Reprint
as at 1 July 2011

Hazardous Substances and New Organisms (Methodology) Order 1998

(SR 1998/217)

Michael Hardie Boys, Governor-General

Order in Council

At Wellington this 27th day of July 1998

Present:
The Right Hon Jenny Shipley presiding in Council

Pursuant to section 9(1) of the Hazardous Substances and New Organisms Act 1996, His Excellency the Governor-General, acting by and with the advice and consent of the Executive Council, makes the following order.

Contents

Note

Changes authorised by section 17C of the Acts and Regulations Publication Act 1989 have been made in this reprint.

A general outline of these changes is set out in the notes at the end of this reprint, together with other explanatory material about this reprint.

This order is administered by the Ministry for the Environment.

Order

1 Title and commencement

(1) This order may be cited as the Hazardous Substances and New Organisms (Methodology) Order 1998.

(2) This order comes into force on 29 July 1998.

2 Interpretation

In this order, unless the context otherwise requires,—

Act means the Hazardous Substances and New Organisms Act 1996

application means an application lodged under Part 5 of the Act

assessment means a process of identifying and assessing risks, costs, and benefits associated with the introduction of hazardous substances or new organisms in the context of applications made under Part 5 of the Act

benefit means the value of a particular positive effect expressed in monetary or non-monetary terms

cost means the value of a particular adverse effect expressed in monetary or non-monetary terms

evaluation means the evaluation by the Authority of the combined assessments of risks, costs, and benefits associated with applications made under Part 5 of the Act for the purposes of deciding whether the application should be approved, approved with conditions, or declined

risk means the combination of the magnitude of an adverse effect and the probability of its occurrence.

3 Establishment of methodology

The methodology set out in the Schedule is the methodology to be used by the Authority for making decisions under Part 5 of the Act.

Schedule
Methodology for making decisions under Part 5 of Act

r 3

Role of Authority

1 The Authority, or any committee appointed by the Authority and responsible for making decisions under Part 5 of the Act, must consistently apply this methodology when making decisions.

Schedule clause 1: amended, on 1 July 2011, by section 53(3) of the Environmental Protection Authority Act 2011 (2011 No 14).

2(1) The Authority must ensure that its chief executive and staff provide administrative, scientific, and technical support to the Authority in its functions, including the application of controls under Part 5 of the Act.

(2) In relation to applications and decision-making, the Authority—

(a) must inform applicants (as far as practicable) of the provisions of the Act and this methodology and, where relevant, of the need to obtain approvals under other enactments:

(b) must arrange any statutory processes, including the notification of applications and the holding of hearings:

(c) must review and verify information contained in applications and submissions from the public or, where appropriate, engage expert bodies to conduct the review and verification or to provide additional information so that the Authority may be expertly informed for the purposes of decision-making:

(d) may facilitate consultation and pre-hearing meetings between applicants and persons who make submissions opposing the application, where these are requested by the applicant and may assist in the early clarification of areas of technical or scientific dispute:

(e) must co-operate with other bodies (for example, government departments, Crown entities, and local bodies), in particular, when a hazardous substance or new organism also requires approvals under other enactments:

(f) may assist applicants to decide on the extent of relevant and appropriate information to be included in any application.

(3) Where assistance is given by the staff of the Authority under subclause (2)(f), that assistance does not prevent the Authority from seeking further information in accordance with section 58 of the Act.

3(1) The Authority must—

(a) direct its chief executive to advise the Authority solely on the basis of an objective and expert review of the substance or organism in an application and the assessment of risks, costs, and benefits relating to that substance or organism:

(b) prohibit its chief executive from making personal submissions on an application:

(c) direct its chief executive to issue a direction to the staff of the Authority—

(i) to advise the Authority solely on the basis of an objective and expert review of the substance or organism in an application and the assessment of risks, costs, and benefits relating to that application:

(ii) to prohibit staff from making personal submissions on an application.

(2) Subclause (1)(b) does not apply where its chief executive has requested the Authority to reassess a hazardous substance or new organism in containment in accordance with the provision of the Act.

4(1) The Authority may, from time to time, issue documents consistent with the Act and this methodology further explaining the role and functions of the chief executive and staff of the Authority.

(2) Documents issued under this clause do not form part of the methodology.

Role of departments

5 When implementing section 58(1)(c) of the Act, the Authority must consult any government department where the application relates to the interests or expertise of that department.

Role of advisory committees

6(1) The Authority may appoint a committee under clause 14 of Schedule 5 of the Crown Entities Act 2004 to advise it on any matter relating to its responsibilities under Part 5 of the Act.

