Council of Australian Governments

Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies

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Principles

A. Introduction

In its report to the Council of Australian Governments (COAG) in February 1994, the Committee on Regulatory Reform reported on key issues relating to the setting of national standards in Australia. Consideration of this issue was initially prompted by a paper which was released by major business associations in September 1992 which argued that Australia's regulatory system requires a major overhaul if the nation is to compete successfully in world markets and attract overseas investment. It suggested that our regulatory system is unnecessarily complex, generates delays, inconsistencies and additional costs for business investment as well as inhibiting risk-taking and enterprise.

The operation of the Mutual Recognition Agreement has also highlighted discrepancies in standards between jurisdictions and has created an impetus for the development of national standards. Under that Agreement, Ministerial Councils can potentially be called upon to make a standard on any product in the marketplace or develop nationally uniform criteria for the registration of any occupation. Given this mechanism for the development of nationally applicable standards, there is a need to ensure that where new standards are considered, they are subject to sufficient scrutiny to guard against the imposition of unnecessary regulation. It is also important to ensure that new standards do not impose excessive requirements on business. The aim of any national standards setting process should be to achieve minimum necessary standards, taking into account economic, environmental, health and safety concerns.

Other matters which were regarded as requiring further consideration were the need to move away from overly prescriptive standards towards performance based standards, the desirability of avoiding duplication in the impact assessment procedures of different jurisdictions when national standards are set, the monitoring of the appropriateness of proposed national standards to ensure that they conform to accepted regulatory principles and the possible adoption of procedures to encourage compliance with national standards.

Ministerial Council agreements are commonly translated into laws and regulations. Rather than create an artificial boundary between the different forms of regulatory control there is a need for a set of consistent principles that can govern the approach of Ministerial Councils and intergovernmental standard-setting bodies in developing all proposals which have a regulatory impact.

These guidelines consider the best processes to follow in determining whether a set of standards and their associated laws and regulations are the appropriate course of action for a

Ministerial Council or other standard-setting body to take. They describe the features of good regulation and conclude by recommending a set of principles for standard setting and regulatory action.

The principles of good regulatory practice apply to decisions of COAG, Ministerial Councils and intergovernmental standard-setting bodies, however they are constituted, and includes bodies established statutorily or administratively by government to deal with national regulatory problems.

The principles apply to agreements or decisions to be given effect, whether at the Commonwealth or State/Territory level, or both, through principal and delegated legislation, administrative directions or other measures which, when implemented, would encourage or force businesses or individuals to pursue their interests in ways they would not otherwise have done (but this does not include purchasing policy or industry assistance schemes). The principles do not apply to agreements or decisions that result in regulation that is minor or machinery in nature and does not substantially alter existing arrangements. Nor do the Principles apply to early "brainstorming" discussions of Ministerial Councils which are not supported by *written* submissions outlining regulatory options or recommendations regarding regulatory action.

Development of voluntary codes and other advisory instruments should take account of these guidelines and principles where there is a reasonable expectation that their promotion and dissemination by standard-setting bodies or by government could be interpreted as requiring compliance. For example, should non-compliance with provisions of a voluntary code be considered as evidence by a court or an administrative body when determining compliance with statutory obligations, such advisory documents are subject to the review process.

It is important to note that regulatory review was considered as part of the Hilmer report on competition policy. Of particular relevance to this exercise is the principle adopted by COAG in February 1994 that:

'Proposals for new regulation that have the potential to restrict competition should include evidence that the competitive effects of the regulation have been considered; that the benefits outweigh the likely costs; and that the restriction is no more restrictive than necessary in the public interest.'

The principles for national regulation making and assessment which are included in the guidelines are consistent with the objectives of national competition policy.

B. Regulatory Impact Assessment

Commonly, Ministerial Councils and other regulatory bodies reach agreement on standards or main elements of a regulatory approach which are then given force through principal or subordinate legislation. 'Regulation', for the purposes of these guidelines, refers to the broad range of legally enforceable instruments which impose mandatory requirements upon business and the community as well as to those voluntary codes and advisory instruments, noted above, for which there is a reasonable expectation of widespread compliance.

The most appropriate form of analysis should be applied to the identified costs and benefits and a conclusion drawn on whether regulation is necessary and what is the most efficient regulatory approach.

Potential regulators should identify the need for regulation and quantify the potential benefits and costs of regulation. The attached Regulatory Impact Statement Guidelines provide

guidance on how to undertake such analysis. A number of State and Territory Governments have produced similar documents which may be of use in assisting the regulatory impact assessment process.

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(1) The Need for Regulation

Before deciding upon a path of government imposed regulation, a number of questions need to be asked. These questions form a framework from which to decide upon the course of action that a Ministerial Council or standard-setting body needs to take.

• Is regulation needed?

What is the problem that needs addressing?
Where is the market failure? Is it a type of market failure that can be addressed without recourse to government regulation? When assessing the need for regulation, an essential first step is to review the adequacy of existing bodies of law (eg trade practices, consumer protection and product liability) which, wherever possible, should be used instead of industry specific regulation. What are the costs, risks or benefits of maintaining the status quo?

• Regulatory failure

Is regulation likely to improve upon market outcomes?

Could regulation lead to worse outcomes?

• Alternative solutions

What are the alternative approaches to dealing with the problem, including non-regulatory action?

• Benefits of regulating

What are the likely benefits, including risk reduction, of the proposed regulation? Who will reap these benefits and how certain are they?

• Cost of regulating

What are the likely costs of the proposed regulation? Who in the community will bear these costs?

