also important to bear in mind the materiality of the uncertainty and how significant the uncertainty is for the decision (clause 29(a)).

Consider the Authority's approach to risk (clause 33 of the Methodology) or how risk averse the Authority should be in giving weight to the residual risk, where residual risk is the risk remaining after the imposition of controls.

See ERMA New Zealand report 'Approach to Risk' for further guidance[6].

Where it is clear that residual risks are non-negligible and where appropriate controls are available, add substitute or delete controls in accordance with sections 77 and 77A of the Act to reduce the residual risk to a tolerable level. If the substance has toxic or ecotoxic properties, consider setting exposure limits under section 77B. While clause 35 is relevant here, in terms of considering the costs and benefits of changing the controls, it has more prominence in items 10 and 13

If changes are made to the controls at this stage then the approach to uncertainty and the approach to risk must be revisited.

Item 8: Undertake combined consideration of all risks and costs, cognisant of proposed controls

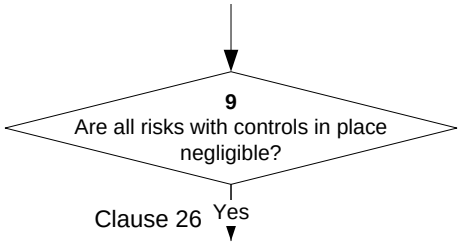
Once the risks and costs have been assessed individually, if appropriate consider all risks and costs together as a 'basket' of risks/costs. This may involve combining groups of risks and costs as indicated in clause 34(a) of the Methodology where this is feasible and appropriate, or using other techniques as indicated in clause 34(b). The purpose of this step is to consider the interactions between different effects and determine whether these may change the level of individual risks.

Item 9: Are all risks with controls in place negligible?

Looking at individual risks in the context of the 'basket' of risks, consider whether all of the residual risks are negligible.

[6] http://www.ermanz.govt.nz/resources/publications/pdfs/ER-OP-03-02.pdf

Item 10:



(from item 9 - if 'yes') Review controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A and 77B

Where all risks are negligible the decision must be made under clause 26 of the Methodology.

Consider the practicality and cost-effectiveness of the proposed individual controls and exposure limits (clause 35). Where relevant and appropriate, add, substitute or delete controls whilst taking into account the view of the applicant, and the cost-effectiveness of the full package of controls.

Item 11:

Is it evident that benefits outweigh costs?

Risks have already been determined to be negligible (item 9). In the unusual circumstance where there are non-negligible costs that are not associated with risks they have been assessed in item 7.

Costs are made up of two components: internal costs or those that accrue to the applicant, and external costs or those that accrue to the wider community.

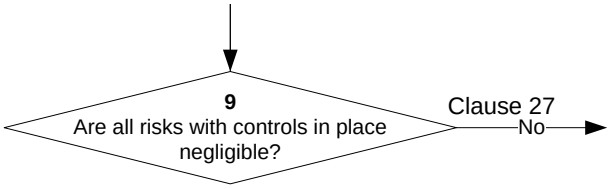
Consider whether there are any non-negligible external costs that are not associated with risks.

If there are no external non-negligible costs then external benefits outweigh external costs. The fact that the application has been submitted is deemed to demonstrate existence of internal or private net benefit, and therefore total benefits outweigh total costs[7]. As indicated above, where risks are deemed to be negligible, and the only identifiable costs resulting from approving an application are shown to accrue to the applicant, then a cost-benefit analysis will not be required. The act of an application being lodged will be deemed by the Authority to indicate that the applicant believes the benefits to be greater than the costs.

However, if this is not the case and there are external non-negligible costs then all benefits need to be assessed (via item 14).

[7]Technical guide 'risks, costs and benefits' page 6 - note that, where risks are negligible and the costs accrue only to the applicant, no explicit cost benefit analysis is required. In effect, the authority takes the act of making an application as evidence that the benefits outweigh the costs". See also protocol series 1 'general requirements for the identification and assessment of risks, costs, and benefits'.

Item 12:



(from item 9 - if 'no') Establish Authority's position on risk averseness and appropriate level of caution

Although 'risk averseness' (approach to risk, clause 33) is considered as a part of the assessment of individual risks, it is good practice to consolidate the view on this if several risks are non-negligible. This consolidation also applies to the consideration of the approach to uncertainty (section 7)

Item 13: **Review controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A and 77B**

This constitutes a decision made under clause 27 of the Methodology (taken in sequence from items 9 and 12).

Consider whether any of the non-negligible risks can be reduced by varying the controls in accordance with sections 77 and 77A of the Act, or whether there are available more cost-effective controls that achieve the same level of effectiveness (section 77A(4)(b) and clause 35(a)).

Where relevant and appropriate, add, substitute or delete controls whilst taking into account the views of the applicant (clause 35(b)), and making sure that the total benefits that result from doing so continue to outweigh the total risks and costs that result.