(2) The Authority may seek the advice of the Māori Advisory Committee established by section 18 of the Environmental Protection Authority Act 2011 on issues that may arise in taking into account the matters referred to in sections 6(d) and 8 of the Act.

Schedule clause 6: substituted, on 1 July 2011, by section 53(3) of the Environmental Protection Authority Act 2011 (2011 No 14).

Public notification

7(1) Where applications are required to be publicly notified, the Authority must—

(a) summarise the application including assessments of risks, costs, and benefits, and include sufficient information to make clear the purpose of the application and the adverse effects of the hazardous substance or new organism, but exclude any information to which section 55(3) to (6) of the Act applies and any information withheld in accordance with the Official Information Act 1982; and

(b) before releasing the summary to any person, give it to the applicant; and

(c) if the applicant does not withdraw the application, make the summary publicly available.

(2) The applicant, after receipt of the summary and consultation with the Authority may, if the information in the summary is unacceptable, withdraw the application (including all the information provided by the applicant).

Information used by Authority

8 The information used by the Authority when considering an application must be relevant and appropriate to the scale and significance of the risks, costs, and benefits associated with the substance or organism.

9 When evaluating the information provided by an applicant (including prescribed information and any additional information) so as to achieve the purpose of the Act, the Authority must—

(a) recognise risks, costs, benefits, and other impacts associated with the substance or organism in an application which relate to the safeguarding of the life-supporting capacity of air, water, soil, and ecosystems, and provide for this principle; and

(b) recognise and provide for the principle of maintenance and enhancement of the capacity of people and communities to provide for—

(i) their own economic, social, and cultural wellbeing; and

(ii) the reasonably foreseeable needs of future generations; and

(c) take into account risks, costs, benefits, and other impacts associated with the substance or organism in an application which relate to—

(i) the sustainability of all native and valued introduced flora and fauna; and

(ii) the intrinsic value of ecosystems; and

(iii) public health; and

(iv) the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna, and other taonga; and

(v) the economic and related benefits to be derived from the use of a particular hazardous substance or new organism; and

(vi) New Zealand's international obligations.

10 Where an application relates to a new organism, the Authority must also evaluate the information provided on the risks, costs, benefits, and any other impacts which relate to—

(a) the significant displacement of any native species within its natural habitat:

(b) the significant deterioration of natural habitats:

(c) the significant adverse effects on human health and safety:

(d) significant adverse effects on New Zealand's inherent genetic diversity:

(e) the ability of the organism to establish an undesirable self-sustaining population anywhere in New Zealand:

(f) the ease with which the organism could be eradicated if it established an undesirable self-sustaining population:

(g) the ability to cause disease, be parasitic, or become a vector for human, animal, or plant disease.

11 Where an application relates to a hazardous substance, the Authority must also evaluate information which addresses the effects of the substance through its life cycle and the risks, costs, and benefits flowing from the following characteristics associated with the substance:

(a) explosiveness:

(b) flammability:

(c) capacity to oxidise:

(d) corrosiveness:

(e) toxicity (including chronic toxicity):

(f) eco-toxicity with or without bio-accumulation:

(g) any 1 or more of the above properties generated when the substance comes into contact with air or water.

Evaluation of risks, costs, and benefits

12 When evaluating assessment of risks associated with the substance or organism in an application, the Authority must take into account—

(a) the nature of the adverse effects; and

(b) the probability of occurrence and the magnitude of each adverse effect; and

(c) the risk assessed as a combination of the magnitude of the adverse effect and the probability of its occurrence; and

(d) the options and proposals for managing the risks identified; and

(e) the uncertainty bounds on the information contained in the assessment expressed quantitatively where possible, but otherwise through narrative statements.

13 When evaluating the assessments of costs and benefits associated with the substance or organism in an application, the Authority must take into account—

(a) the costs and benefits associated with the application and whether the costs and benefits are monetary or non-monetary; and

(b) the magnitude or expected value of the costs and benefits and the uncertainty bounds on the expected value; and

(c) the distributional effects of the costs and benefits over time, space, and groups in the community.

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

Submissions

15 When considering submissions made on publicly notified applications in accordance with section 54 of the Act, the Authority must have regard to any evidence in those submissions that is relevant to the assessment of the risks, costs, and benefits of introducing the substance or organism.

16 When considering submissions addressing scientific evidence or uncertainty, the Authority must take account of the scientific basis or authority for the information contained in the submission.

Experts

17 The chief executive of the Authority or the Authority may appoint experts to review the information contained in applications, including the risk assessments and proposals for risk management.