• Public consultation

What is the feedback from public consultation on the points above?

• Support for regulation

What support is there for the proposed regulations, including support from suppliers and consumers and other parties bearing the costs of regulation?

• Impact on competition

What is the impact of the proposed regulatory measure on competition, including the introduction of new processes and techniques?

(2) The Need for Quantitative Analysis

Where a possible need for regulation is identified, quantitative analysis is needed to support this position and to establish the most efficient form which this regulation might take.

The basic feature of economic appraisal is its systematic examination of all the advantages and disadvantages of each practicable alternative way of achieving an objective. As set out below, there are a number of different approaches to quantitative analysis. Depending on the circumstances, one or more of the following techniques may be employed:

Risk analysis. This methodology is of use in addressing the threshold issue of whether or not to regulate. In making such an assessment, risk analysis should involve: an appraisal of the current level of risk to the exposed population due to the specific cause under consideration; the reduction in risk which will result from the introduction of the proposed measures; consideration of whether the proposed measures are the most effective available to deal with the risk; and whether there is an alternative use of available resources which will result in greater overall benefit to the community. Risk assessment should be used in conjunction with other quantitative assessment techniques.

Cost-benefit analysis. This technique requires that all the major costs and benefits of a proposal be quantified in money terms and is generally preferred over cost-effectiveness analysis. In this way, the outcomes of a range of options are translated into comparable terms in order to facilitate evaluation and decision-making.

Cost-benefit analysis is most effective in instances where there is sound information on which to base the analysis. However, it should also be noted that cost-benefit analysis should involve consideration of the distribution of benefits and costs, as well as taking account of impacts which cannot be valued quantitatively.

Cost-effectiveness analysis. This type of appraisal compares the costs of different initial project options with the same or similar outputs and can be used where it is difficult to place a dollar value on the major benefits of a proposal. This method therefore only allows a decision maker to compare options that have similar objectives and is somewhat limited in that it only enables comparisons of cost in only one dimension of benefit. However, it may be more readily applicable to social and community services (eg an anti-discrimination legislative proposal) than cost-benefit analysis. Nonetheless, it should be noted that cost-effectiveness analysis still requires the valuation of as many benefits of a proposal as possible.

Two additional points can be made. Firstly, impact assessment should attempt to assess all costs and benefits to the greatest extent possible, that is, not just economic ones. For example, social and environmental, public health and consumer safety effects should be considered. Secondly, the level of assessment will depend upon an estimation of the likely impact. Regulations with significant net costs or benefits will need detailed quantitative assessment.

As a general principle, the level of detail within the analysis should be commensurate with the impact of proposed regulatory measures and should adequately identify and where appropriate, quantify, the major costs and benefits of the proposal.

C. Principles of Good Regulation

This section outlines the principles of regulation in a general sense and the broad parameters within which standards and regulations should be developed. The first of these is that, as a general rule, the burden of proof that a regulation is necessary remains with the proponents of regulatory action.

Minimising the impact of regulation

Working from an initial presumption against new or increased regulation, the overall goal is the effective enforcement of stated objectives. Regulatory measures and instruments should be the minimum required to achieve the pre-determined and desirable outcomes. It may be necessary to introduce new regulation which replaces existing and less satisfactory regulation.

Legislation should entail the minimum necessary amount of regulation to achieve the objectives. Only those parts of a product standard originally developed for voluntary compliance by private standards writers which are necessary to satisfy regulatory objectives should be referenced in mandatory regulatory instruments adopted by government. Referencing of such voluntary standards should only occur following the application of these guidelines and principles.

Any assessment process for the development of regulations and/or standards should be scientifically rigorous, including, where appropriate, a risk assessment process which takes into account public health and safety and environmental protection.

Minimising the impact on competition

Regulation should be designed to have minimal impact on competition. Although it may be necessary, for example, to regulate some aspects of commercial practice, regulation should avoid imposing barriers to entry, exit or innovation. To meet the requirements of National Competition Policy, regulation should not restrict competition unless it can be demonstrated that:

- the benefits to the community from a restriction on competition outweigh the costs; and
- that the objectives of regulation can only be achieved by restricting competition.

Predictability of outcomes

Regulation should have clearly identifiable outcomes and unless prescriptive requirements are unavoidable in order to ensure public safety in high-risk situations, performance-based requirements that specify outcomes rather than inputs or other prescriptive requirements should be used. This principle should also apply to any standards that might be referred to in regulation.

International standards and practices

Wherever possible, regulatory measures or standards should be compatible with relevant international or internationally accepted standards or practices in order to minimise the

impediments to trade. Compatibility in this context does not necessarily imply uniformity, however.

National regulations or mandatory standards should be consistent with Australia's international obligations. Australia has obligations under the GATT Technical Barriers to Trade Agreement (Standards Code) and the World Trade Organisation's Sanitary and Phytosanitary Measures (SPS) Code. Regulators may refer to the Standards Code relating to the International Standards Organisation's Code of Good Practice for the Preparation, Adoption and Application of Standards.

Regulations should not restrict international trade

There should be no discrimination in the way regulatory measures, mandatory standards or conformity procedures are applied between domestic products or imported products, nor between imports from different supplying countries. Regulations should not be applied in a way that creates unnecessary obstacles to international trade. Even if they differ, standards from other countries should be accepted as equivalent to Australian standards if they adequately meet the objectives of Australian standards.

Regular review of regulation

Regulation should be reviewed periodically. Review should take place at intervals of no more than 10 years. This may be achieved through agreements to incorporate sunset provisions in legislative instruments.

