Environmental Risk Management Authority Decision

Application for the reassessment of:
Water dispersible granule or wettable powder containing 750g/kg quintozene

Application number: ERMA200692

May 2011

Contents

1 Summary of decision

1.1. Following consideration of the application for reassessment, the Committee declines the further importation or manufacture of the substance, "water dispersible granule or wettable powder containing 750g/kg quintozene" (approval code HSR000742).

1.2. The decision to revoke the approval for the importation and manufacture of water dispersible granule or wettable powder containing 750g/kg quintozene comes into effect immediately. A prohibition on the use of the substance will come into effect 28 days after publication of the direction in the *New Zealand Gazette.*

1.3. Any existing stocks of the substance identified in paragraph 1.1 must be disposed of prior to a date three months from the publication of the direction in the *New Zealand Gazette*.

1.4. Stored water dispersible granule or wettable powder containing 750g/kg quintozene may be disposed of by:

(a) treating the substance using a method that changes the characteristics or composition of the substance so that the substance or any product of such treatment is no longer a hazardous substance; or

(b) exporting the substance from New Zealand as waste for environmentally sound disposal provided that such export complies with the relevant requirements of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal and the OECD Decision C(2001)107 on the Control of Transboundary Movement of Wastes Destined for Recovery Operations.

1.5. In paragraph 1.4(a), treating the substance does not include:

(a) application to or discharge to any environmental medium; or

(b) dilution of the substance with any other substance before discharge into the environment; or

(c) depositing the substance in a landfill or a sewage facility; or

(d) depositing the substance in an incinerator unless in doing so the substance is treated in accordance with subclause (1)(a).

2 Background

2.1 Water dispersible granule or wettable powder containing 750g/kg quintozene is used as a fungicide to treat non-grazed turf (recreational turf, specifically golf and bowling greens) and ornamental and vegetable seedlings (or soil) and flower bulbs, prior to or shortly after planting.

2.2 AMVAC (the United States based manufacturer) has confirmed that quintozene and the only product currently registered which matches approval HSR000742, Terraclor 75WP, is contaminated with "dioxin" (toxicologically significant polychlorinated dibenzo-para-dioxins and polychlorinated dibenzofurans).

3 The reassessment process

Grounds

3.1 The reassessment of water dispersible granule or wettable powder containing 750g/kg quintozene was initiated after notification by AMVAC to ERMA New Zealand of the dioxin contamination of the quintozene and the only product currently registered which matches the above substance approval, Terraclor 75WP.

3.2 On 28 September 2010 the Chief Executive of ERMA New Zealand submitted an application to establish whether there were sufficient grounds to justify a reassessment of water dispersible granule or wettable powder containing 750g/kg quintozene.

3.3 On 14 October 2010 the Authority decided that there were grounds for reassessment of water dispersible granule or wettable powder containing 750g/kg quintozene, based on section 62 of the Act.

The application

3.4 An application for the reassessment of water dispersible granule or wettable powder containing 750g/kg quintozene was prepared by the staff of ERMA New Zealand (the Agency) on behalf of the Chief Executive under section 63 of the Act.

3.5 The Agency sought information from a wide range of sources in the preparation of the application, mainly in respect of the New Zealand lifecycle and use of water dispersible granule or wettable powder containing 750g/kg quintozene and benefits associated with its use.

3.6 The Chief Executive formally submitted the application for reassessment on 31 January 2011.

3.7 Due to the toxicological significance of the contamination by dioxin the recommendation from the Chief Executive was to revoke the approval of water dispersible granule or wettable powder containing 750g/kg quintozene, allowing for a six month phase-out period for use of existing stocks.

Ministerial call in

3.8 The Minister for the Environment was advised of the application on 2 February 2011 (under section 53(4)(a)) and given the opportunity to "call-in" the application under section 68. This action was not initiated.

Notification of the application

3.9 In accordance with section 53, the application was publicly notified on the ERMA New Zealand website on 2 February 2011 and advertised in the New Zealand Herald, the Dominion Post, the Christchurch Press and the Otago Daily Times.

3.10 The application summary was also sent to government agencies which were identified as having a specific interest in the application and interested parties who had indicated that they wished to be notified of applications of this type.

