

SUBMISSIONS SOUGHT ON PROPOSED REVISIONS TO HSNO (METHODOLOGY) ORDER 1998

Introduction

1. The Minister for the Environment has requested the Environmental Risk Management Authority (ERMA, the Authority), under section 9(2) of the Hazardous Substances and New Organisms (HSNO) Act 1996, to develop a proposed revised Methodology and to give the public the opportunity to make submissions on it.
2. Therefore this paper proposes revisions to the HSNO (Methodology) Order 1998 (the 1998 Order) and invites submissions on these proposals. The results of this consultation process will be reported back to the Minister.
3. As the Methodology is a technical document Annex A contains a proposed revised Methodology which demonstrates how these policy proposals might be given effect. The Annex should be read in conjunction with this paper. It is noted that the final drafting of a revised Methodology will be undertaken by the Parliamentary Counsel Office (PCO) and the Annex in no way commits PCO.
4. Reasons for revising the 1998 Order include:
 - enhancing robustness by reflecting ERMA's ten years of decision making experience under the current Methodology Order
 - removing redundancies, improving clarity and ensuring consistency
 - accommodating changes to the HSNO Act, including those arising from the HSNO Amendment Acts of 2003, 2004 and 2005
 - implementing a Cabinet Committee directive (refer CBC (08) 20/24) by providing for the Authority to have particular regard to information about segregation and traceability schemes which the Hazardous Substances and New Organisms (Genetically Modified Organisms - Information Requirements for Segregation and Tracing) Regulations 2008 prescribe must be supplied with applications for conditional release of genetically modified organisms.

Background Information

5. Section 9 of the HSNO Act requires ERMA to develop a proposed Methodology, to be established by Order-in-Council, that it shall consistently apply when making decisions under Part 5 of the Act. The Methodology is required to include an assessment of monetary and non-monetary costs and benefits, and the Authority cannot determine any application under Part 5 until the Order-in-Council has been made.
6. The current HSNO (Methodology) Order was established by Order-in-Council in 1998 (the 1998 Order). It describes the decision-making framework that the Authority applies in making decisions about whether or not to approve applications for new organisms and hazardous substances.
7. In mid 2001 the Authority commenced an internal review of the Methodology to evaluate experience with its operation. A number of changes were proposed and outlined in a discussion document which was released in March 2002. Based on the results of this consultation and the Authority's further consideration of the issues, a draft revised Methodology was completed and sent to the Minister in August 2002.

8. A number of activities then intervened, including the Government's response to the report of the Royal Commission on Genetic Modification, the recommendations of the Review of the Capability of ERMA relating to the Risk Management of New Organisms (the Nahkies report), and the introduction of the New Organisms and Other Matters (NOOM) Bill. Subsequent to the inclusion of material to address these matters a second round of consultation was conducted in 2003. Comment was sought only on those matters that had been changed since the first consultation round. The results of this consultation were reported to the Minister in 2004, however the revision of the Methodology was not progressed at that time and so the 1998 Order remained in place.
9. Because a significant period of time has passed since the earlier rounds of consultation, this paper includes a discussion of the proposed changes to the Methodology which were previously consulted on, as well as some new proposed changes.

Proposed changes

Regrouping and reordering

10. It is proposed that the clauses of the Methodology be regrouped and re-ordered so as to improve the flow of the document, and to ensure consistency in its use. For example it is proposed that a new section, headed "General Provisions", be created. This section will gather together in one place a number of existing clauses relating to the decision-making process and approaches that apply regardless of the application type.

Changes in terminology

11. Changes in the "definitions" section are proposed to reduce the use of multiple terms for the same concept. This duplication has occurred because the decision-making sections of the HSNO Act require the Authority to weigh "adverse" and "positive" (or "beneficial") effects, while section 9 of the Act requires that the Methodology includes an assessment of monetary and non-monetary costs and benefits – and hence the 1998 Order uses the terms "risks", "costs" and "benefits". This use of different terminology has created some difficulty for the Authority in writing decisions that are consistent with both the Methodology and the Act.
12. Therefore changes are proposed to define "cost" as a component of "adverse effect", and "benefit" as a component of "beneficial effect". This will enable a clearer understanding of the probabilistic nature of costs and benefits and avoid the complications resulting from the overlaps in the Act. The "assessment of effects" has also been defined in order to clarify that it is a process in which both the magnitude of the effect and the probability (likelihood) of occurrence of that level of effect are estimated.