Flexibility of standards and regulations

Specified outcomes of standards and regulatory measures should be capable of revision to enable them to be adjusted and updated as circumstances change. However, it is important to ensure that amendments to regulatory measures and instruments do not result in undue uncertainty in business operations and in so doing, impose excessive costs on that sector.

The exercise of bureaucratic discretion

Good regulation should attempt to standardise the exercise of bureaucratic discretion, so as to reduce discrepancies between government regulators, reduce uncertainty and lower compliance costs. This, however, should not preclude an appropriate degree of flexibility to permit regulators to deal quickly with exceptional or changing circumstances or recognise individual needs. Nor should it ignore the danger of administrative action effectively constituting regulation and thus avoiding disciplines of regulation review. There is a need for transparency and procedural fairness in regulation review and administrative decisions should be subject to effective administrative review processes.

D. Features of Good Regulation

In formulating national standards and regulatory measures according to the above principles, Ministerial Councils and other regulatory bodies should also take into account the following practical objectives.

Minimising regulatory burden on the public

Legislation should entail the minimum necessary regulation to achieve the objectives. When designing measures or standards, regulators should ensure that the potential regulatory burden of alternative measures on the community is identified. Non-regulatory alternatives to regulation should be explicitly considered, including the option of not introducing new regulation.

Minimising administrative burden

Regulators should develop standards or regulatory measures in a way that minimises the financial impact of administration and enforcement of regulation on governments and the sectors of the community which will be affected by them.

Particular attention should be paid to minimising financial impact in instances where different levels of government are involved. A regulator at one level of government may impose enforcement responsibilities on another level of government that the latter does not have the resources to carry out. This may undermine the effectiveness of regulation.

Regulatory impact assessment

Proposed regulation should be subject to a regulatory impact assessment process, which quantifies the costs and benefits of the proposal to the greatest extent possible. Incentive effects should also be made explicit in any regulatory proposal.

Accountability

As set out in the protocols for the operation of Ministerial Councils, it is the responsibility of Ministers to ensure that they are in a position to appropriately represent their Government at Council meetings. Therefore, to the greatest extent possible, Ministers should obtain full government agreement on matters which may involve regulatory action before they are considered at Ministerial Council level.

Where a Minister is dissatisfied with the outcome of the impact assessment process, the Minister may seek the agreement of his/her Head of Government to request an independent review of the assessment process.

Compliance strategies and enforcement

Regulatory measures should contain compliance strategies which ensure the greatest degree of compliance at the lowest cost to all parties. Incentive effects should be made explicit in any regulatory proposals. Measures to encourage compliance may include regulatory clarity, brevity, public education and consultation and the choice of alternative regulatory approaches with compliance in mind.

The special characteristics of process regulation need to be considered. For example, the number of licenses, certifications, approvals, authorities etc. should be kept to the minimum necessary to achieve the regulatory objectives.

The regulatory burden can be reduced if the public is required to undertake a minimum level of interaction with government to, for example, renew permits/ licenses or file information. This can be achieved through measures such as 'one stop shops'; mutual recognition of approval processes within government as well as between governments; better forms and process design.

Having taken these steps to facilitate compliance, regulators also need to consider the feasibility of enforcing regulatory requirements through the detection of non-compliance.

Mandatory regulatory instruments should contain appropriate sanctions to enforce compliance and penalise non-compliance. However, enforcement options should differentiate between the good corporate citizen and the renegade, to ensure that 'last resort' penalties are used most effectively (rarely) but model behaviour is encouraged. Enforcement measures should not have the effect of encouraging otherwise good corporate citizens to subvert compliance measures.

Consideration of secondary effects

Regulatory measures should be designed and/or alternative approaches to regulation chosen with explicit consideration of secondary effects and the nature of these effects outlined.

Inclusion of standards in appendices

Standards should be referenced as current editions in appendices to regulatory instruments rather than embodied in such instruments themselves. It may be appropriate in some circumstances for regulations to reference a specific standard (eg AS 1234).

A disadvantage of only referencing the title of a standard (eg AS1234) is that impact assessment is carried out only on the initial instrument and referenced standard. The standard, however, may be subsequently changed or updated. This may result in significant changes to the costs or benefits of regulation, with no opportunity to review the implications of such a change. This can have the effect of transferring regulatory power from governments to standard setters. To prevent this, it may be appropriate in some circumstances for regulatory instruments to reference a specific version of a standard by referring to its date (eg AS 1234, 1993). If an amended version of a standard is to be adopted any changes to this standard would then require amendment of the regulatory instrument and hence further impact assessment.

Performance-based regulations

Regulatory instruments should be performance-based, that is, they should focus on outcomes rather than inputs. 'Deemed to comply' provisions may be used in instances where certainty is needed. In such cases, regulations might reference a standard or a number of standards deemed to comply with the regulation. There should be no restrictions on the use of other standards as long as the objectives of the regulation are met.

Plain language drafting

Where possible, regulatory instruments should be drafted in ‘plain language’ to improve clarity and simplicity, reduce uncertainty and enable the public to understand better the implications of regulatory measures.

Date of effect

The dates of commencement of proposed standards and regulatory measures should be carefully planned to avoid or mitigate unintended or unnecessary market consequences, such as the necessity to discard non-complying stock and to allow transition to compliance with new regulatory requirements.

Advertising the introduction of standards and regulations

Public consultation usually only involves interested parties. Therefore, once produced,, new regulatory measures should be advertised to bring them to the attention of the wider community.