Public submissions

3.11 Two submissions were received, both of which supported the proposal to revoke the approval for all uses of quintozene-containing substances. One submitter supported the proposed 6 month phase-out period to allow holders of stock to use the product up. The other submitter believed that there should be no permitted phase-out period for the use of quintozene-containing substances.

Appointment of the Committee

3.12 The following members of the Authority were appointed to consider the application (in accordance with a delegation under section 19(2)(b)): Dr Val Orchard and Dr Deborah Read (Chair).

Update Paper

3.13 The Agency prepared an update paper to provide the Committee and submitters with a review of the submissions received in response to the public notification of the reassessment application.

3.14 The submissions received did not alter the Agency's proposals.

3.15 The update paper was circulated on 13 April 2011.

Information available for consideration

3.16 The Committee had available for its consideration: the application, the written submissions and the update paper.

3.17 The Committee also received a report from Ngā Kaihautū Tikanga Taiao. This report supported the immediate revocation of the approval of the substance.

3.18 The Committee is satisfied that it had sufficient information, both relevant and appropriate to the risks, costs and benefits of the substance to enable it to consider the application (clause 8).

4 The decision-making framework

Legislative basis for the application

4.1 The application for the reassessment of water dispersible granule or wettable powder containing 750g/kg quintozene was lodged pursuant to section 63 of the Act and was deemed to be an application made under section 29. Section 29 requires the Authority to consider adverse and positive effects of a substance and to make a decision based on whether or not the positive effects of the substance outweigh the adverse effects of the substance.

4.2 In making this decision, the Committee has applied the relevant sections of the Act and followed the relevant provisions of the Methodology[1] as detailed in the decision path set out in **Appendix A** to this decision.

4.3 References made to a section in this document mean that section of the Act, references to a clause refers to the relevant clause in the Methodology.

Māori interests and concerns

4.4 As required by Sections 6(d) and 8 of the Act, the Committee's decision making takes into account the relationship of Māori and their culture and traditions with their ancestral lands, water and other taonga, as well as the principles of the Treaty of Waitangi (Tiriti ō Waitangi).

Principles of the Treaty of Waitangi

4.5 Section 8 of the Act requires the Authority, when considering applications, to take into account the principles of the Treaty of Waitangi. Of particular relevance to this application is the principle of active protection affirmed by the Court of Appeal in the Lands case (1987).

4.6 This principle refers to the Crown's obligation to take positive steps to ensure that Māori interests are protected, and to consider them in line with the interests guaranteed to Māori in Article II of the Treaty. Specifically the Court noted that "… the duty of the Crown is not merely passive but extends to active protection of Maori people in the use of their lands and waters to the fullest extent practicable".

Relationship of Maori to the environment

4.7 The Agency noted that quintozene and substances containing quintozene trigger a number of hazardous properties giving rise to cultural risk including the deterioration of the mauri of taonga flora and fauna species, the environment and the general health and well-being of individuals and the community.

4.8 At recent national hui and wānanga with Māori practitioners of Kaitiakitanga, participants have strongly believed that if a substance such as quintozene together with its dioxin contaminant does not have potentially significant or non-negligible benefits to Māori to enhance the mauri of taonga flora and fauna species, whānau[2], hapū[3] and iwi[4] and the overall relationship of Māori to the environment, then in accordance with the principles of Kaitiakitanga, Māori would be inclined to decline any continuation of such a substance and its use in Aotearoa.

[1] Hazardous Substances and New Organisms (Methodology) Order 1998

[2] Families
[3] Sub-tribe
[4] Communities

Ngā Kaihautū Tikanga Taiao report

4.9 Ngā Kaihautū Tikanga Taiao (Ngā Kaihautū), a committee established under Part 4A of the Act to provide advice to the Authority, provided a report recommending the approval for water dispersible granule or wettable powder containing 750 g/kg quintozene be revoked immediately.

4.10 Ngā Kaihautū based its recommendation on the conclusion that the adverse effects on people, the environment and native flora and fauna clearly outweigh the continued use of quintozene-based formulations which was found to have no significant level of benefit.