Removal of duplication

13. A number of clauses in the 1998 Order largely repeat detail, including repeating matters to be taken into account which are already set out in the Act. It is therefore proposed to remove much of this repetition, however where matters in the Act are repeated they will have further “method” associated with them. As a result it is proposed that the following clauses in the 1998 Order be deleted:

- clause 13: no longer necessary because of the redefinition of risk;
- clause 15: redundant as it repeats material dealt with elsewhere in the Methodology;
- clauses 21, 30, and 31: redundant as they simply repeat the Act; and
- clause 28: redundant as covers same ground as other clauses in Methodology.

Information requirements

14. The clauses relating to information to be considered are spread throughout the 1998 Order and analysis has shown that they can be modified to improve clarity and consistency and remove redundancy. It is proposed that they be reworded and grouped together.

Addressing uncertainty

15. Existing clauses referring to uncertainty (clauses 29 to 32) are complex. The Nahkies report commented on this complexity and suggested that the approach to dealing with these issues be simplified. Greater clarity and ease of application will be achieved if these clauses are condensed and reworded. Clauses 17 and 18 are proposed in Annex A (replacing existing clause 32) to allow for meaningful implementation of section 7 of the Act.

Treaty of Waitangi (Te Tiriti o Waitangi)

16. There is a gap in the Methodology with respect to section 8 of the Act, requiring the Authority to take into account the principles of the Treaty of Waitangi (Te Tiriti o Waitangi). It is proposed that this be addressed using the wording set out in Clause 22 of Annex A.

The Authority’s approach to risk

17. As a result of submissions made during the previous consultation and in order to provide for clarity it is proposed that two new characteristics be added to the list of characteristics to be considered when evaluating adverse effects, which may lead to the Authority being more or less risk averse (clause 33 in Annex A).

18. These are:

- the distribution of the effect over time, geographical space, communities and ecological groupings; and
- the extent to which the magnitude of the effect is sufficiently serious to warrant particular consideration.

19. Adding these characteristics will ensure that there is explicit recognition of distributional effects, and of issues relating to low probability and high consequence effects.

Different types of application

20. A key objective of the earlier review of the 1998 Order was to make it more workable in practice. Experience has shown that the “one size fits all approach” inherent in the 1998 Order has proven to be too inflexible and overly cumbersome when dealing with the range of different approvals and risks encountered in decision-making. Decisions on rapid assessments, section 26 determinations and grounds for reassessment for example have their own decision-making criteria explicitly set out in the Act. This has been exacerbated with the new approvals introduced in the HSNO Amendment Act 2003. Applying the full assessment and evaluation requirements of the Methodology equally to all these decisions is an unnecessary and expensive process.
21. Therefore it is proposed that the revised Methodology distinguish between different types of applications, and in particular differentiate between those applications where the Act requires a full assessment of both adverse and beneficial effects, and those where the Act requires consideration of adverse effects only. In the case of full assessments the Methodology should be applied in its entirety.
22. For other applications when the assessment of adverse effects is negligible the provisions of that particular section are sufficient, and a full assessment including all Part 2 matters is not necessary. The proposed changes therefore provide for appropriate assessment of each type of application as defined in the Act, and this will also meet the recommendation in the Nahkies report for the Methodology to provide more flexibility in decision-making and a more condensed approach to the assessment of low risk applications.

Implementing the Hazardous Substances and New Organisms (Genetically Modified Organisms - Information Requirements for Segregation and Tracing) Regulations 2008

23. The Minister for the Environment has also requested that ERMA provide advice on a revised Methodology which incorporates a Cabinet Committee directive that the Authority would have particular regard to imposing prescribed information about segregation and traceability schemes as controls when considering an application to conditionally release a genetically modified (GM) organism, particularly any GM crop (refer CBC (08) 20/24).
24. The Hazardous Substances and New Organisms (Genetically Modified Organisms - Information Requirements for Segregation and Tracing) Regulations 2008 prescribe information to be provided by an applicant with an application for the conditional release of a genetically modified organism (GMO). This information relates to the measures the applicant intends to take to keep the GMO separate from other organisms and enable the GMO to be traced after it is released with controls.
25. Therefore it is proposed in clause 25(a) of Annex A that the Authority must have particular regard to this prescribed information when making a decision about the controls to be imposed on any conditional release approval.

