

Decision Paths

Number 2, Series 2

(Including Amendment Notice 2002/8)

Section 9 of the HSNO Act requires the Environmental Risk Management Authority to develop a decision-making methodology, which includes an assessment of monetary and non-monetary costs and benefits, and to apply it consistently. This methodology has been approved by the Government and established as an Order-in-Council.

To supplement the Methodology Order additional information is being published in the form of a set of Protocols. The Protocols indicate how the Authority proposes to confront some of the more problematic issues it is likely to face in its decision-making. They also outline how the Authority will interpret some of the key concepts found in the Act and the Methodology.

In preparing these Protocols the Authority has been conscious of both its needs, as a decision-maker, and the needs of its stakeholders. As decision-maker, the Authority recognises the value of Protocols as a means of assisting it to produce high quality decisions consistently over time. Similarly, stakeholder groups can benefit from the additional clarification of the way in which the Authority makes decisions.

The current series (series 2) of protocols was released in October 1999. It updates and supercedes the initial set of documents released in July 1998. The Protocols will continue to be refined over time as further information or insights into the Authority's decision-making become available.

DECISION PATHS

Introduction

Decisions made by the Authority will generally follow set paths, depending on the type of application, intended to ensure that all relevant considerations are applied and in the right order. This Protocol sets out the decision paths that are followed.

The use of decision paths is intended to give consistency in the approach of the Authority, to assist in building up a history of precedents and to provide some certainty to applicants about how their applications will be treated.

The decision paths present a schematic view of the Authority's consideration of applications. Nothing in these paths derogates from the obligation to comply with the provisions of the HSNO Act or the Methodology.

In all cases the sequence described starts with the formal receipt of an application. It is assumed that informal processes prior to that point (for example, discussions with ERMA New Zealand staff) will have established whether an application is valid and which type of application should be made.

Decision paths for the six approval types identified in the Act are set out below as follows:

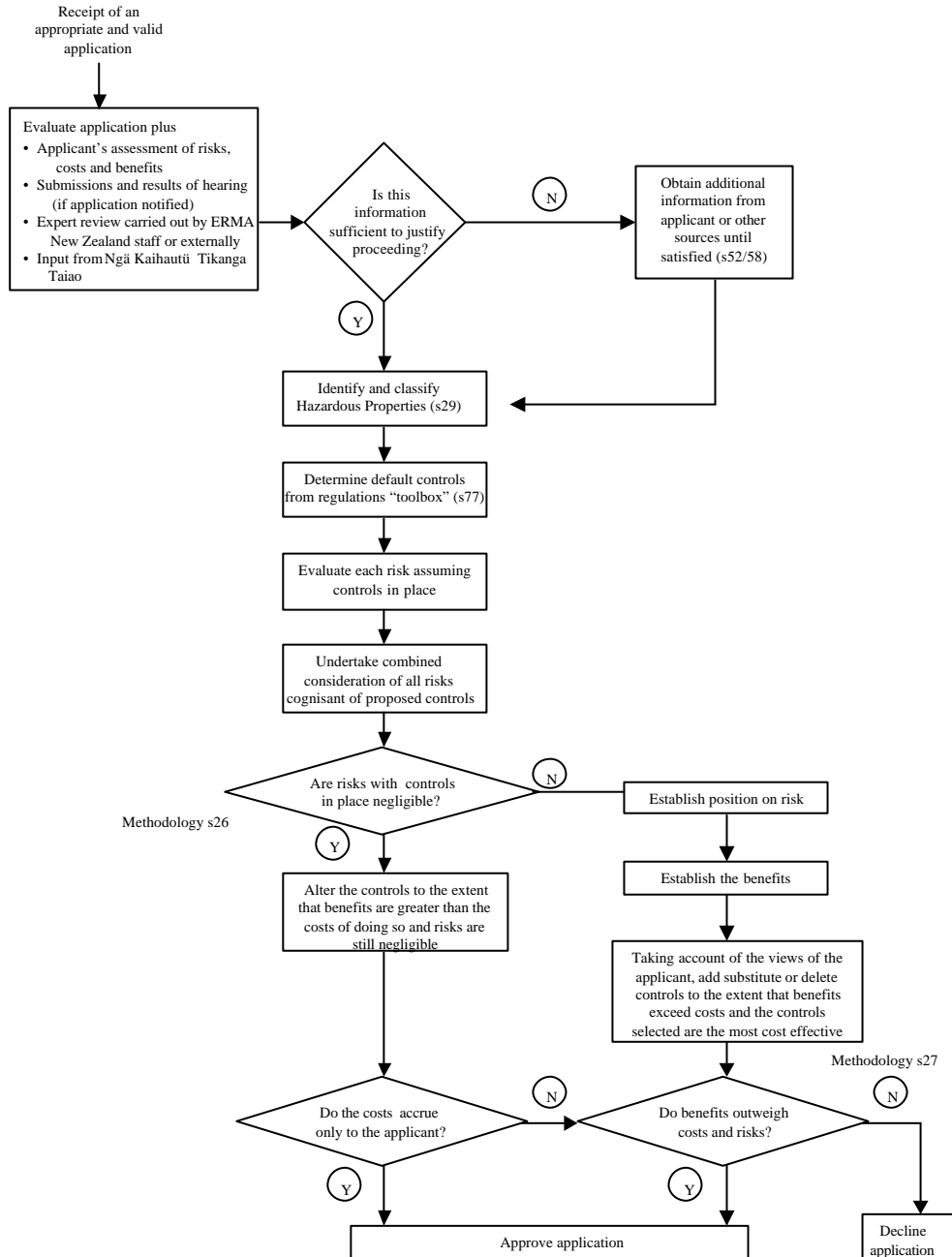
- Figure 1 Decision path for applications to import or manufacture a hazardous substance (Section 28 of Act).
- Figure 1a Decision path for applications to import or manufacture a hazardous substance under the option of rapid assessment for a substance with a similar composition and similar hazardous properties to one already approved (Section 28A(2)(a)).
- Figure 1b Decision path for applications to import or manufacture a hazardous substance under the option of rapid assessment for a substance which has one or more hazardous properties, and the least degree of hazard for each of those hazardous properties (Section 28A(2)(b)).
- Figure 2 Decision path for applications to import or release a new organism (Section 34) incorporating the option of rapid assessment (Section 35).
- Figure 3 Decision path for applications to develop/import/field test in containment any new organism that is not a genetically modified organism (Section 40), incorporating the option of rapid assessment for a genetically modified organism (Section 42)
- Figure 3a Decision path for applications to develop or field test any GMO in containment, excluding the option of rapid assessment for development (Section 42)
- Figure 4 Decision path for applications to import or manufacture any hazardous substance in containment (Section 31).
- Figure 5 Decision path for applications to import or manufacture any hazardous substance for release in an emergency or to release any new organism from containment in an emergency (Section 47).