Ethical considerations

4.11 In preparing this decision, the Committee has taken into account the ERMA New Zealand ethics framework.

4.12 This framework was developed as a tool to assist in the ERMA New Zealand decision-making process in terms of:

- asking the 'right' questions in order to identify ethical issues that need to be considered; and
- using the answers to those questions to explore how ethical considerations should be addressed.

4.13 The foundation of the framework is a set of ethical principles, supported by procedural guidelines and standards. The two general principles embodied in the Act and the Methodology are:

- respect for the environment; and
- respect for people (including past, present and future generations).

4.14 Under these general principles lies a set of specific principles which includes concern for animal welfare, concern for co-operation, concern for cultural identity, concern for sustainability and concern for peoples' wellbeing.

4.15 The primary mechanisms for supporting the principles outlined in the framework and for evaluating whether or not they are upheld are the following procedural standards:

- honesty and integrity;
- transparency and openness;
- a sound methodology;
- community and expert consultation; and
- fair decision-making process.

4.16 In its consideration, the Committee has been mindful of the criteria in the procedural standards listed above, and has reviewed all of the information made available to it in the context of the principles and procedural standards. The Committee has been respectful of the views expressed by the applicant and submitters.

5 Hazard classifications

5.1 In the application for the reassessment of the substance "water dispersible granule or wettable powder containing 750g/kg quintozene", the Agency provided a review of the hazard classifications of the substance. Since the main reason for the reassessment is the availability of new information relating to the dioxin contamination of the product, the Agency did not thoroughly review the classification of quintozene.

5.2 The Committee agrees that the classifications of water dispersible granule or wettable powder containing 750 g/kg quintozene are unchanged as a result of this reassessment. The hazard classification of the substance is set out in Table 1.

Table 1: Summary of the classifications of quintozene 'water dispersible granule or wettable powder containing 750 g/kg quintozene'

Hazard Class	**water dispersible granule or wettable powder containing 750 g/kg quintozene** (Approval # HSR000742)
Eye irritancy	6.4A
Contact sensitisation	6.5B
Target organ systemic toxicity	6.9B
Aquatic ecotoxicity	9.1A*
Terrestrial invertebrate ecotoxicity	9.4A*

* These classifications were not reviewed

6 International obligations

6.1 The Stockholm Convention on Persistent Organic Pollutants (the Stockholm Convention), to which New Zealand is a signatory, is relevant to the on-going use of quintozene in New Zealand.

6.2 The Stockholm Convention aims to protect human health and the environment by banning the production and use of some of the most toxic chemicals known to humankind. The Convention became international law in May 2004, was ratified by New Zealand in September 2004, and entered into force for New Zealand on 23 December 2004. Persistent Organic Pollutants (POPs) are organic compounds that:

- do not break down readily in the environment;
- are capable of long-range transport, bioaccumulation in human and animal tissue (and can biomagnify in food chains);
- pose a risk of causing adverse effects to human health and the environment.

6.3 The 12 organochlorine (chlorine-containing) chemicals initially listed as POPs under the Stockholm Convention in 2004 include the following contaminants that are found in quintozene:

- **dioxins and furans** (polychlorinated dibenzo-para-dioxins or PCDDs, and polychlorinated dibenzofurans or PCDFs), and
- **hexachlorobenzene**.

6.4 Dioxins are released to the environment in very small amounts through a number of industrial and domestic activities, particularly the open burning of wastes. New Zealand is obligated under the convention to take measures to reduce, and where feasible ultimately eliminate, releases of dioxin. Although levels of dioxins in New Zealand foods (including our meats, dairy products and fish) are low and below the World Health Organization guidelines, it is prudent to further minimise our exposure to dioxins where practicable.

6.5 In 2009, additional compounds added to the coverage of the Stockholm Convention included:

- **pentachlorobenzene** (produced unintentionally and used as a chemical intermediate for the production of quintozene, and formerly in dyestuff carriers, as a fungicide and flame retardant; very toxic to aquatic organisms).

Conclusion

6.6 The Committee considers that the national commitment to the Stockholm Convention, to reduce dioxin emissions and to institute sound management of other POPs, such as HCB and pentachlorobenzene supports the conclusion that use of quintozene should be discontinued.