Making a Submission

26. ERMA New Zealand welcomes comments or suggestions from the public in relation to these proposals. The closing date for submissions is **Monday 8 December 2008**.
27. In order for submissions to be acknowledged the name and contact details (postal or email address) of the person or organisation making the submission should be provided. If for privacy reasons you do not wish these details to be publicly released with your submission, you can include this information in a covering letter and leave it off the submission itself. The Authority may choose to release the submissions received, and once released submissions may be posted on the ERMA New Zealand website.
28. Submissions must be provided in writing and should be clearly marked as a "Submission on Methodology Revision". There will not be any opportunity to make oral submissions to the Authority.
29. Submissions may be:
 - a. emailed to methodology@ermanız.govt.nz;
 - b. faxed to (04) 914 0433;
 - c. or posted to:

Submission on Methodology Revision
ERMA New Zealand
PO Box 131
Wellington
30. Contact for any enquiries:

Libby Harrison - Acting General Manager Strategy & Analysis
Libby.Harrison@ermanız.govt.nz
(04) 918 4828
31. Copies of the HSNO (Methodology) Order 1998 and the HSNO Act 1996 can be downloaded at www.legislation.govt.nz

Annex A Proposed Revised Methodology

REVISED DECISION-MAKING METHODOLOGY PROPOSED BY THE ENVIRONMENTAL RISK MANAGEMENT AUTHORITY

This proposed Methodology contains explanatory notes which are not a part of the proposed Methodology itself but are intended to assist in explaining what is proposed.

DEFINITIONS

In this order, unless the context otherwise requires, -

“**Act**” means the Hazardous Substances and New Organisms Act 1996 and subsequent amendments.

“**Application**” means an application lodged under Part 5 of the Act.

“**Identification of effects**” means a broad-based, systematic process of identifying effects by considering possible sources of effect, exposure pathways, and potential impacts. Identification is a preliminary step intended to list effects that might need to be assessed.

Explanatory note: The Act defines “Effect” as including any potential or probable effect, any positive or adverse effect, any temporary or permanent effect, any past, present, or future effects, any acute or chronic effect, and any cumulative effect which arises over time or in combination with other effects.

“**Assessment of effects**” is the process of estimating, either quantitatively or qualitatively, the magnitude and the likelihood of occurrence of beneficial or adverse effects.

Explanatory note: The assessment of effects results in a measure of a level of effect that has two components (magnitude and likelihood). The level of effect is therefore equivalent to the level of risk. The level of risk is a combination of the magnitude of an effect and the likelihood of that particular magnitude of effect occurring. As risk is commonly thought of as having a negative outcome the term ‘effect’ is used.

“**Adverse effect**” is an effect that is judged to have an adverse outcome.

“**Beneficial effect**” is an effect that is judged to have a beneficial outcome. The terms ‘beneficial effect’ and ‘positive effect’ are equivalent.

“**Benefit**” is equivalent in meaning to “beneficial effect”.

“**Cost**” is equivalent in meaning to “adverse effect”.

Explanatory note: Changes are proposed in the “definitions” section to reduce the use of multiple terms for the same concept. This has occurred because the decision-making sections of the HSNO Act use the terms “adverse effect”, “beneficial effect”, and “positive effect”, while section 9 of the Act requires that the Methodology includes an assessment of monetary and non-monetary costs and benefits.

INTRODUCTION

1. The Authority, or any Committee of the Authority, or any person to whom the Authority delegates decision-making powers, must consistently apply this Methodology when making decisions under Part 5 of the Act.

Explanatory note: This means that the clauses of the Methodology that are relevant to a decision must be applied in a consistent way for similar decisions. It directs the Authority or any person to whom the Authority delegates decision-making powers both to adopt a consistent process for all decision making and to apply the process in a consistent way to similar cases, but does not detract from case-by-case decision making if the circumstances are different.

