Appendix E: Decision path for the reassessment of 1080

Context

This decision path describes the decision-making process for the application to import and manufacture 1080 and formulated substances containing 1080. This application is made under section 63 (Reassessment) of the HSNO Act, and determined under section 29 of the Act.

Introduction

The purpose of the decision path is to provide the Authority with guidance so that all relevant matters in the HSNO Act and the Methodology have been addressed. It does not attempt to direct the weighting that the Authority may decide to make on individual aspects of an application.

In this document 'section' refers to sections of the HSNO Act, and 'clause' refers to clauses of the ERMA New Zealand Methodology.

The decision path has two parts –

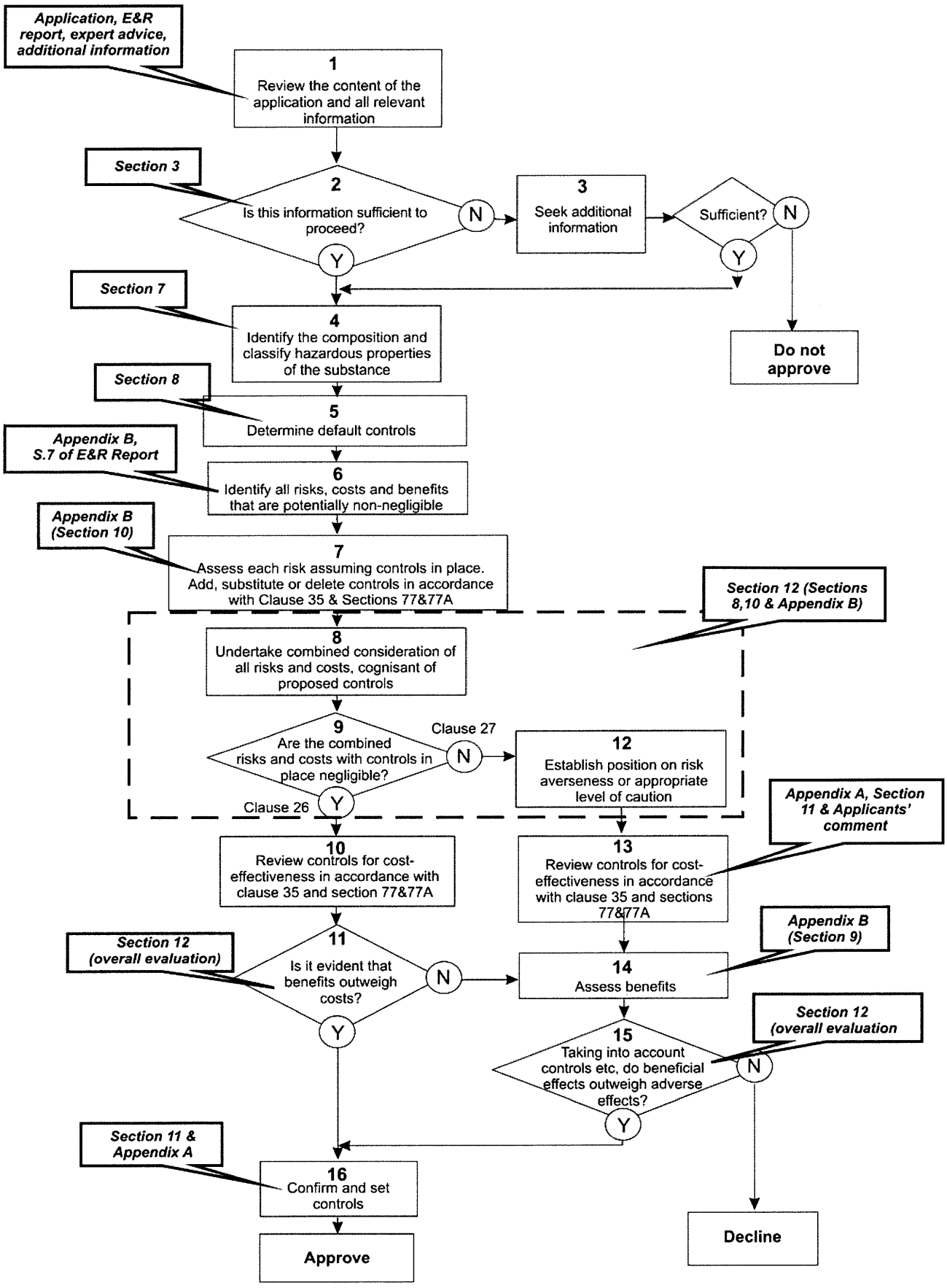
- **Flowchart** (a logic diagram showing the process prescribed in the Methodology and the HSNO Act to be followed in making a decision), and
- **Explanatory notes** (discussion of each step of the process).