- Figure 6 Decision path for applications to tranship a hazardous substance or new organisms (Section 51).
- Figure 7 Decision path for requests for reassessment of any hazardous substance or any new organism in containment.

Reassessments may be requested under Section 63 of the Act and if accepted, will be treated as applications, ie the appropriate decision path will be selected from those set out below.

DECISION PATHS

Figure 1 Decision path for applications to import or manufacture a hazardous substances (Section 28 of Act)



- Note:
1. The requirement under the Act to consider 'the likely effects of the substance being unavailable' is incorporated into the consideration of benefits and costs.
 2. The Authority may decline an application if there is insufficient information for it to assess the adverse effects.

Figure 1a Decision path for applications to import or manufacture a hazardous substance under the option of rapid assessment for a substance with a similar composition and similar hazardous properties to one already approved (Section 28A(2)(a))

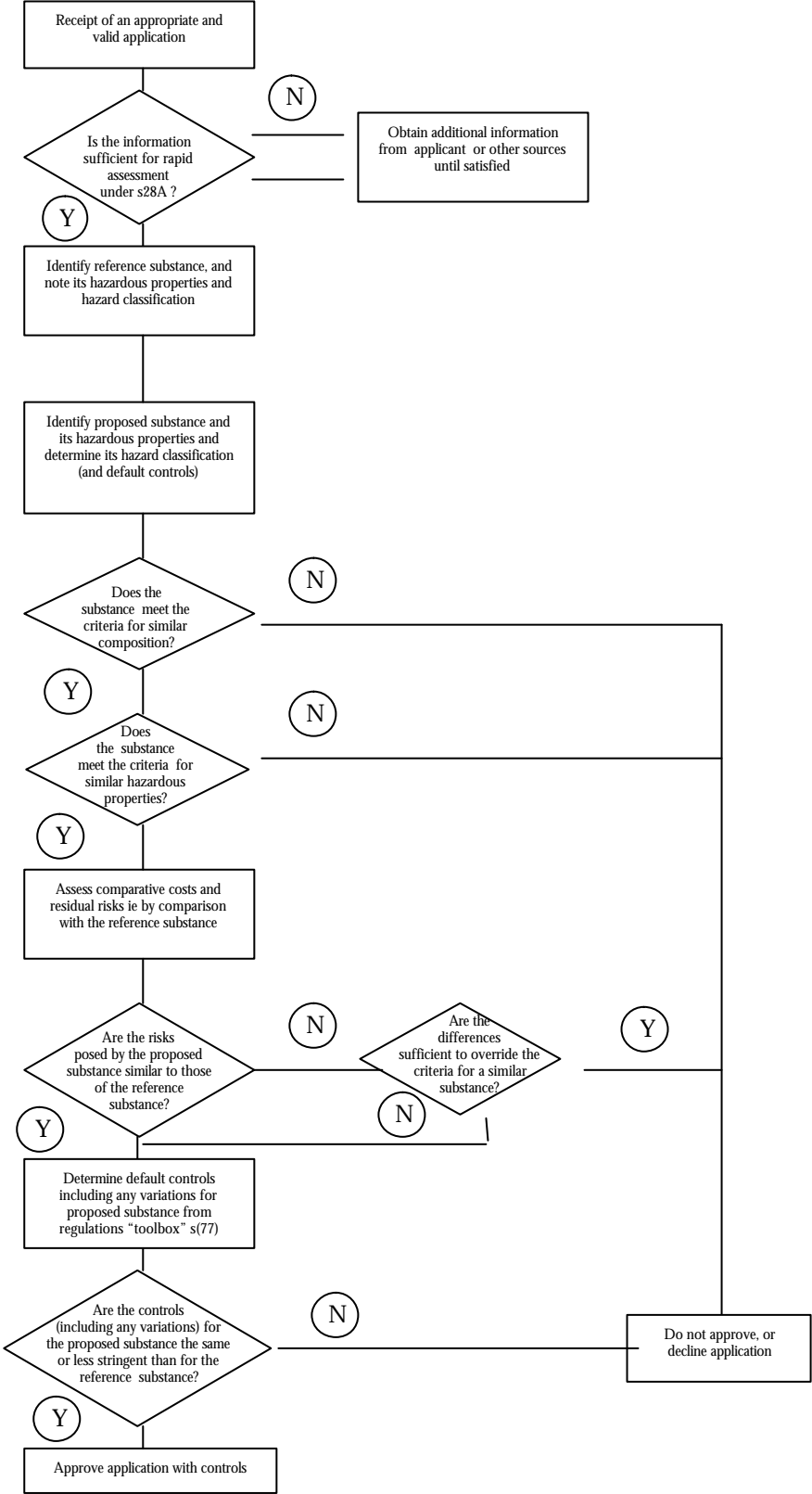


Figure 1b Decision path for applications to import or manufacture a hazardous substance under the option of rapid assessment for a substance which has one or more hazardous properties, and the least degree of hazard for each of those hazardous properties (Section 28A(2)(b)).