2.
 - (a) The Authority may, from time to time, issue guidance material consistent with the Act and this Methodology further explaining the application of the provisions of the Act and the clauses of this Methodology.
 - (b) Material issued under this clause does not form part of the Methodology.

Explanatory note: Examples of such material would include the Protocols and the User Guides.

ROLES AND RESPONSIBILITIES

The Authority

3. In relation to applications and decision-making, the Authority must
 - (a) as far as is practicable ensure that applicants are informed of the provisions of the Act and this Methodology;
 - (b) arrange any statutory processes, including the notification of applications and the holding of hearings;
 - (c) review and evaluate the information contained in applications and submissions; and
 - (d) arrange for the provision of additional information as required, so that the Authority may be adequately informed for the purposes of decision-making.

Explanatory note: This clause instructs the Authority, however in practice the Authority will usually arrange for these activities to be carried out by the Chief Executive, the staff of the Authority, advisory committees, or external experts.

The Chief Executive and Staff of the Authority

4. The Authority will ensure that the Chief Executive and the staff of the Authority provide administrative support and professional advice, so that the Authority is adequately informed in its decision-making role.
5. The Authority will prohibit the Chief Executive from making personal submissions on applications, and will direct the Chief Executive to prohibit staff from making personal submissions on applications.

6. The Authority may direct the Chief Executive to:

- (a) facilitate consultation and pre-hearing meetings with and between applicants and persons who make submissions, and assist in the early clarification of areas of dispute; and
- (b) assist applicants in deciding on the extent of relevant and appropriate information to be included in any application, provided that no advice given by the staff of the Authority shall prevent the Authority from seeking further information in accordance with sections 52 and 58 of the Act.

Advisory Committees

7. The Authority may also appoint advisory committees to advise it on any matter relating to its decision-making responsibilities.

GENERAL PROVISIONS FOR ALL APPLICATION TYPES

Public Summary

8. Where applications are required to be publicly notified, the Authority must:

- (a) require the applicant to provide a summary of the application, including the purpose of the application and the potentially significant effects;
- (b) revise the summary provided by the applicant if the Authority considers it necessary to do so; and
- (c) if the applicant does not withdraw the application, make the summary publicly available.

Explanatory note: The summary should exclude any information to which sections 55(3) to 55(4B) of the Act applies and any information withheld in accordance with the Official Information Act 1982. If the applicant and the Authority cannot agree on the content of the summary, the applicant may withdraw the application (including all the information provided by the applicant). This summary is separate from and does not constitute the notice required for public notification.

Information to be Considered

9. When considering an application the Authority must:

- (a) consider any relevant information about the effects of the substance or organism; and
- (b) take into account the basis or authority for the information and the level of uncertainty associated with that information.

Explanatory note: When considering information the Authority will consider any relevant information (including information about cultural, economic, environmental, ethical, health, international or spiritual effects), and will take into account the reliability and authority of the information, including the source of the information, and the methodologies used to derive and/or analyse the information.

10. The Authority must take into account information that it obtains from the following sources, amongst others:

- (a) the applicant, including the application and any additional information provided under sections 52 or 58 of the Act;
- (b) submissions received from any person under section 54 of the Act or from departments or local authorities or Crown entities under section 58 of the Act; including advice on any existing regulatory requirements relating to the application;
- (c) advice or reports prepared by the Chief Executive, any advisory committee appointed by the Authority, or any expert appointed by the Authority or the Chief Executive; and
- (d) any other information the Authority considers necessary.

11. The information used by the Authority when considering an application must be relevant to the nature and size of the effects associated with the substance or organism taking into account the type and purpose of the application and the characteristics of the substance or organism.

12. The Authority may, subject to section 55(4) to 55(4B) of the Act, take into account information produced for or by other agencies in New Zealand and overseas (including standards, approvals, registrations, assessments, and other material) after having regard to the quality of the information and to the extent to which it relates to New Zealand circumstances and the requirements of the Act.