7 Alternatives

7.1 In the application for the reassessment of water dispersible granule or wettable powder containing 750g/kg quintozene, the Agency reviewed the potential alternatives to this substance for use on turf and for use on ornamentals and vegetables and concluded that alternatives exist for the uses of quintozene.

8 Controls

8.1 In the application, the Agency assessed the current controls assigned as part of the existing approval. These controls were based on the substance's hazardous properties as set out in the HSNO Regulations. These controls were used as a basis for evaluation in the application.

9 Comparison of risk, costs and benefits

9.1 The Committee is required under the Act, to consider whether or not the positive effects (benefits) of using water dispersible granule or wettable powder containing 750g/kg quintozene outweigh the adverse effects (risks and costs) of its use after taking account of all safety precautions that might be imposed and the likely effects of the substance being unavailable.

9.2 In the application, the Agency evaluated the risks, costs and benefits in association with the current controls and found that there are significant (non-negligible) risks

associated with the use of water dispersible granule or wettable powder containing 750g/kg quintozene in New Zealand which potentially outweighed the benefits.

Level of adverse effects

9.3 Taking the Agency's assessment into account, the Committee considers that:

- the adverse effects on human health both from the water dispersible granule or wettable powder containing 750g/kg quintozene and its dioxin contaminant are **non-negligible**; and

- the adverse effects on aquatic ecosystems, terrestrial vertebrates and invertebrates both from the water dispersible granule or wettable powder containing 750g/kg quintozene and its dioxin contaminant are **non-negligible**.

- the risks from the dioxin contaminant could not be fully assessed, but that the level of risk is potentially **non-negligible** due to the persistent and bioaccumulative properties of the dioxin contaminant.

Level of benefits

9.4 The Committee notes the assessment of benefits contained in the Agency's reassessment application, which indicated that use of water dispersible granule or wettable powder containing 750g/kg quintozene and its dioxin contaminant provides a **negligible** level of benefit.

Likely effects of the substance being unavailable

9.5 The Committee notes that alternative substances have been identified for all of the use scenarios. The risks associated with the substance becoming unavailable are considered to be **negligible**.

Conclusion

9.6 Upon reviewing all the information contained in the application and received from submitters, the Committee accepts the Agency's evaluation that the benefits do not outweigh the adverse effects for the use of water dispersible granule or wettable powder containing 750g/kg quintozene.

10 Decision

10.1 Pursuant to sections 63 and 29, the Committee has considered this application to reassess water dispersible granule or wettable powder containing 750g/kg quintozene.

10.2 Based on consideration and analysis of the information provided on the possible effects of water dispersible granule or wettable powder containing 750g/kg quintozene and its dioxin contaminant, in accordance with the Act and the Methodology, and taking into account the application of current controls, the Committee is satisfied that, for the reasons set out in this decision –

- the adverse effects (risks and costs) of water dispersible granule or wettable powder containing 750g/kg quintozene and its dioxin contaminant (Approval number HSR000742) outweigh the positive effects (benefits) associated with its import and use.

10.3 Accordingly, the Committee declines to approve the continued importation or manufacture of water dispersible granule or wettable powder containing 750g/kg quintozene (Approval number HSR000742).

10.4 The Committee will issue a direction prohibiting the use of the substance from a date 28 days from publication of the direction in the *New Zealand Gazette* and requiring the substance to be disposed of prior to the date 3 months from publication of the direction in the *New Zealand Gazette.*

10.5 The disposal is to be by:

(a) treating the substance using a method that changes the characteristics or composition of the substance so that the substance or any product of such treatment is no longer a hazardous substance; or
(b) exporting the substance from New Zealand as waste for environmentally sound disposal provided that such export complies with the relevant requirements of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal and the OECD Decision C(2001)107 on the Control of Transboundary Movement of Wastes Destined for Recovery Operations.

10.6 In paragraph 10.5(a), treating the substance does not include:

(a) application to or discharge to any environmental medium; or
(b) dilution of the substance with any other substance before discharge into the environment; or
(c) depositing the substance in a landfill or a sewage facility; or
(d) depositing the substance in an incinerator unless in doing so the substance is treated in accordance with subclause (1)(a).