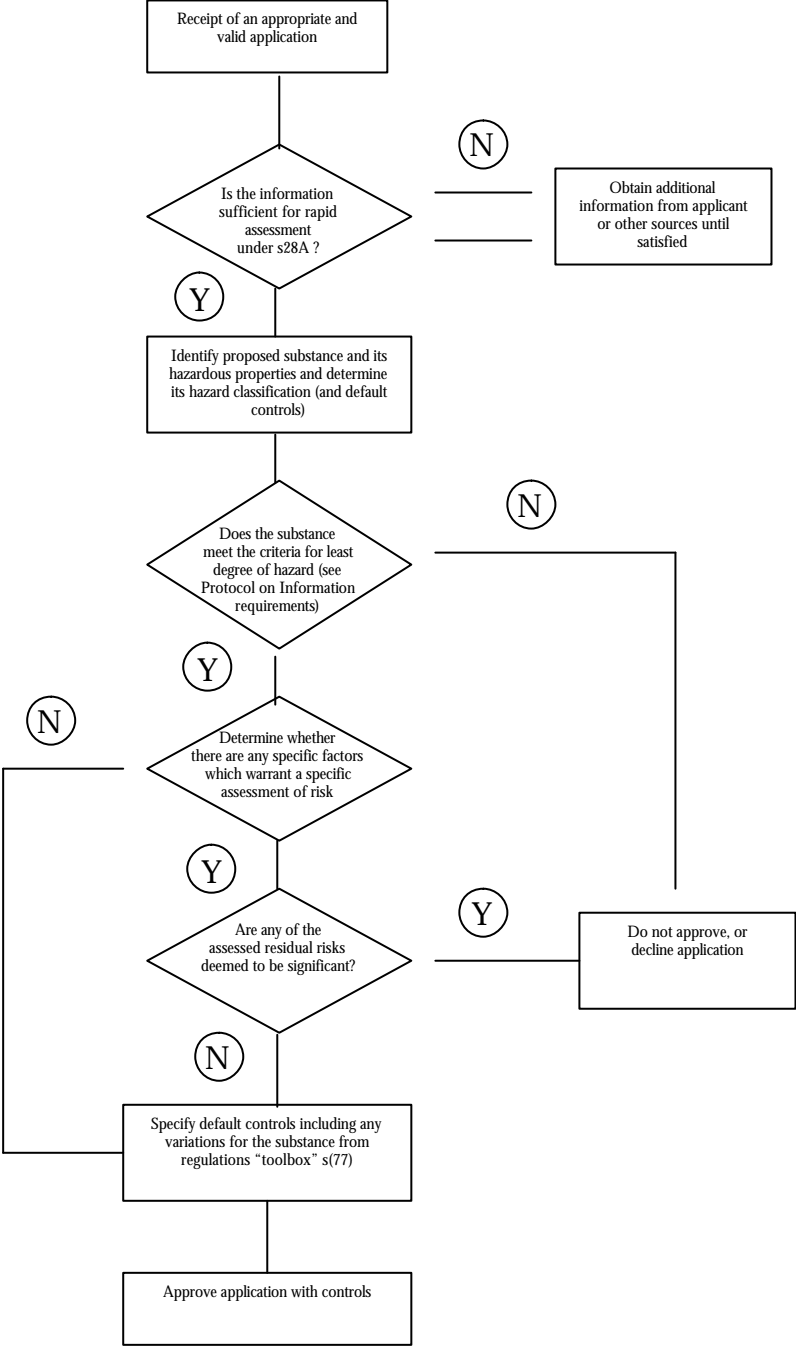
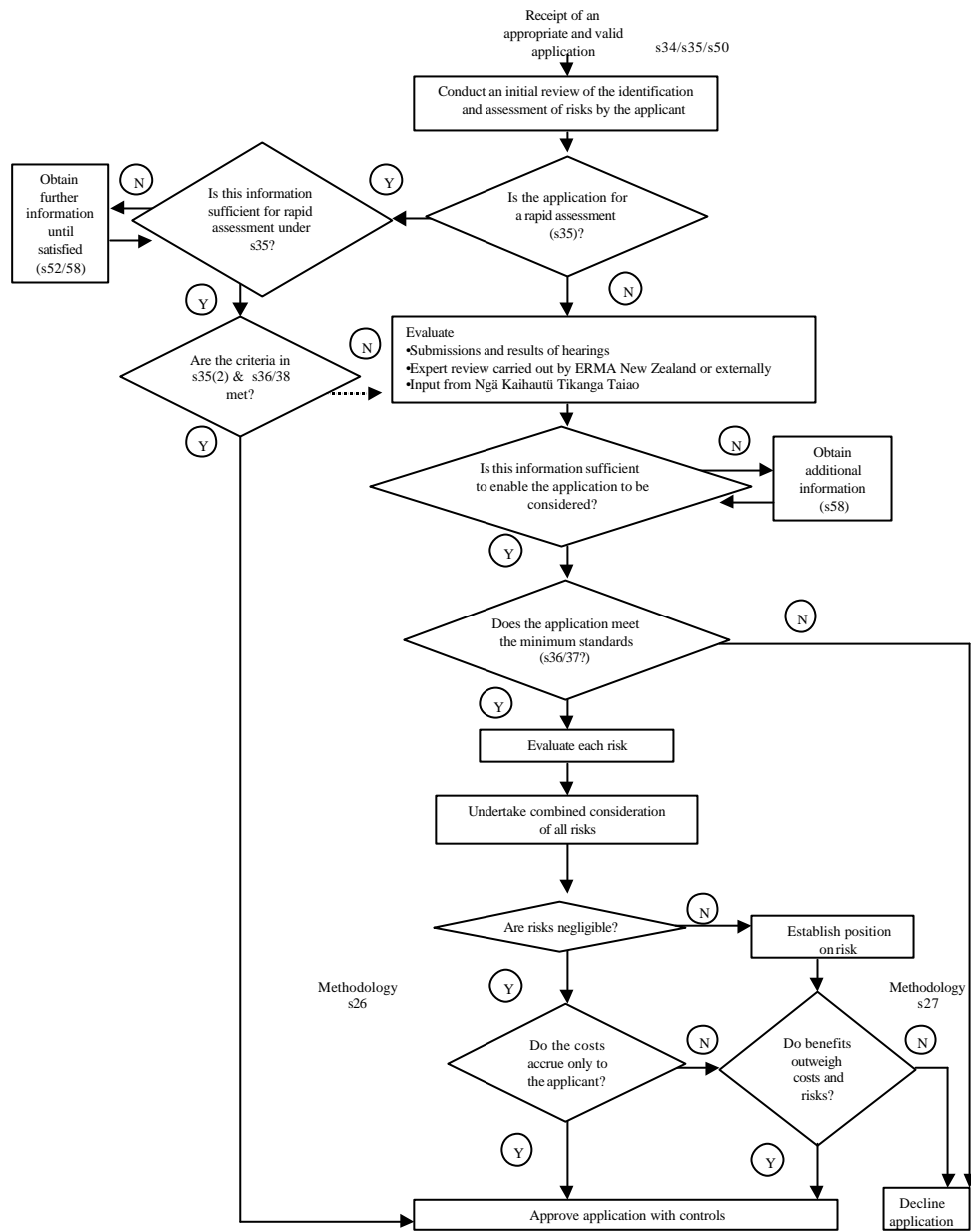