Public consultation

Public consultation is an important part of any regulatory development process. Consultation should occur when the course of regulatory action is being considered and a draft impact assessment statement is being produced. This will give interested parties a firm proposal to consider. Consultation should occur as widely as possible but at the least, should include those most likely to be affected by regulatory action (eg consumer and business organisations) which might provide valuable feedback on the costs and benefits of regulation and on the impact assessment analysis generally. Consultation will also provide feedback on the level of support for the proposed regulation.

E. Assessment of National Standards Proposed to be adopted by a Ministerial Council or other Intergovernmental Standard-Setting Body

All national (intergovernmental) standards which require agreement by Ministerial Councils or standard-setting bodies (including standards developed by other bodies) should be subject to a nationally consistent assessment process. The process is set out below.

(1) Minimum Assessment Requirements

Where a Ministerial Council or standard-setting body proposes to agree to regulatory action or adopt a standard, it must first certify that the regulatory impact assessment process has been adequately completed. The assessment process does not necessarily have to be carried out by the Ministerial Council but the Council or body should provide a statement certifying that the assessment process has been adequately undertaken and that the results justify the adoption of the regulatory measure. Most governments have regulatory impact assessment processes in place. The completion of regulatory impact assessments by Ministerial Councils and standard-setting bodies should remove the need to duplicate this analysis.

Adequate completion means that:

1. an impact statement for the proposed regulatory measures has been prepared which:

- demonstrates the need for regulation,
- details the objectives of measures proposed,
- outlines the alternative approaches considered (including non-regulatory options) and explains why an alternative approach was not adopted,
- documents which groups benefit from regulation and which groups pay the direct and indirect costs of implementation,
- demonstrates that the benefits of introducing regulation outweigh the costs (including compliance and administrative costs),
- demonstrates that proposed regulation is consistent with relevant international standards (or justifies the extent of inconsistency), and
- sets a date for review and/or sunsetting of regulatory instruments;

2. advertisements have been placed in all jurisdictions to give notice of the intention to adopt regulatory measures, to advise that the impact statement is available on request and to invite submissions;

3. a list of persons/groups who made submissions or were consulted and a summary of their views has been prepared; and

4. the Council or other intergovernmental standard-setting body has considered the views expressed during the consultation process.

The Australian Government Office of Regulation Review will have a role in assisting Ministerial Councils and national regulatory bodies in the preparation of Regulatory Impact Statements and advising on whether they are consistent with the requirements agreed in these Principles and Guidelines. Attachment A sets out the mechanisms through which this will be achieved.

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(2) Review

If, at the conclusion of the impact assessment process outlined above, there is some dissatisfaction with the process or adequacy of the analysis by which its conclusions were reached, two or more jurisdictions may request a review of the proposed national standard. The Ministerial Council or other intergovernmental standard-setting body must then defer its consideration of the standard and commission a review.

The process of independent review would be triggered if two Heads of Government write to the Chair of the Ministerial Council or standard-setting body requesting an independent review of the assessment process. Upon completion, the review body will report back to the relevant Ministerial Council or standard-setting body.

The Ministerial Council is to nominate an independent body to conduct the review. This might include a regulatory review body in any jurisdiction, an appropriate specialist body or a consultant. Jurisdictions which request the review will meet its cost and agree to make

resources available for the conduct of the review if the Ministerial Council decides to use State or Territory Government regulatory review units to conduct the review.

The review body's task is to reassess the impact statement and report on whether it can be demonstrated that the assessment process has been carried out according to the guidelines for adequate completion noted above. It is not intended that the independent review should necessarily repeat the quantitative analysis. The review body may also comment on any aspect of the proposed regulation and will have access to public submissions made in the course of the assessment process.

The report of the independent review body would become a public document and will be considered by the Ministerial Council or standard-setting body in its discussion of the adoption of the proposed regulatory measures. Once the report has been considered, the Council or standard-setting body's consideration of whether or not the regulation should be adopted by member governments can proceed.

The initial impact assessment and any review of that assessment are designed to provide the best possible information for decision making by the Ministerial Council or standard-setting body. The impact assessment will not usually bind them or the participating governments since most Ministerial Councils are not formally established and do not have formal and binding voting arrangements. Their purpose is to develop a national consensus in relation to the matters which they consider.

If, upon the advice of the review body, a State or Australian Government regulatory review body, or other advice, the impact assessment is found to have been faulty, the Council retains discretion in its use of the impact assessment to inform its decision making.

If a Ministerial Council or standard-setting body fails to act on the recommendations of the review, the matter may be further examined by Heads of Government.

Attachment A

The Australian Government Office of Regulation Review will provide advice and assistance on the preparation of Regulatory Impact Statements prepared for Ministerial Councils and standard setting bodies and monitor the compliance with the requirements of the COAG Principles and Guidelines. The process to be followed is as detailed in paragraphs one through ten below.

1. When developing regulatory proposals, Ministerial Councils or standard setting bodies (or bodies preparing advice on regulatory issues for these decision-making fora) should consult early with the Office of Regulation Review and seek advice about whether a Regulatory Impact Statement should be prepared. Furthermore, forward notice should be given to the Office of Regulation Review that a Regulatory Impact Statement will be drafted on a relevant topic.

2. A draft Regulatory Impact Statement for a regulatory proposal should be sent for advice to the Office of Regulation Review by the Ministerial Council or standard setting body (or its secretariat or advisory committee) as soon as practicable and before the Regulatory Impact Statement is made available for public comment. Where a Trans Tasman (such as TTMRA) issue is involved , the ORR should refer it to the Regulation Impact Analysis Unit of the NZ Ministry of Economic Development, to allow for comment-feedback to the ORR.