10.7 In considering this application, the Committee is concerned that quintozene use has already created contaminated sites. Accordingly, the Committee requests that the Agency informs the Ministry for the Environment that certain types of sites such as bulb treatment areas and seed beds may be potentially contaminated with dioxin.

10.8 In accordance with clause 36(2)(b), the Committee records that, in reaching its decision, it has applied the balancing tests required under section 29 and clause 26 and has relied in particular on the following criteria in the Act and the Methodology:

- clause 8 – information to be relevant and appropriate;
- clause 9 – equivalent of sections 5, 6 and 8;
- clause 11 – characteristics of substance;
- clause 12 – evaluation of assessment of risks;
- clause 13 – evaluation of assessment of costs and benefits;
- clause 14 – costs and benefits accruing to New Zealand;
- clause 15 – regard to evidence in submissions;
- clause 16 – take account of scientific basis for scientific evidence or uncertainty;
- clause 21 – the decision accords with the requirements of the Act and regulations;
- clause 22 – the evaluation of risks, costs and benefits – relevant considerations;
- clause 24 – the use of recognised risk identification, assessment, evaluation and management techniques;
- clause 25 – the evaluation of risks and taking account of degree of uncertainty;
- clause 26 – evident that risks and costs are outweighed by benefits;
- clause 29 – determine the materiality and significance of any uncertainty;
- clause 30 – take account of the need for caution where uncertainty is not resolved;
- clause 32 – establish range of uncertainty;
- clause 33 – the extent to which 'risk characteristics' exist; and
- clause 34 – the aggregation and comparison of risks, costs and benefits.

19 May 2011

Dr Deborah Read — Date
Chair

Appendix A: Decision Pathway

Context

This decision path describes the decision-making process for reassessments under section 63 of the Act. These reassessments are deemed to be applications are 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 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 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 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 A1: Flowchart for decision

Decision path for applications to reassess a hazardous substance, application made under section 63 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.