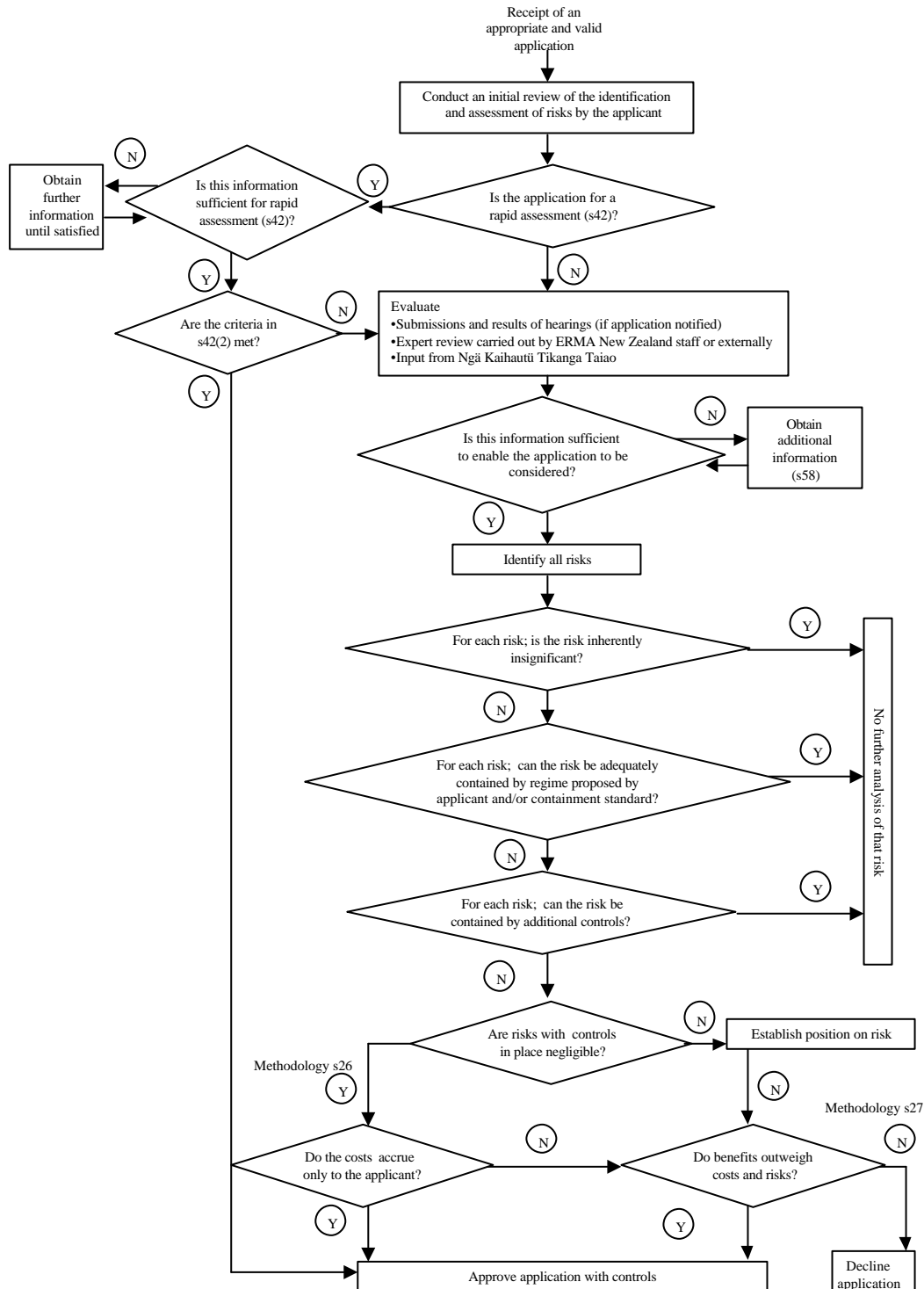