18(1) The applicant must be informed of the Authority's intention to appoint an expert (but not the name of the intended expert) before the release of any information contained in the application to that expert, and the Authority must take into account any comments by the applicant before proceeding to appoint an expert and release information.

(2) The applicant may withdraw the application at any time.

19 Any expert appointed under clause 17 may be required by the Authority to appear at a hearing of the application concerned, to present any material provided by them, and be questioned on that material.

Information produced for other bodies

20 The Authority may, subject to section 55(4) to (6) 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—

(a) the quality of the information (including the status of the relevant agency), the reliability and authority of the information, and the rigour and completeness of the decision-making where the information is in the form of an approval; and

(b) the extent to which it relates to New Zealand circumstances and the requirements of the Act.

Decision-making

21 Decisions by the Authority must be in accordance with the specific requirements of the Act and the regulations made under the Act.

22(1) The Authority must evaluate risks, costs, and, where applicable, benefits, taking into account—

(a) the nature and characteristics of the substance or organism; and

(b) the applicant's assessments and, where applicable, proposals for the management of the risks concerned; and

(c) any submissions received; and

(d) the reviews prepared by the chief executive or any expert appointed by the Authority or the chief executive.

(2) Subclause (1) does not limit any discretion that the Authority may have under the Act.

23 The Authority may, in accordance with section 58 of the Act, obtain further information in order to gain a sufficient understanding of the actual or potential effects caused by the substance or organism and the means of managing those effects.

24 The Authority, its chief executive, its staff, and any appointed expert must use recognised risk identification, assessment, evaluation, and management techniques.

25(1) When evaluating risks, the Authority must begin with a consideration of the scientific evidence relating to the application and take into account the degree of uncertainty attaching to that evidence.

(2) Where evidence relating to an application refers to other values and matters relevant to Part 2 of the Act, including the relationship of Māori culture and traditions with their ancestral lands and taonga, the Authority must also consider the values and other matters in that evidence.

26 Taking into account the measures available (if any) for risk management, the Authority may approve an application where a substance or organism poses negligible risks to the environment and human health and safety if it is evident that the benefits associated with that substance or organism outweigh the costs.

27(1) Where clause 26 does not apply, the Authority must take into account the extent to which the risks and any costs associated with that substance or organism may be outweighed by benefits.

(2) Where an application is for a new organism and that organism causes any of the effects in section 36 of the Act, clause 26 and subclause (1) do not apply and the Authority must decline the application.

28(1) The Authority may, from time to time, issue explanatory material relating to the calculation of monetary and non-monetary costs and benefits.

(2) Explanatory material issued under this clause does not form part of the methodology.

Uncertainty

29 Where the Authority encounters scientific and technical uncertainty relating to the potential adverse effects of a substance or organism, or where there is disputed scientific or technical information, the Authority—

(a) must determine the materiality and significance to the application of the uncertainty or dispute taking into account the extent of agreement on the scope and meaning of the scientific evidence; and

(b) may, where the uncertainty or dispute is material or significant, facilitate discussion between the parties concerned to clarify the uncertainty or dispute.

30 Where any scientific or technical uncertainty or dispute is not resolved to the Authority's satisfaction during its consideration of the application, the Authority must take into account the need for caution in managing the adverse effects of the substance or (to the extent provided for under the Act) the organism concerned.

31 Where the Authority considers that uncertainty arises from an absence of information, or inconclusive or contradictory information, or information from an unreliable source, the Authority may request the applicant to provide further information in accordance with section 58 of the Act and must take full account of any additional information provided.

32 Where the Authority considers there is uncertainty in relation to costs, benefits, and risks (including, where applicable, the scope for managing those risks), the Authority must attempt to establish the range of uncertainty and must take into account the probability of the costs, benefits, and risks being either more or less than the levels given in evidence.

Approach to risk

33 When considering applications, the Authority must have regard to the extent to which the following risk characteristics exist:

(a) exposure to the risk is involuntary:

(b) the risk will persist over time:

(c) the risk is subject to uncontrollable spread and is likely to extend its effects beyond the immediate location of incidence:

(d) the potential adverse effects are irreversible:

(e) the risk is not known or understood by the general public and there is little experience or understanding of possible measures for managing the potential adverse effects.

Aggregation and comparison of risks, costs, and benefits

34 When evaluating the combined impact of risks, costs, and benefits, the Authority must, as far as possible,—

(a) combine groups of risks, costs, and benefits using common units of measurement, including where applicable, monetary valuations; and

(b) use other techniques where common units are not possible, including the identification of dominant risks (being risks that may have a deciding influence), and the ranking of risks in order of significance.