3. The Office of Regulation Review will assess the Regulatory Impact Statement within two weeks. The main focus of this assessment will be whether the Regulatory Impact Statement meets the requirements set out in the Principles and Guidelines. In particular, the Office of Regulation Review will assess:

• whether the Regulatory Impact Statement guidelines have been followed;

• whether the type and level of analysis are adequate and commensurate with the potential economic and social impact of the proposal; and

• whether alternatives to regulation have been adequately considered.

The Office of Regulation Review will advise the Ministerial Council or standard setting body (or its secretariat or advisory committee) of its assessment. This advice should incorporate any comments from NZ relating to a Trans-Tasman issue. That advice may or may not be adopted by the Ministerial Council or standard setting body.

4. The Ministerial Council or standard setting body may consult further with the Office of Regulation Review as the Regulatory Impact Statement is developed.

5. Upon completion, a final version of the Regulatory Impact Statement should be sent to the Office of Regulation Review. The Ministerial Council or standard setting body should await the final comments of the Office of Regulation Review prior to public release of the Regulatory Impact Statement.

6. The Regulatory Impact Statement may be developed further following its public release, taking into account outcomes from community consultation. The final Regulatory Impact Statement should be forwarded to the Office of Regulation Review prior to a decision being made by a Ministerial Council or standard setting body.

7. Following a decision by the Ministerial Council or standard setting body to proceed with a regulatory course of action, the decision making body should respond to any issues that have not been dealt with in the way recommended by the Office of Regulation Review.

8. Both Office of Regulation Review comments and any responses made by Ministerial Councils and standard setting bodies should be available to State, Territory and Australian Government Cabinets.

9. The Office of Regulation Review is to report to the Commonwealth-State Committee on Regulatory Reform if, in its opinion, decisions of Ministerial Councils or standard setting bodies are inconsistent with COAG guidelines. The Committee on Regulatory Reform will in turn advise COAG concerning major issues.

10. A Ministerial Council may decide that a situation requiring a regulatory response is an emergency. In these cases, a Regulatory Impact Statement need not be prepared before the regulation comes into effect. However, the Chair of the Ministerial Council must write to the Prime Minister before making the regulation:

• seeking agreement to waive the need for a Regulatory Impact Statement; and

• explaining why the situation was an emergency and why no transitional measures were available.

If the situation was an emergency, the Ministerial Council would be expected to prepare a Regulatory Impact Statement within 12 months of making the regulation.

Alternatively, in emergency cases the briefing material prepared for a Ministerial Council or standard setting body can be provided to the Office of Regulation Review, which will advise whether the key elements of a Regulatory Impact Statement are addressed in such material. If so, the Office of Regulation Review can "post assess" the material as complying with the COAG Regulatory Impact Statement Guidelines.

For multi-staged decision-making processes, where a Regulatory Impact Statement is prepared in accordance with these guidelines, a RIS will not generally be required for follow-up or subsequent regulation which implements the original decision, unless significant additional regulation is contemplated.

The Office of Regulation Review does not have any power over decisions made by Ministerial Councils and standard-setting bodies. COAG has directed the Office to provide independent advice on the adequacy of Regulatory Impact Statements prepared for both public consultation and decision by Ministerial Councils and national standard setting bodies. In fulfilling this role the Office does not support any particular regulatory approach or jurisdiction. The Office can only assist and advise as to whether a Regulatory Impact Statement is consistent with the Principles and Guidelines. However, the attention of Heads of Government can be drawn to regulatory proposals for which Regulatory Impact Statements are seriously inadequate.

Guidelines

Regulatory Impact Assessment

One of the key features of the Council of Australian Governments' (COAG) report on a Framework for National Standard Setting and Regulatory Action is a requirement for all regulatory proposals to undergo impact assessment. Impact assessment serves a number of important purposes. It provides policy analysts and decision makers with information on:

- the appropriateness or otherwise of government regulatory action in any particular circumstance;
- the most effective form that government intervention might take to achieve a desired objective;
- the relative social costs and benefits of regulation; and
- who in the community will reap the benefits or incur the costs of regulation.

Information on impact assessment should be presented in the form of a regulatory impact statement (RIS). The objective of this part of the Framework is to give policy analysts information on how to prepare an RIS and a basic understanding of the quantitative tools available to measure the impact of government action. The depth of analysis needed will depend to a large degree on the level of impact a proposal might have. As a minimum, some preliminary analysis of the potential magnitude of costs and benefits will be required in all cases to determine if the likely effects are significant enough to warrant quantitative analysis, and to justify the costs of carrying out such analysis.

The information provided below is unlikely to be sufficient on its own to enable formal quantitative analysis to be carried out. This will require the professional expertise of those trained in the field. There should be enough information, however, to give policy makers a good understanding of the techniques available and make some assessment of which might be the most appropriate for the task at hand.

The next section discusses the purpose and contents of an RIS and gives an overview of the main tools available for impact assessment which are covered in more depth later on. This is followed by a consideration of the threshold question: Is government intervention necessary or desirable? A closer look is then taken at risk analysis, cost-benefit analysis and cost effectiveness analysis respectively. Finally, there is a short discussion of some of the issues that need to be taken into account when deciding which techniques are the most appropriate in different circumstances.