Figure 2 Decision path for applications to import or release a new organism (Section 34) Including the option of rapid assessment (Section 35)



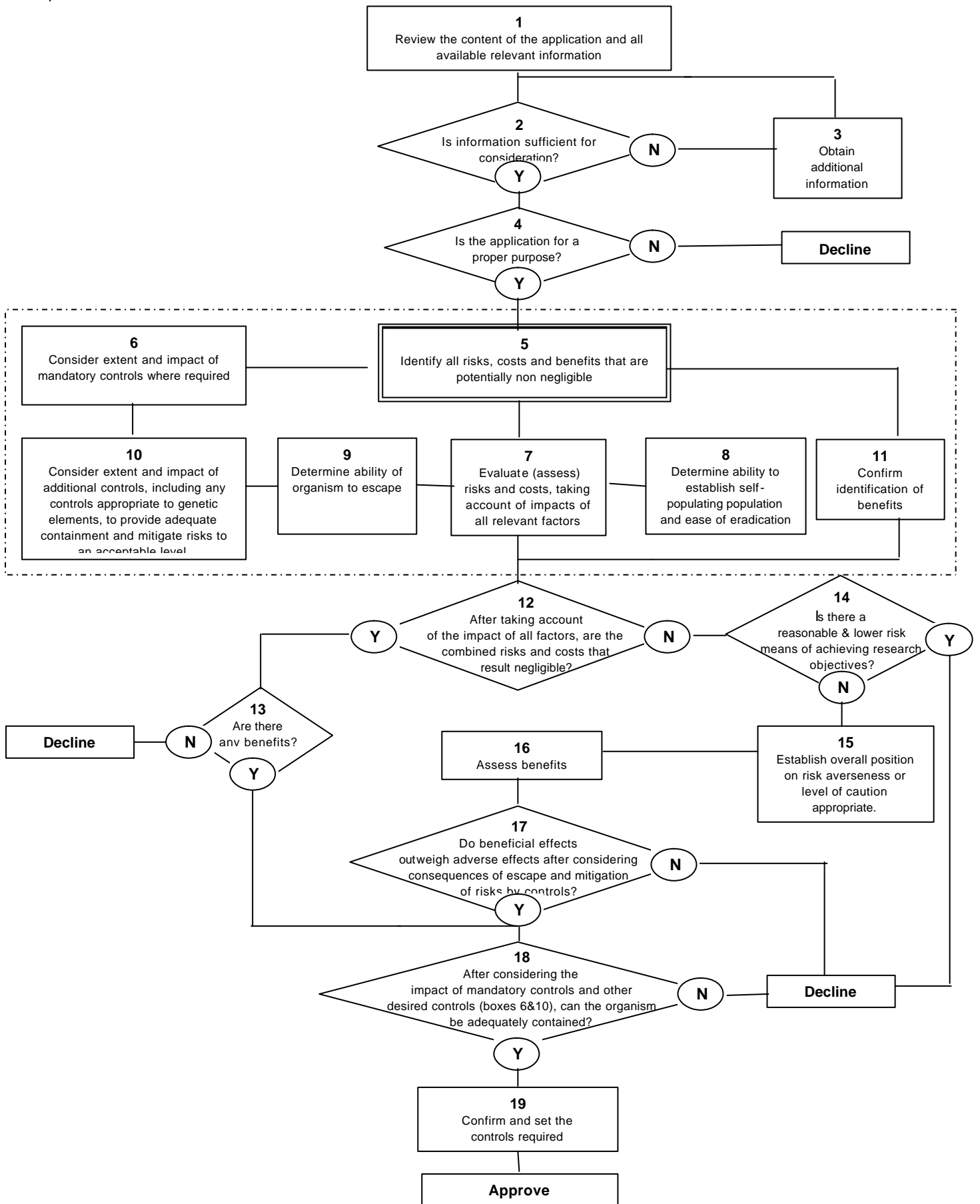
- Note:
1. The Authority may decline an application if insufficient information is available to it to enable it to assess the adverse effects.
 2. The applicant has the discretion to decide whether or not to proceed to full assessment should their application fail the rapid assessment criteria.