Experts

13. The Authority or the Chief Executive may appoint external experts to provide advice on an application.

Explanatory note: Where an application contains confidential information, the external expert will be required to sign a binding confidentiality agreement. The applicant will be informed of the intention of the Authority or the Chief Executive to appoint an expert, and the identity of the intended expert, before the release of any confidential information contained in the application to that expert. The Authority or the Chief Executive will take into account any comments by the applicant before proceeding to appoint that expert and release information.

14. The applicant will be given the opportunity to withdraw the application prior to the release of information to an expert.

15. Any expert appointed under clause 13 may be required by the Authority to appear at a hearing of the application concerned, to present any advice provided by the expert, and be questioned on that advice.

Best Practice Methods

16. The Authority must use current best practice methods for identifying, assessing and weighing up effects, and for setting controls.

Explanatory note: From time to time the Authority may publish guidance material describing these best practice methods.

Uncertainty

17. Where there is significant uncertainty in information relevant to the consideration of an application, the Authority must take steps to clarify the extent of the uncertainty, and where necessary to reduce the uncertainty.

18. Where, after taking any steps under clause 17 to reduce uncertainty, the Authority considers there to be residual uncertainty that would impact on the decision, the Authority must take into account the need for caution and consider the significance of this uncertainty in making a decision.

Effects to be considered

19. Where the provisions of Part 5 of the Act require effects to be assessed or weighed, the effects considered must include, amongst other things:

- (a) those associated with Part 2 of the Act; and
- (b) those associated with the specific sections in Part 5 of the Act that relate to the type of application being considered.

Explanatory note: This clause makes it clear that the Authority will consider effects and matters arising from both the principles in section 5 and the matters in section 6, in conjunction with the effects and matters that arise from the specific provisions in the Act dealing with the application.

20. In taking into account the principles and matters in Part 2 of the Act, those principles and matters that relate to both beneficial and adverse effects must be considered.

21. The effects to be considered are those that relate to New Zealand, to New Zealand's interests, and to New Zealand's international obligations.

Application of the Principles of the Treaty of Waitangi (Te Tiriti o Waitangi)

22. In accordance with section 8 of the Act, in making decisions under Part 5 of the Act the Authority must take into account the principles of the Treaty of Waitangi (Te Tiriti o Waitangi).

Explanatory Note: In applying this clause the Authority will be guided by judicial interpretations of the principles of the Treaty of Waitangi (Te Tiriti o Waitangi), currently including the need to:

- (a) establish relationships which are in the nature of partnership having regard to the other requirements of the Act;*
- (b) act reasonably, honourably and in good faith;*
- (c) make informed decisions on matters affecting the interests of Māori;*
- (d) actively protect Māori interests as far as is reasonably practicable; and*
- (e) avoid actions which would prevent the redress of Treaty claims.*

It is acknowledged that the interpretation of the principles may change over time and the wording provides for this possibility.

Application of Controls

23. When making a decision under Part 5 of the Act for the containment of a new organism or a hazardous substance the Authority must:

- (a) consider the effectiveness of the types of controls provided for under the Act and, where relevant, any further controls required to achieve the level of risk management required by the Authority, taking into account the likely effectiveness of the implementation of the controls; and
- (b) before controls are finalised, invite the applicant to comment on the cost-effective application of controls to achieve the level of risk management required by the Authority.

Explanatory note: The level of risk management required by the Authority is that required to reduce the level of risk to an acceptable level. The level of acceptable risk is established by first assessing, and then where relevant weighing up, adverse and beneficial effects.

24. When making a decision under Part 5 of the Act which involves the exercise of the discretion under sections 77 and 77A of the Act for the management of hazardous substances, the Authority must:

- (a) consider the implications of making the controls more or less stringent, including the likely effectiveness of the implementation of possible controls; and
- (b) before controls are finalised, invite the applicant to comment on the cost-effective application of controls to achieve the level of risk management required by the Authority.

25. When making a decision under Part 5 which involves the exercise of discretion under sections 38D and 38K the Authority must:

- (a) have particular regard to any prescribed information provided by the applicant;
- (b) consider the effectiveness of the types of controls listed in sections 38D(1) and 38K(1) of the Act and, where relevant, any further controls required to achieve the level of risk management required by the Authority, taking into account the likely effectiveness of the implementation of the controls;
- (c) before controls are finalised, invite the applicant to comment on the cost-effective application of controls to achieve the level of risk management required by the Authority.