Regulatory Impact Statements

The purpose of preparing a regulatory impact statement (RIS) is to draw conclusions on whether regulation is necessary, and if so, on what the most efficient regulatory approach might be. Completion of a RIS should ensure that new or amended regulatory proposals are subject to proper analysis and scrutiny as to their necessity, efficiency and net impact on community welfare. Governments should then be able to make well-based decisions. The process emphasises the importance of identifying the effects on groups who will be affected by changes in the regulatory environment, and consideration of alternatives to the proposed regulation.

Impact assessment is a two step process: first, identifying the need for regulation; and second, quantifying the potential benefits and costs of different methods of regulation. In demonstrating the need for the regulation, the RIS should show that an economic or social problem exists, define an objective for regulatory intervention, and show that alternative mechanisms for achieving the stated objective are not practicable or more efficient.

How to prepare a RIS

The basic feature of a RIS is the systematic examination of the advantages and disadvantages of possible methods of achieving the objective. There are a number of different approaches available, including:

- risk analysis;
- cost benefit analysis; and
- cost effectiveness analysis.

There is no general rule to suggest that one technique should be used in all the circumstances. The analytical requirements of regulatory review procedures are flexible and do not prescribe the use of any particular technique. Table 1 provides an overview of the techniques available for impact analysis and their advantages and disadvantages. Some regulatory proposals are better analysed by using one technique rather than another, or by using a combination of them.

A RIS should attempt to assess all costs and benefits to the greatest extent possible. Where relevant, economic, social, environmental, public health and consumer safety effects should be considered.

The contents of a RIS

The key prerequisites for an RIS are that an initial assessment indicates that regulation is necessary and that the groups affected have been given, to the extent possible, advance notice of any new regulation or amendment and have been consulted adequately, unless there are very sound reasons for not taking such steps.

The following details should be outlined in an RIS.

• **Statement of the problem:** why is government action being considered in the first place? What is the problem being addressed? For example, this should state the market failure that the proposal seeks to remedy.

• **Objective**: the objective which the regulation is intended to fulfil must be stated in relation to the problem. The objectives of a regulation are the outcomes, goals, standards or targets which governments seek to attain to correct the problem.

• **Statement of the proposed regulation and alternatives:** this should describe the proposed regulation and distinct alternatives in sufficient detail to allow comparative assessment and evaluation in the rest of the RIS.

• **Costs and benefits:** there should be an outline of the costs and benefits of the proposal(s) being considered. This should include direct and indirect economic and social costs and

benefits. There should also be analysis of distinct alternatives (including 'do nothing') to the proposed regulation.

• **Consultation**: a RIS must outline who has been or will be consulted, and who will be affected by the proposed action. On a case by case basis, this may involve consultation between departments, with interest groups, with other levels of government and with the community generally.

• **Evaluation**: there should be an evaluation of the relative impacts of the proposal and any alternatives, to show that the desired policy objective cannot be achieved at a lower cost to business and the community at large.

• **Review**: there should be consideration of how the regulation will be monitored for amendment or removal. Increasingly, sunset provisions are regarded as an appropriate way of ensuring regulatory action remains justified in changing circumstances.

The requirements of a RIS should be flexible because all elements will not be relevant to all proposals.

If it is established that a regulatory process is unavoidable, regard should be had to the following broad principles in settling the details of a regulatory regime:

- simplicity;
- equity;
- efficiency;
- avoiding excessive rigidity; and
- need for periodic reviews of relevance and performance.

A number of more specific principles underlying those above were outlined earlier in the report to which this paper is an attachment.

Table 1: Summary of regulatory techniques

Technique	*Description*	*Advantages*	*Disadvantages*
Risk analysis (basic)	Quantitative assessment of the magnitudes of the risk affected by proposal.	Provides an indication of whether a proposal will be effective in significantly reducing risks. Recognises trade-offs in risk-related policies.	Risk impacts may be diverse and not commensurate. The costs of achieving risk reduction and other non-risk impacts are not addressed.
Risk-risk analysis	Assessment of all risk effects of a proposal, including those in response to	Provides a limited recognition of other regulatory effects.	Risk impacts may be diverse and not commensurate.

Technique	*Description*	*Advantages*	*Disadvantages*
	costs.	Recognises trade-offs in risk-related policies.	Does not recognise other non-risk effects or costs.
Risk-benefit analysis	Evaluates the benefits associated with a proposal in comparison with its risks.	Considers all risks, benefits and costs.	Factors to be considered are not commensurate.
Cost-benefit analysis	Involves the identification and calculation of all costs and benefits.	Reflects favourable and adverse effects of a proposal from the view of society as a whole.	Some important benefit and cost components may not be measurable and, hence, given less weight.
	An important criterion is if benefits exceed costs, a proposal is potentially desirable.	Addresses whether a proposal is in society's best interests.	Criterion may be less convincing if distributional impacts are considered important.
Cost-effectiveness analysis	Involves the calculation of a cost per unit of prescribed benefit achieved for different proposals.	Eliminates more costly proposals from consideration.	Does not resolve the choice of the optimal level of benefits.
	A proposal that can generate the same benefit at least cost compared to others is preferred.	Provides an index of the relative efficacy of proposals in generating a benefit.	Does not resolve the question whether a proposal would lead to net social gains. Criterion is inconclusive when different benefits are generated by different proposals.

Source: Based on Viscusi (1992) and Bentkover, Covello, Mumpower (1986)

Step 1: The Threshold Question: Is Government Intervention Required?