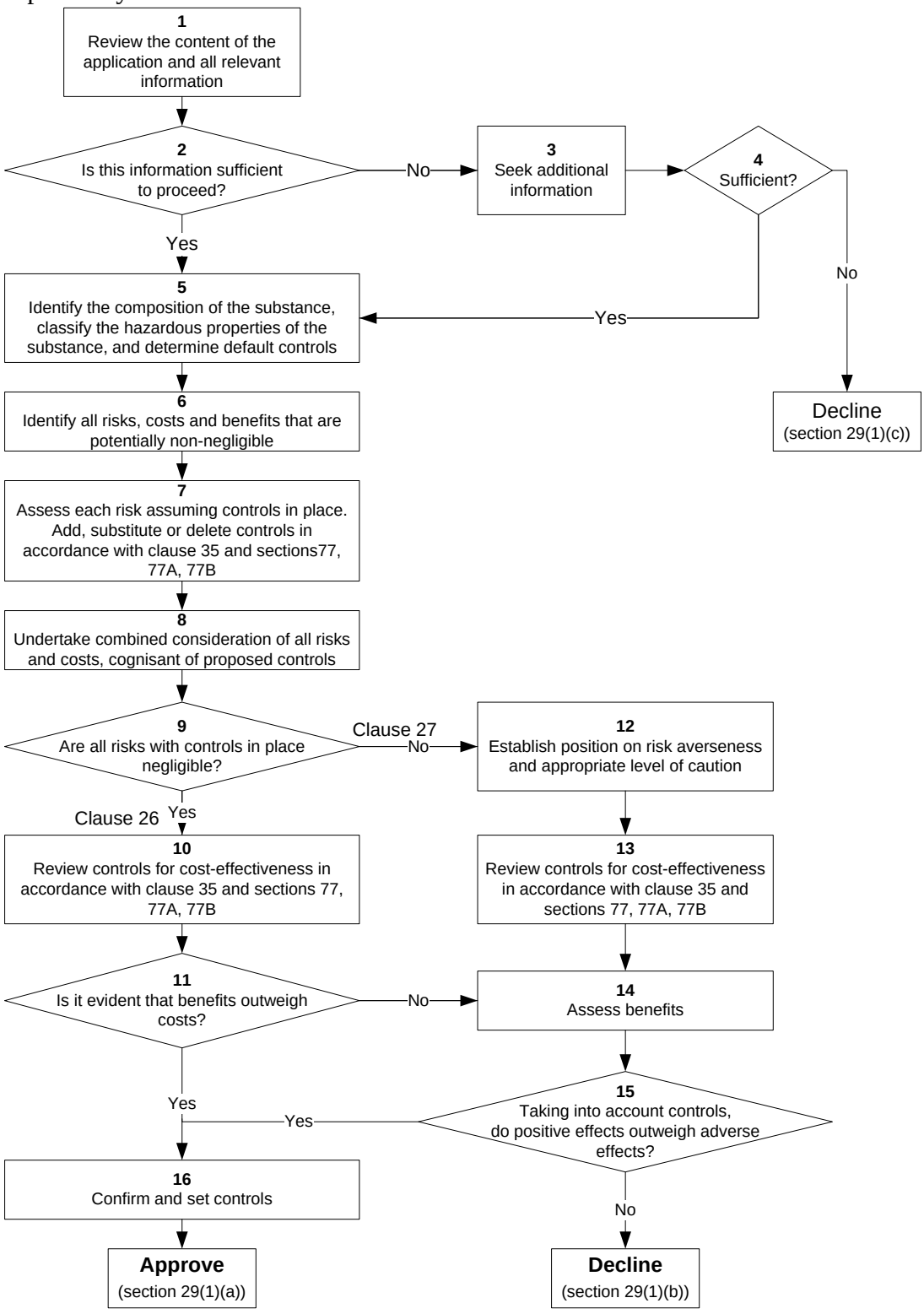


Figure A1: Explanatory notes

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

Review the application, the update paper, 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; i.e. 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**[5]

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

[5] 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.

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.[6.] 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[7], 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.

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

[6] Effects on the natural environment, effects on human health and safety, effects on Māori culture and traditions, effects on society and community, effects on the market economy.
[7] 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".

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[8].

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.

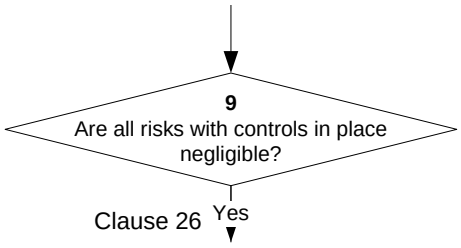
Item 8: **Undertake combined consideration of all risks and costs, cognisant of proposed controls**

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.

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.

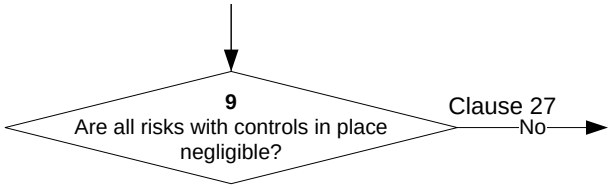
[8] www.ermanz.govt.nz/resources/publications/pdfs/ER-OP-03-02.pdf

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[9]. 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).

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

[9] 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".

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[10]. 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 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.

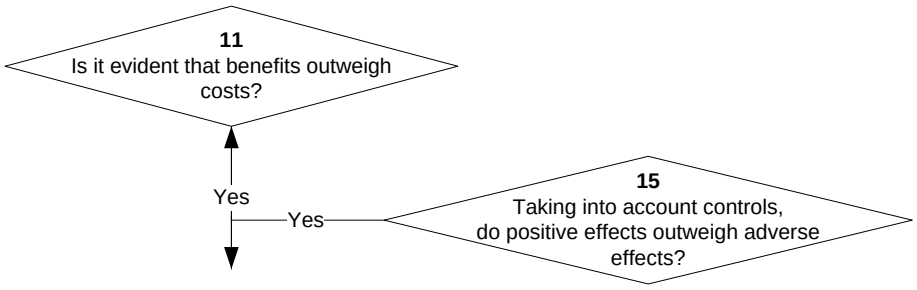
Item 15: **Taking into account controls, do positive effects outweigh adverse effects?**

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.

[10] This principle derives from Protocol Series 1, and is restated in the technical guide "Risks, Costs and Benefits".