Explanatory note: Clause 25(a) reflects the Cabinet Committee directive that the Authority would have particular regard to imposing prescribed information about segregation and traceability schemes as controls when considering an application to conditionally release a GMO, particularly any GM crop (refer CBC (08) 20/24).

Presentation of Decisions

26. The Authority must publicly notify its decisions.

27. When giving its decision to the applicant and to any persons who have made submissions, the Authority must:

- (a) state whether the application is approved with or without controls, or declined; and
- (b) where the application relates to a hazardous substance and is approved, state the classification of the substance and:
 - (i) whether the controls specified in the regulations for that classification have been attached to the substance(s) or;
 - (ii) whether those controls have been varied by the Authority under sections 77 or 77A of the Act and attached to the substance(s), and if so state the reasons.
- (c) where the application is approved and relates to a new organism or hazardous substance in containment, state the controls attached to that approval in accordance with the Third Schedule to the Act;
- (d) where the application is approved and relates to the conditional release of a new organism, state the controls attached to that approval; and where the application was originally made under section 34 state the reasons for considering it as a conditional release; and
- (e) state the reasons for the Authority's decision, including the criteria in the Act relied on by the Authority in reaching its decision.

CONSIDERATION OF DIFFERENT TYPES OF APPLICATIONS

Full Assessments

28. The term “full assessment” refers to decisions made under sections 29, 38, 38C and 45 of the Act.

Explanatory note: Full assessments are decisions where the Authority must consider both the adverse and beneficial effects associated with the substance or the organism.

Identification of effects

29. The Authority must identify the adverse and beneficial effects associated with the substance or organism that is the subject of an application, and from those determine the effects that it considers are not negligible.

Explanatory note: A negligible risk is one where the level of risk, measured as a combination of the magnitude and likelihood of that magnitude occurring, is such that the risk (with controls in place where relevant) does not require active risk management. A negligible level of risk does not mean that the magnitude of the risk would be negligible if it occurred.

Assessment and weighing of effects

30. When assessing and weighing effects, both the magnitude of the effects and the likelihood of occurrence must be considered.

31. The Authority must assess those effects that it has determined are not negligible. The Authority must include in every such assessment analysis of:

- (a) the source and nature of the effects, the exposure pathways and the areas of impact of the effects arising;
- (b) the magnitude of the effects and their likelihood of occurrence, and the expression of the effects in either monetary or non-monetary terms; and
- (c) the distribution of effects over time, geographical space, communities and ecological groupings.

32. When assessing adverse effects associated with the substance or organism, the Authority must also consider the scope for reducing adverse effects by the application of controls where relevant, or by providing for the containment of the organism.

33. When assessing and weighing effects the Authority must take account of the following characteristics of each adverse effect and consider the extent to which they will lead the Authority to be more or less “risk averse” -

- (a) the extent to which exposure to the effect is involuntary;
- (b) the extent to which the effect will persist over time;
- (c) the extent to which the effect is subject to uncontrollable spread and is likely to extend its impact beyond the immediate location of incidence;
- (d) the extent to which the effect is irreversible;
- (e) the extent to which the effect is not known or understood by the general public and there is little experience or understanding of possible measures for managing the potential adverse effect;
- (f) the distribution of the effect over time, geographical space, communities and ecological groupings; and
- (g) the extent to which the magnitude of the effect is sufficiently serious to warrant particular consideration.

Explanatory note: This clause sets out the factors that give the Authority the flexibility to determine the particular weights to be applied in deciding how risk averse it will be in making decisions about particular risks.

34. When assessing and weighing effects, the Authority must, as far as possible, combine groups of effects using common units of measurement, including monetary valuations where applicable, and use other techniques (such as identification of dominant risks and the ranking of risks) where common units are not possible.

35. For applications where:

- (a) the Authority determines that the adverse effects are negligible, after taking into account the measures available (if any) for the management of adverse effects, and;
- (b) the Authority is satisfied beneficial effects exist which would outweigh the adverse effects;

a full assessment of beneficial effects is not required in order for the Authority to approve the substance or organism.