Government intervention in the market is justified if there is what economists term to be 'market failure'. Box 1 describes these concepts in more detail. Market failure may arise if there is:

• imperfect competition;

• externalities;

• public goods; and

• imperfect or costly information.

Box 1: Types of market failure

Many of the problems which governments seek to redress through intervention originate in some sort of market failure. In this context, the word 'market' is used broadly and encompasses a wide range of potential interactions between members of the community, be they individuals, governments or business. Market failure can occur for a number of reasons.

Imperfect competition - Markets can fail to produce efficient and/or equitable outcomes if imperfect competition exists. Monopolies (where there is a single seller that is able to determine the price level), oligopolies (where a few sellers act strategically to influence the price of the good) and monopsonies (where there is a single buyer) are examples of imperfect competition. Governments may choose to intervene in markets to guard against the adverse outcomes that may be produced by imperfect competition.

Externalities - These are the spillover effects, both positive and negative, that result from market transactions. Often the prices of goods and services do not recognise the presence of externalities. For example, the environmental pollution caused by electricity generation may not be reflected in electricity prices. Governments may choose to impose emission controls, or pollution taxes to reflect this type of externality. As a result consumers will face prices that more accurately reflect all the costs to the economy and the environment of their consumption and their decisions will be weighted accordingly.

Public goods - These are goods characterised by non-rivalry in consumption. That is, consumption of the good by one person does not prevent it from being consumed by others. It might be impossible to prevent people from consuming such goods, which can make getting people to pay for them difficult. Markets will often fail to provide public goods for these reasons. An example might be a lighthouse or a fireworks display. Often governments provide public goods because they would not be supplied if left to the market.

Imperfect or costly information - The competitive market model assumes that prices and other relevant information is available at no cost. Furthermore, it assumes that the information obtained is perfect. Neither of these assumptions hold in reality, and costs and accuracy of information varies greatly. Markets sometimes fail, therefore, because of a lack of information or because the cost of obtaining information is too high to make it worthwhile. An example of government intervention in the presence of imperfect information are so called 'lemon laws' which protect used car buyers.

The framework developed below is a generic approach and can be used to analyse the need for government intervention in the case of any type of market failure. The framework is outlined in Figure 1. It involves several sequential steps.

1. Identify the main type of market failure, for example, imperfect competition, externality, public good or other.

2. Identify the precise nature of the market failure for each of those identified. For example:

- externalities - air (greenhouse gases), water (blue green algae);
- imperfect competition - the presence of a monopoly; and
- public goods - vaccination programs.

3. Estimate the magnitude of the market failure using appropriate indicators such as economic, social, environmental or other relevant criteria and determine if the externality is major, moderate or minor.

- If the market failure is moderate to major, explore if there is a case for government intervention.
- If the market failure is minor, there is unlikely to be a case for government intervention.

4. What form should government intervention take?

Government intervention to correct market failure can be direct or indirect.

Direct government intervention results in, for example, government undertaking to provide the good or service or contracting the private sector to do so. In the case of externalities, examples of direct government intervention may be to provide a water purification plant, lung cancer screening, food inspection services or infrastructure to remote areas (eg water, electricity, telecommunications).

Indirect government intervention to correct market failure seeks to create a suitable environment for the market to operate, up to and including regulatory solutions. The main types of indirect government intervention are as follows:

• Suasion

Will publicity, moral, social or political pressure be sufficient to modify behaviour?

• Pure market approaches

The objective here is to create a market by defining property rights to correct the market failure. The questions to be asked and the decision making pathway are described as follows:

- can property rights be defined? For example, the right to uncontaminated food, clean air and water and safe goods and services.
- is information available for this purpose?
- will research generate this information?
- can property rights be assigned?
- can property rights be traded?

- are benefits greater than costs?

If property rights cannot be adequately defined and assigned, the next best alternative is to use economic approaches.

- Economic approaches

Here economic instruments are used to send more accurate market signals to individuals and groups about the relative costs and benefits of their actions.

Can tradeable permits or licences be instituted to 're-create' a market environment?

Will solutions such as taxes, charges and licence fees have the desired impact in correcting market failure? Taxes and charges are the most efficient since they send the correct market signals and internalise the cost of the market failure. The tax forces the producer to face both the private and social costs of their actions.

If a system of taxes and charges cannot be developed or would not work effectively, a further option is to look at the feasibility of incentives such as subsidies and tax exemptions. Incentive-based approaches are less preferred than taxes and charges since government have to generate a source of funds to support incentives. Increasing taxes to fund subsidies is likely to distort behaviour elsewhere in the economy.

- Regulatory approaches

If market-based solutions like those described above cannot correct the market failure, governments may need to consider command and control instruments, that is, regulatory approaches. A regulatory approach should be the last option. Economically, they are the least efficient and may impose significant costs on the community.

In some circumstances, for example, areas related to health, safety and the environment, regulatory approaches may be unavoidable. In the past, however, governments have often seen regulatory approaches as the first option. This may, in part, be because it is only in the last few decades that more sophisticated market-based approaches have been developed, greatly expanding the options available to improve economic and social outcomes without recourse to regulatory approaches.