As for item 7, if the substance has toxic or ecotoxic properties, consider exposure limits under section 77B.

Item 14: **(if 'no' from item 11 or in sequence from item 13) Assess benefits**

Assess benefits or positive effects in terms of clause 13 of the Methodology.

Since benefits are not certain, they are assessed in the same way as risks. Thus the assessment involves estimating the magnitude of the effect if it should occur and the likelihood of it occurring. This assessment also includes consideration of the Authority's approach to uncertainty or how cautious the Authority will be in the face of uncertainty (section 7). Where there is uncertainty, it may be necessary to estimate scenarios for lower and upper bounds for the positive effect.

An understanding of the distributional implications of a proposal is an important part of any consideration of costs and benefits, and the distribution of benefits should be considered in the same way as for the distribution of risks and costs. The Authority will in particular look to identify those situations where the beneficiaries of an application are different from those who bear the costs[8]. This is important not only for reasons related to fairness but also in forming a view of just how robust any claim of an overall net benefit might be. It is much more difficult to sustain a claim of an overall net benefit if those who enjoy the benefits are

[8] This principle derives from Protocol Series 1, and is restated in the Technical Guide 'Risks, Costs and Benefits'.

different to those who will bear the costs. Thus where benefits accrue to one area or sector and risks and costs are borne by another area or sector then the Authority may choose to be more risk averse and to place a higher weight on the risks and costs.

As for risks and costs, the assessment is carried out with the default controls in place.

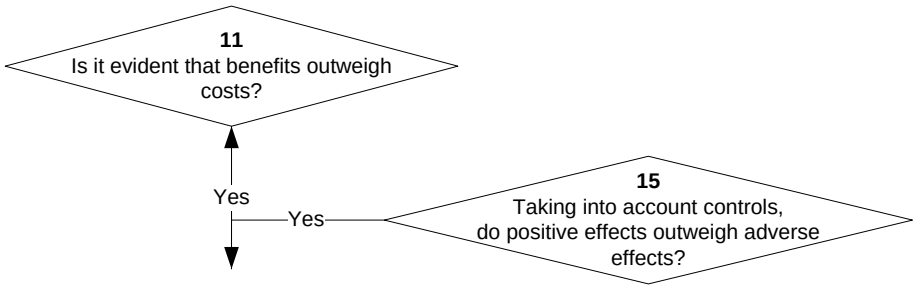
Item 15: **Taking into account controls, do positive effects outweigh adverse effects?**

In weighing up positive and adverse effects, consider clause 34 of the Methodology. Where possible combine groups of risks, costs and benefits or use other techniques such as dominant risks and ranking of risks. The weighing up process takes into account controls proposed in items 5, 7, 10 and/or 13.

Where this item is taken in sequence from items 12, 13 and 14 (i.e. risks are not negligible) it constitutes a decision made under clause 27 of the Methodology.

Where this item is taken in sequence from items 9, 10, 11 and 14 (i.e. risks are negligible, and there are external non-negligible costs) it constitutes a decision made under clause 26 of the Methodology.

Item 16:



(if 'yes' from items 11 or 15) Confirm and set controls

Controls have been considered at the earlier stages of the process (items 5, 7, 10 and/or 13). The final step in the decision-making process brings together all the proposed controls, and reviews them for overlaps, gaps and inconsistencies. Once these have been resolved the controls are confirmed.

Appendix 2: Controls for NTNCS2

Note: Please refer to the regulations for the requirements prescribed for each control and the modifications listed as set out in section 4 of this document.

Table A2.1: Controls for NTNCS2 – codes, regulations and variations.

Control Code[9]	Regulation[10]	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, E and F
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	Controls F2 and T7 are combined
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	

[9] 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.

[10] 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[9]</th><th>Regulation[10]</th><th>Topic</th><th>Variations</th></tr>
<tr><td></td><td></td><td>duties of persons in charge
Regulations 32 and 33 – Accessibility of information
Regulations 34, 35, 36(1)-(7) – Comprehensibility, Clarity and Durability of information</td><td></td></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[11]</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</td><td></td></tr>
</table>

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

Control Code[9]	Regulation[10]	Topic	Variations
		duties of suppliers Regulation 38 – Documentation duties of persons in charge of places of work Regulation 39 – General content requirements for documentation Regulation 47 – Information not included in approval Regulation 48 – Location and presentation requirements for documentation Regulation 49 – Documentation requirements for vehicles Regulation 50 – Documentation to be supplied on request	
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	

Control Code[9]	Regulation[10]	Topic	Variations
		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	
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.*

Control Code[9]	Regulation[10]	Topic	Variations
			(5) In this clause, pipework— *(a) means piping that—* *(i) is connected to a stationary container; and* *(ii) is used to transfer a hazardous substance into or out of the stationary container; and* *(b) includes a process pipeline or a transfer line.*
EM13	42	Level 3 emergency management requirements: signage	
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.			
NTNCS2 shall only be used as a veterinary medicine.			