36. For applications for hazardous substances considered under section 29 where the Authority determines that the adverse effects are not negligible, after taking into account the measures (if any) for the management of those effects, the Authority will consider a full assessment of the beneficial effects associated with the substance (including relevant monetary and non-monetary benefits) before considering whether the beneficial effects of the substance outweigh the adverse effects.

37. For applications for new organisms considered under sections 38, 38C and 45 where the Authority determines that the adverse effects are not negligible, after taking into account the measures (if any) for the management of those effects (including where relevant the containment of the organism), the Authority will undertake a full assessment of the beneficial effects associated with the organism (including relevant monetary and non-monetary benefits) before considering whether the beneficial effects of the organism outweigh the adverse effects.

Other Part 5 decisions

Explanatory note: This part of the Methodology indicates the way in which certain assessments of effects will incorporate the elements of a full assessment, including the provisions of Part 2 of the Act. It specifies that where an assessment of adverse effects is determined to be negligible the provisions of that particular section will be sufficient for the purposes of making a decision, without having to perform a full assessment.

Rapid Assessments

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| <p>38. When considering an application for the rapid assessment of adverse effects under sections 35, 38I, 42, 42A or 42B of the Act for a new organism or section 28A of the Act for a hazardous substance:</p> <ul style="list-style-type: none">(a) consideration by the Authority of whether the application meets the criteria set out in the relevant sections will be sufficient for the purposes of making a decision;(b) where, after taking into account the approach to risk in clause 33 of this Methodology the Authority considers that the set criteria do not satisfactorily deal with all of the adverse effects that may impact on the matters set out in Part 2 of the Act, the Authority must carry out a full assessment of effects to determine whether they are negligible or not. |
| <p>39. If the criteria set down in the Act for rapid assessment are not met or if it is considered that an application involves adverse effects that are not negligible, then the Authority</p> <ul style="list-style-type: none">(a) may in the case of applications under sections 35, 42, 42A, 42B or 28A of the Act and if the applicant agrees, reconsider the application as a full assessment. In this event the rapid assessment application is “not approved” rather than declined,(b) must in the case of an application under section 38I, proceed to consider the application as a full assessment. |

Section 26 Determinations

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| <p>40. When considering an application under section 26, of the Act:</p> <ul style="list-style-type: none">(a) the Authority must consider the information set out under section 26(2)(a)-(c) in determining the application; and(b) the consideration of this information will be sufficient for the purposes of making a decision. |
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Grounds for Reassessment under Section 62

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| <p>41. Requests to the Authority to determine whether there are grounds for reassessing any hazardous substances, or new organisms in containment, or new organisms released with controls, must be considered in terms of the provisions of section 62(2) of the Act and any other grounds that the Authority considers to be relevant.</p> |
| <p>42. Where the Authority considers the reassessment of a hazardous substance approval under section 63A the Authority will treat the reassessment application as if it were an application under section 28 and must:</p> <ul style="list-style-type: none">(a) decide whether to consider the application under section 28A or under section 29; and(b) consider information that is relevant to the nature of the reassessment and to the provisions under which it is being considered. |

Emergency Use including Special Emergencies

43. When considering an application under sections 47 or 49D of the Act:

- (a) the Authority must consider whether or not the substance or organism meets the criteria set out in sections 48 or 49F respectively in deciding whether to approve or decline the application; and
- (b) the consideration of those criteria will be sufficient for the purposes of making a decision.

Hazardous Substances in containment under Section 32

44. When considering an application under section 32 of the Act:

- (a) the Authority must consider whether or not the substance meets the criteria set out in section 32 in deciding whether to approve or decline the application; and
- (b) the consideration of those criteria will be sufficient for the purposes of making a decision, except when the application has been made for the purpose in section 30(ca) where the Authority must also consider in particular section 6(f) of the Act.

Explanatory note: Section 30(ca) enables hazardous substance to be manufactured in, or imported into containment for the purpose of re-export only and not used in New Zealand. Thus for these types of applications relevant international matters should be considered.

Transshipment

45. When considering an application under section 51 of the Act:

- (a) the Authority must consider whether or not the substance or organism meets the criteria set out in section 51(2) in deciding whether to approve or decline the application; and
- (b) the consideration of those criteria will be sufficient for the purposes of making a decision.