Figure 3 Decision path for applications to develop/import/field test in containment any new organism that is not a genetically modified organism (Section 40), incorporating the option of rapid assessment for a genetically modified organism (Section 42)



Note: The applicant has the opportunity to withdraw their application if they do not want it to go through a full assessment.

Figure 3a Decision path for applications to develop or field test any GMO in containment, excluding the option of rapid assessment for development (Section 42)



NOTES to Figure 3a

Items 1, 2 & 3: Information that should be reviewed includes that in the application, the E&R Report, from experts and in submissions (where relevant). Review should occur in terms of section 40(2) of the Act and clauses 8, 15, 16, 20 and 22 of the Methodology. Additional information may need to be sought under s58 of the Act.

Item 4: Acceptable purposes are set out in s39 of the Act

Item 5: The range of risks, costs and benefits to be identified should be that covered by clauses 9, 10 and 11 of the Methodology. However, effects arising from the transfer of genetic elements must also be considered as set out in s44A(2) of the Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Act 2002 (referred to in the further text as “the GMO Act”). There are two steps within this part of the process:

Step 1: The identification of every possible risk, cost and benefit that can be thought of, to ensure that a starting position is as comprehensive as possible.

Step 2: The elimination of those risks, costs and benefits that can be readily concluded to be negligible or irrelevant, having regard to the characteristics of the organism and the circumstances of the application.

Item 6: Mandatory controls are set out in section 45A of the GMO Act. These relate to removal and/or destruction of material from the site rather than to risks per sé.

Item 7: The phrase “characterisation” is used as a convenient shorthand for all of the aspects of risk that need to be considered in the assessment process. The evaluation (assessment) of risks and costs should be carried out in accordance with clauses 22 and 25, 29 to 32 (dealing with uncertainty), and 12 to 14 of the Methodology and relevant clauses of the GMO Act.

The process of risk assessment is not linear. It is very iterative. In essence all of the steps must be repeated until a satisfactory conclusion is reached. However, in general terms the steps in the assessment process should be as follows, for each risk.

Step 1: Characterisation of the risk in the absence of containment and other controls, taking account of the ability of the organism to establish a self-sustaining population where relevant, and taking account of the requirement in the GMO Act to consider risks from “genetic elements” (The issue of self-sustaining populations is mainly relevant to ecological risks, and usually less so to risks to human health and safety.)

Step 2: Consideration of the extent to which the risk will be mitigated by the ability to eradicate the organism if it becomes established

Step 3: Consideration of the extent to which the risk will be mitigated by the setting of containment and other controls, including the mandatory controls in the GMO Act. (Controls include contingency plans for recovering the organism or dealing with effects, in the event that controls fail.)

Step 4: Characterisation of the overall risk, taking account of all of the other steps above and considering in particular the issue of whether the consequences of breach of controls would be sufficiently serious (see Step 1) to warrant giving this particular emphasis in the overall characterisation.

Step 5: Consideration of how risk averse or cautious the Authority should be in giving weight to the resulting or remaining risk, in terms of cl 33 of the Methodology.

Item 8: Section 37 of the Act requires that the Authority takes account of the ability of the organism to establish an undesirable self sustaining population and the ease of eradication. This needs to be considered in an integrated way in the assessment process because of the reference to “undesirable”. Undesirable means (in effect) able to create risks.

Item 9: Section 44 requires the Authority to consider the ability of the organism to escape from containment. Although strictly speaking, this requirement does not apply to development applications, it is prudent and good practice to consider it anyway. This element must be considered in an integrated way in the assessment process because the ability to escape depends on the containment controls set.

Item 10: Controls additional to those mandated in the GMO Act will need to be considered, in order to mitigate risks to whatever level is considered to be appropriate, and to provide adequate containment. Controls need to provide for the matters set out in the 3rd Schedule to the HSNO Act.

Section 45A of the GMO Act also provides for the Authority to set controls for the removal or destruction of genetic elements, if the Authority so decides, i.e. as a matter for the discretion of the Authority. The impact of these controls also needs to be considered

Items 11 and 13 Item 11 is included for completeness and is straightforward. It provides for potential or possible benefits to be confirmed as benefits able to be considered in making a decision. The same issue is raised again at Item 13, but at this stage as a decision point rather than just an item of information.

Item 12: In considering whether resulting risks are negligible, an holistic view needs to be taken. In particular the issue of the level of risk if containment or other controls fail needs to be considered, as well as the probability of such a failure.

Item 13: This item taken in sequence from item 12 constitutes a decision made under clause 26 of the Methodology. In this case the existence of benefits is sufficient to outweigh negligible risk.