Of necessity the words in the boxes in the flowchart are brief, and key words are used to summarise the activity required. The explanatory notes provide a comprehensive description of each of the numbered items in the flowchart, and describe the processes that should be followed to achieve the described outcome. Additional cross-references to the relevant sections in the E&R Report and the draft decision are also included for ease of reference.

1080 Decision Making Committee

Decision path for 1080 and formulated substances containing 1080 – FLOWCHART (application made under section 28 of the Act and determined under section 29)

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



EXPLANATORY NOTES

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 28(2) of the Act and clauses 8, 15, 16 and 20 of the Methodology. Additional information may need to be sought under section 52 and 58 of the Act. When considering the adequacy of the information the information category should be considered.
If the applicant is not able to provide sufficient information for consideration then the application is not approved. In these circumstances the Authority may choose to decline the application, or the application may lapse.

Item 4: Confirm the composition of the substance and establish the hazard classifications for the identified substance.

Item 5: Determine the default controls for the specified hazardous properties using the regulations 'toolbox'.

Item 6: The range of risks, costs and benefits to be identified should be that covered by clauses 9, 10 and 11 of the Methodology. This is a two step process.

Step 1: Identify all possible risks, costs and benefits

Step 2: Eliminate those risks, costs and benefits that can be readily concluded to be negligible

Item 7: The assessment of risks and costs should be carried out in accordance with clauses 12 to 14, 22, 25, and 29 to 32 of the Methodology. The process of risk assessment includes the estimation of the likelihood and magnitude of each effect. The assessment is carried out with the default controls in place.

The assessment also includes the following steps.

Step 1: Consideration of the extent to which the risk will be mitigated by the default controls.

Step 2: Consideration of how risk averse or cautious the Authority should be in giving weight to the residual risk (clause 33 of the Methodology), where residual risk is the risk remaining after the imposition of controls.

Note that only risks and costs are assessed at this stage, since assessment of benefits depends on whether the decision follows the clause 26 or clause 27 path.
Add substitute or delete controls in accordance with section 77 of the Act.

Item 8: Once the risks and costs have been assessed individually, consider all risks and costs together.

Item 9: Consider whether any residual risks are negligible. An holistic perspective should be adopted, taking into account the particular characteristics of the substance and the feasibility of the combined controls.

Item 10: This item taken in sequence from item 9 constitutes a decision made under clause 26 of the Methodology.
Consider (a) whether any of the non-negligible risks can be reduced by varying the controls in accordance with section 77 of the Act, and (b) the cost-effectiveness of the controls. Where relevant and appropriate, add, substitute or delete controls whilst taking into account the view of the applicant, and making sure that the benefits of doing so outweigh the costs.

Item 11: This item constitutes a decision made under clause 26 of the Methodology. If risks are negligible and there are no external costs (costs accrue only to the applicant), then the fact that the application has been submitted is deemed to demonstrate existence of benefit, and no further benefits need be considered. However, if external costs exist then all benefits need to be assessed

Item 12: 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 section 7 of the Act dealing with caution in the face of scientific and technical uncertainty.

Item 13: This constitutes a decision made under clause 27 of the Methodology (taken in sequence from items 9, 12, 13 and 14).
Consider (a) whether any of the non-negligible risks can be reduced by varying the controls in accordance with section 77 of the Act, and (b) the cost-effectiveness of the controls. Where relevant and appropriate, add, substitute or delete controls whilst taking into account the view of the applicant, and making sure that the benefits of doing so outweigh the costs.

Item 14: Assess benefits in terms of clause 13 of the Methodology.

Item 15: In weighing up adverse and beneficial effects, clause 34 of the Methodology applies. The weighing up process takes into account controls proposed in items 5, 10 and/or13.
Where this item is taken in sequence from items 12, 13 and 14 (ie risks are not negligible) it constitutes a decision made under clause 27 of the Methodology, and adverse effects comprise risks and costs.
Where this item is taken in sequence from items 9, 10, 11 and 14 (ie risks are negligible, and costs do not accrue only to the applicant) it constitutes a decision made under clause 26 of the Methodology, and adverse effects comprise costs.

Item 16: Controls have been considered at the earlier stages of the process (items 5, 10 and/or 13). However, the final step in the decision-making process confirms and sets the controls.