Application of controls

35 When exercising the discretion under section 77 of the Act for the management of hazardous substances, the Authority must—

(a) consider the costs and benefits of making the controls more or less stringent (including the likely effectiveness of the implementation of possible controls); and

(b) invite the applicant to comment on the cost-effective application of controls to achieve a specified level of risk management.

Presentation of decisions

36(1) The Authority must publicly notify its decision.

(2) When giving its decision to the applicant and to those persons who have made submissions, the Authority must—

(a) state whether the application is approved, with or without controls, or declined; and

(b) state the criteria in the Act and in this methodology relied on by the Authority in reaching its decision; and

(c) 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; or

(ii) whether those controls have been varied by the Authority and attached to the substance; and

(d) 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 Schedule 3 of the Act; and

(e) state the reasons for the Authority's decision.

Marie Shroff,
Clerk of the Executive Council.

Issued under the authority of the Acts and Regulations Publication Act 1989.
Date of notification in *Gazette*: 28 July 1998.

Contents

Notes

1 General

This is a reprint of the Hazardous Substances and New Organisms (Methodology) Order 1998. The reprint incorporates all the amendments to the order as at 1 July 2011, as specified in the list of amendments at the end of these notes.

Relevant provisions of any amending enactments that contain transitional, savings, or application provisions that cannot be compiled in the reprint are also included, after the principal enactment, in chronological order. For more information, *see* http://www.pco.parliament.govt.nz/reprints/.

2 Status of reprints

Under section 16D of the Acts and Regulations Publication Act 1989, reprints are presumed to correctly state, as at the date of the reprint, the law enacted by the principal enactment and by the amendments to that enactment. This presumption applies even though editorial changes authorised by section 17C of the Acts and Regulations Publication Act 1989 have been made in the reprint.

This presumption may be rebutted by producing the official volumes of statutes or statutory regulations in which the principal enactment and its amendments are contained.

3 How reprints are prepared

A number of editorial conventions are followed in the preparation of reprints. For example, the enacting words are not included in Acts, and provisions that are repealed or revoked are omitted. For a detailed list of the editorial conventions, *see* http://www.pco.parliament.govt.nz/editorial-conventions/ or Part 8 of the *Tables of New Zealand Acts and Ordinances and Statutory Regulations and Deemed Regulations in Force*.

4 Changes made under section 17C of the Acts and Regulations Publication Act 1989

Section 17C of the Acts and Regulations Publication Act 1989 authorises the making of editorial changes in a reprint as set out in sections 17D and 17E of that Act so that, to the extent permitted, the format and style of the reprinted

enactment is consistent with current legislative drafting practice. Changes that would alter the effect of the legislation are not permitted.

A new format of legislation was introduced on 1 January 2000. Changes to legislative drafting style have also been made since 1997, and are ongoing. To the extent permitted by section 17C of the Acts and Regulations Publication Act 1989, all legislation reprinted after 1 January 2000 is in the new format for legislation and reflects current drafting practice at the time of the reprint.

In outline, the editorial changes made in reprints under the authority of section 17C of the Acts and Regulations Publication Act 1989 are set out below, and they have been applied, where relevant, in the preparation of this reprint:

- omission of unnecessary referential words (such as "of this section" and "of this Act")
- typeface and type size (Times Roman, generally in 11.5 point)
- layout of provisions, including:
  - indentation
  - position of section headings (eg, the number and heading now appear above the section)
- format of definitions (eg, the defined term now appears in bold type, without quotation marks)
- format of dates (eg, a date formerly expressed as "the 1st day of January 1999" is now expressed as "1 January 1999")
- position of the date of assent (it now appears on the front page of each Act)
- punctuation (eg, colons are not used after definitions)
- Parts numbered with roman numerals are replaced with arabic numerals, and all cross-references are changed accordingly
- case and appearance of letters and words, including:
  - format of headings (eg, headings where each word formerly appeared with an initial capital letter followed by small capital letters are amended so that the heading appears in bold, with only the first word (and any proper nouns) appearing with an initial capital letter)
  - small capital letters in section and subsection references are now capital letters
- schedules are renumbered (eg, Schedule 1 replaces First Schedule), and all cross-references are changed accordingly
- running heads (the information that appears at the top of each page)

- format of two-column schedules of consequential amendments, and schedules of repeals (eg, they are rearranged into alphabetical order, rather than chronological).

5 List of amendments incorporated in this reprint (most recent first)

Environmental Protection Authority Act 2011 (2011 No 14): section 53(3)

Wellington, New Zealand:
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