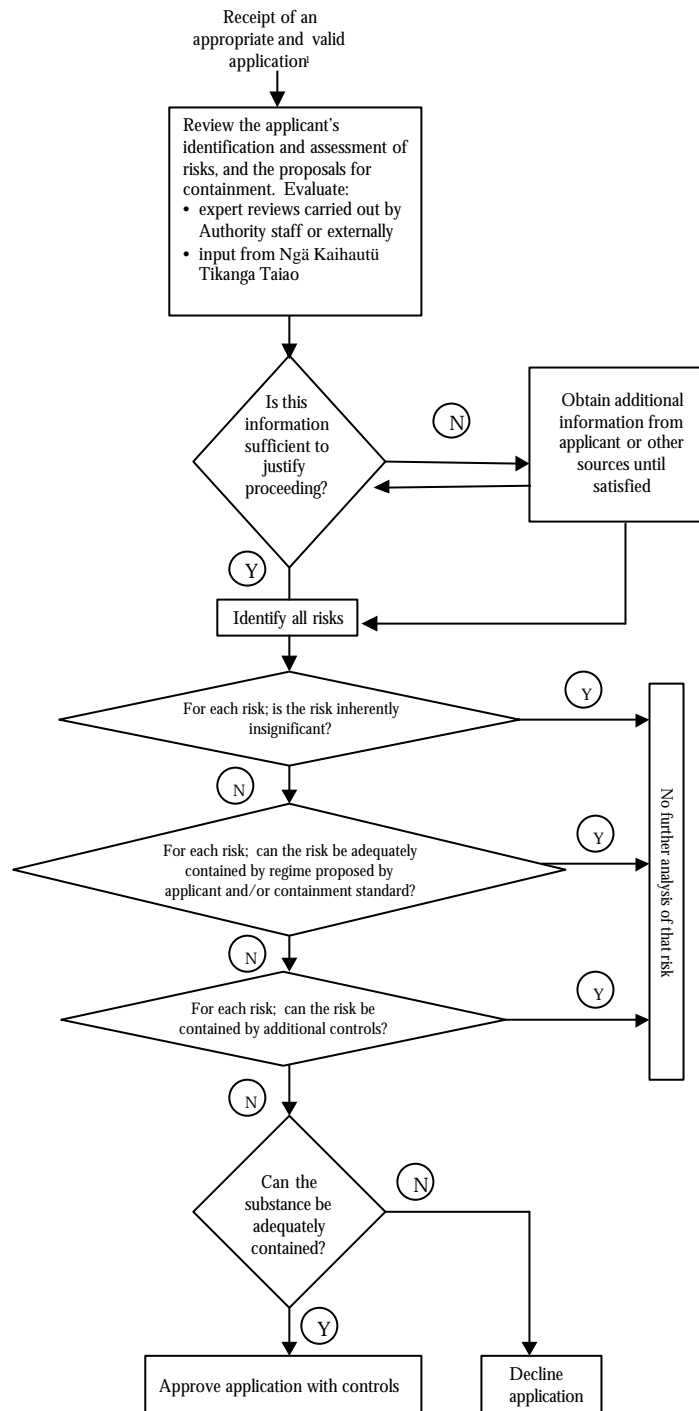
Item 14: Section 44A of the GMO Act requires alternative means of achieving research objectives to be taken account of. The word “reasonable” is used to reflect the availability of some discretion to the Authority, i.e. the following steps apply:

Step 1: Are there other ways of achieving the research objectives which pose less risk (taking account of the mitigating impact of controls as well as the absence of controls).

Step 2: Is the difference sufficient to justify declining the application.

- Item 15:** Although “risk averseness” is considered as a part of the assessment of individual risks, it is good practice to consolidate the view on this if risks are non-negligible. Clause 33 of the Methodology applies, as does s7 of the Act dealing with caution in the face of scientific and technical uncertainty. If risks are negligible, then risk averseness is irrelevant and should not need to be consolidated.
- Item 16:** Benefits should be assessed in terms of clause 13 of the Methodology.
- Item 17:** This constitutes a decision made under clause 27 of the Methodology. In weighing up risks, costs and benefits, clause 34 of the Methodology applies.
- Item 18:** The meaning of the phrase adequacy of containment needs to be extended so that it covers both the satisfactory biological and/or physical containment of the organism, and the satisfactory application of the mandatory and (if appropriate) voluntary containment controls set out in the GMO Amendment Act.
- Item 19:** Containment and other controls will have been effectively set at the earlier stages of the process (Items 6, 10, 13, 17 and 18). However, controls should be confirmed as the final step in the decision-making process.

Figure 4 Decision path for applications to import or manufacture any hazardous substance in containment (Section 31)



Note¹: This assumes that the application is for one of the purposes specified in section 30 of the Act.

