Appendix A: Decision Path for Applications Determined under Section 29 of the Hazardous Substances and New Organisms Act 1996

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A1 Decision path for applications to import or manufacture a hazardous substance

This decision path describes the decision-making process for applications to **import or manufacture a hazardous substance**. These applications are made under section 28 and determined under section 29 of the Hazardous Substances and New Organisms Act 1996 (HSNO Act).

The purpose of the decision path is to provide the Authority with guidance so that **all relevant matters** in the Act and Hazardous Substances and New Organisms (Methodology) Order 1998 (the Methodology) are addressed. It does not attempt to direct the weighting that the Authority may decide to make on individual aspects of an application.

A2 Composition of decision path

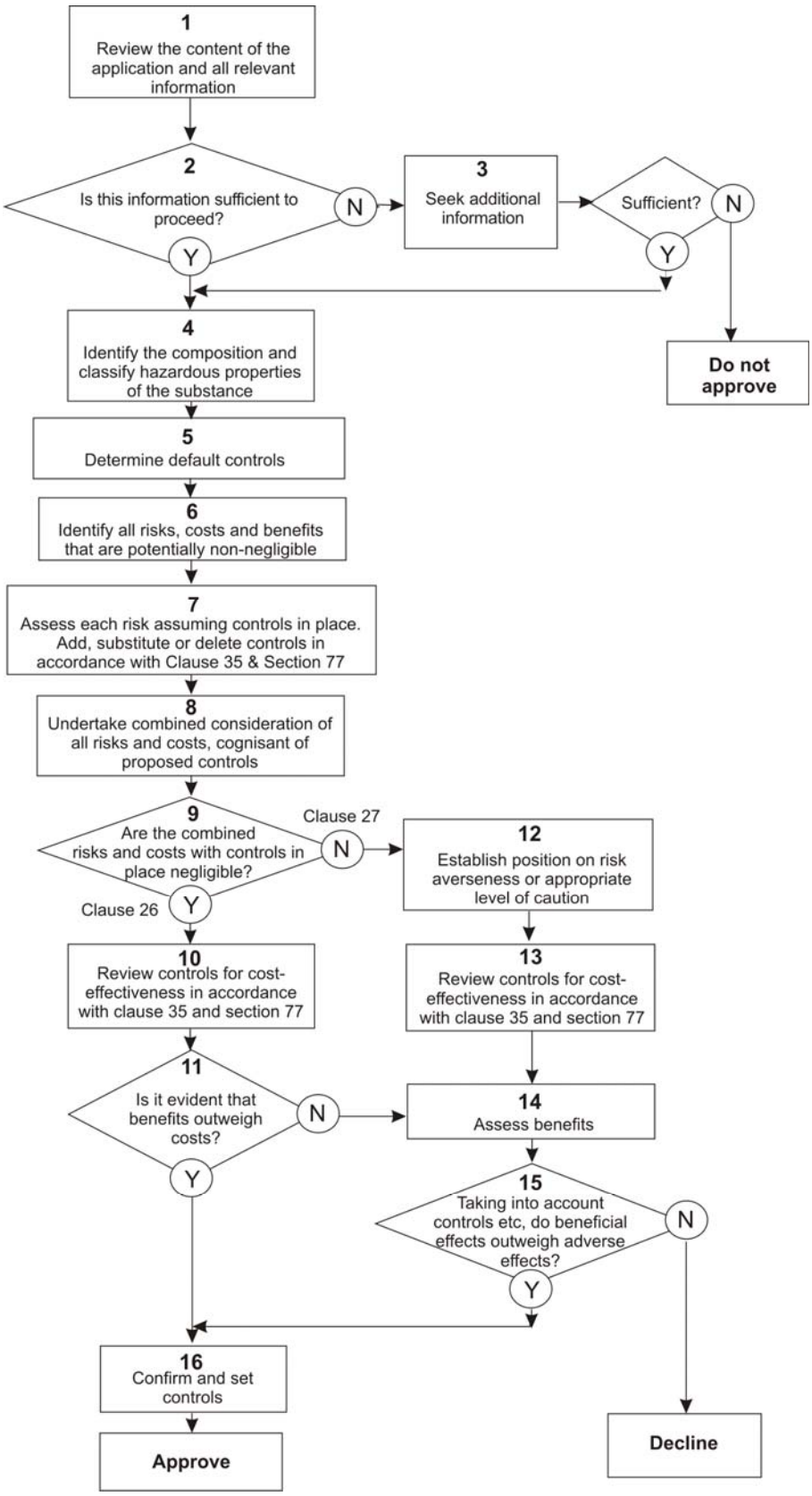
The decision path has two parts.

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

Of necessity the words 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.

For proper interpretation of the decision path it is important to work through the flowchart in conjunction with the explanatory notes (see section A3 after the flowchart).

Figure A.1: Decision-making process for applications to import or manufacture a hazardous substance



A3 Explanatory notes to the flowchart

Items 1, 2 and 3

Information that should be reviewed includes that in the application, the Evaluation and Review Report, from experts and in submissions (where relevant). Review should occur in terms of section 28(2) of the HSNO Act and clauses 8, 15, 16 and 20 of the Methodology. Additional information may need to be sought under sections 52 and 58 of the HSNO 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'.

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 the 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 HSNO Act.

Item 8

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

Item 9

Consider whether any residual risks are negligible. Adopt a holistic perspective, 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, and (b) the cost-effectiveness of the controls. Where relevant and appropriate, add, substitute or delete controls while taking into account the applicant's view, and making sure 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 (ie, costs accrue only to the applicant), then the fact the application has been submitted is deemed to demonstrate the 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 HSNO 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 HSNO Act and (b) the cost-effectiveness of the controls. Where relevant and appropriate, add, substitute or delete controls while taking into account the applicant's view 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/or 13.

When 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.

When 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.