Figure 5: Decision path for applications to import or manufacture any hazardous substance for release in an emergency or release any new organism from containment in an emergency (Section 47)

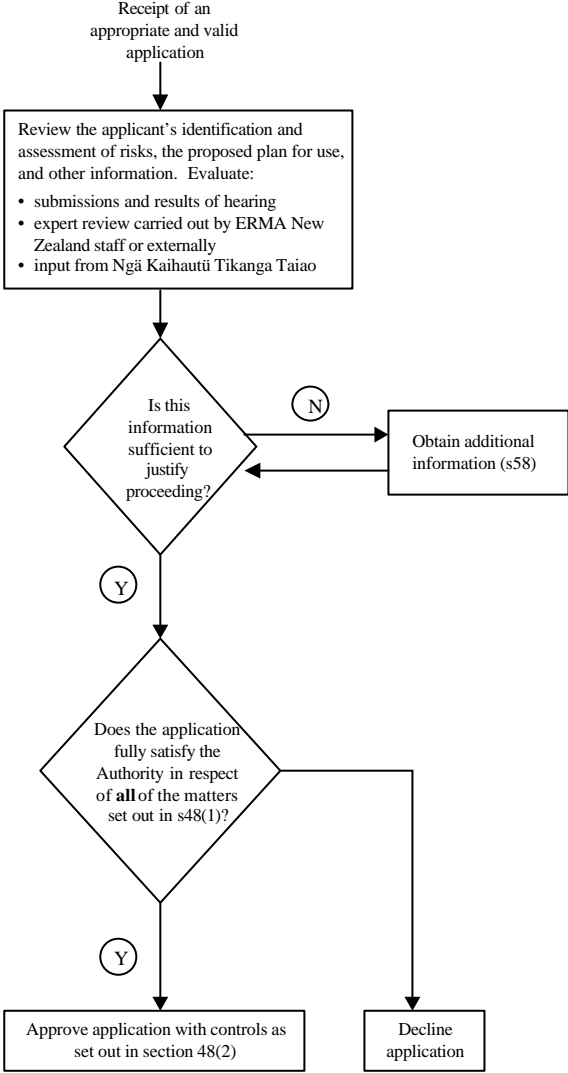
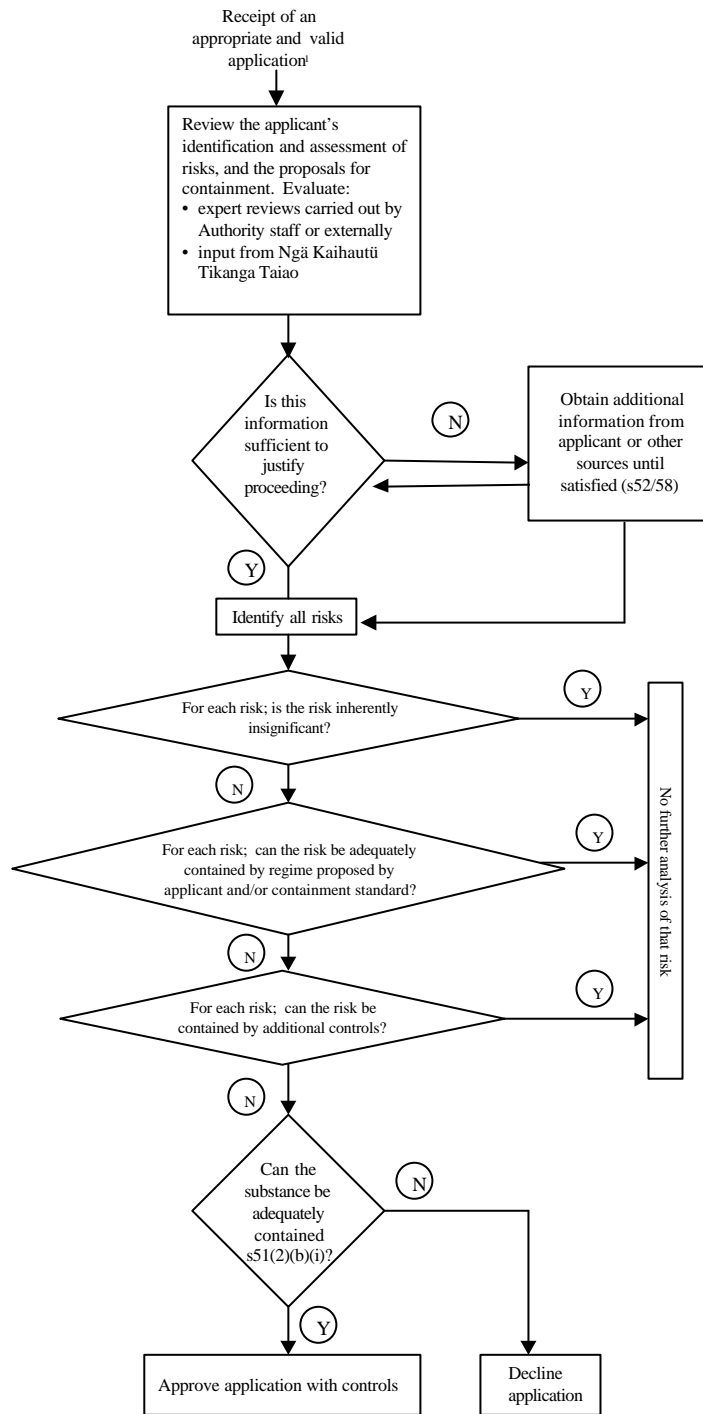


Figure 6:

Decision path for application to tranship a hazardous substance or new organism (Section 51)



Note¹: This assumes that the application is not for a prohibited organism listed in Schedule 2 of the Act.

Figure 7 Decision path for requests to see whether there are grounds for a reassessment of any hazardous substance or any new organism in containment.