5. Which form of government action is the most appropriate?

Having analysed the problem of market failure using the above framework, it may be apparent that a single instrument may not be the answer to correct the market failure. A mix of instruments may be more appropriate in some instances. In making the final decision, the following questions need to be asked:

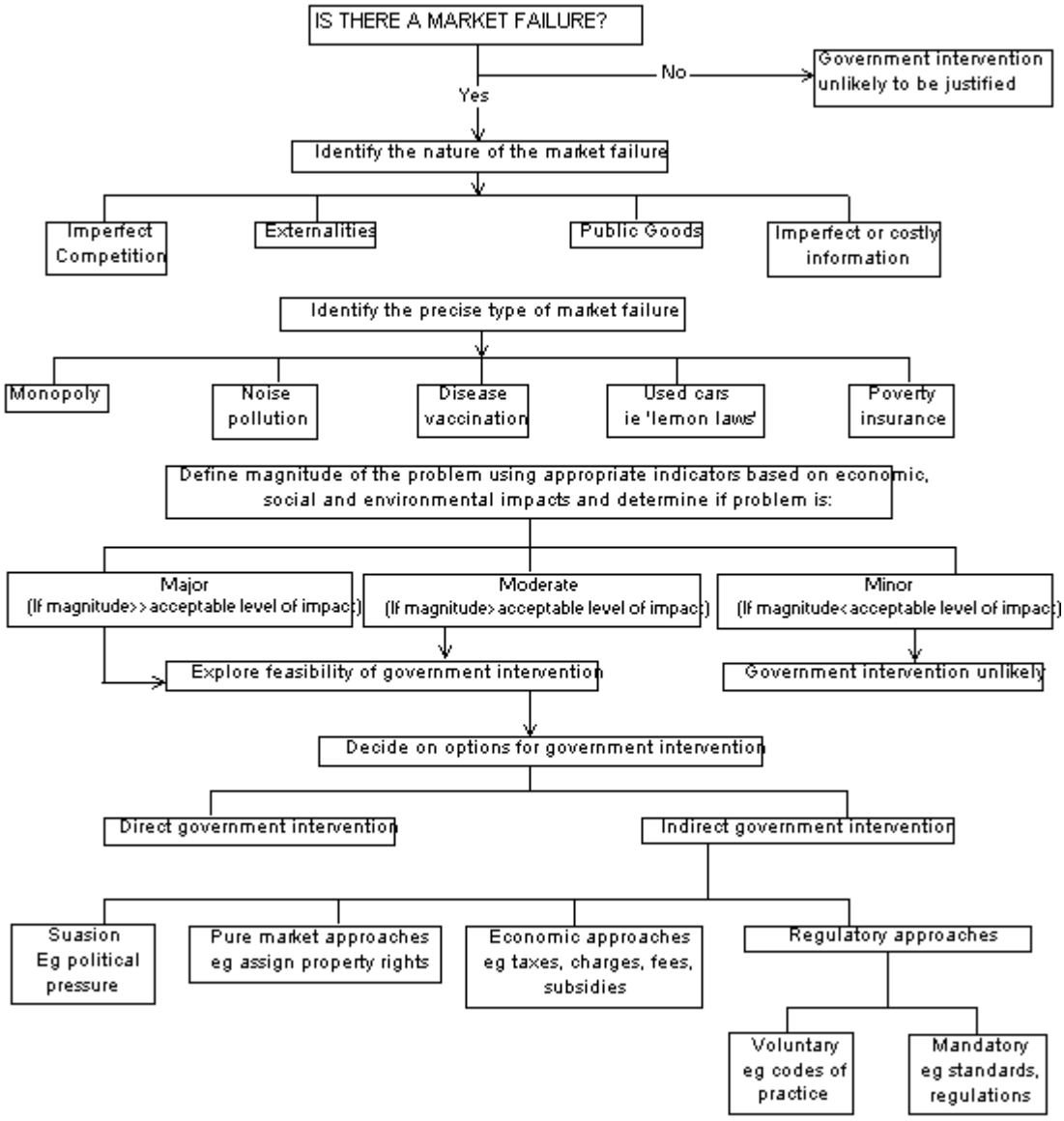
- what is (are) the most appropriate instrument(s)?;
- is it equitable?;
- what is the risk to government?;
- is it practicable to implement?;
- does an implementing agency exist?;
- what are the costs of monitoring and evaluation?; and

- is it consistent with government policy?

The more significant the problem governments are seeking to address, the more significant the likely impact of any government intervention. To ensure that the costs of government action do not outweigh the benefits, careful analysis needs to be conducted on proposals for government intervention, whether in the form of market, economic or regulatory approaches.

After the first stage of a RIS is completed, that is, determining if a market failure exists that warrants government intervention and considering which form of action could potentially redress the market failure, the next step is to analyse the costs and benefits of alternative proposals to determine if any result in net benefits and/or which generate the greatest benefits for the least cost.

Figure 1: DECISION FRAMEWORK FOR GOVERNMENT INTERVENTION



Step 2: Quantifying the Impact of Government Action

Risk analysis

If intervention relates to public health and safety, as it often does, risk analysis can be a useful tool. It can also be used to measure other types of risks, for example, commercial risk, or risk to the environment. Risk analysis can serve a number of functions. By comparing the risk associated with the status quo with that after government intervention, it can be used to determine more accurately whether intervention is appropriate and/or worthwhile. Risk analysis can also be used as an input into other assessment techniques like cost-benefit analysis and cost effectiveness analysis.

Risk analysis, in its most basic form, involves quantitative assessment of the magnitudes of the risk affected by the proposal. The contents of a risk analysis can easily be extended by the assessment of additional information, such as benefits or associated risks. Risk analysis can also be used as an input to other forms of analysis, such as cost-benefit analysis and cost-effectiveness analysis.

Risk analysis is a valuable tool in further addressing the threshold issue of whether or not to regulate, but it can also be used for other purposes. These range from assessing the mechanical impact of regulation on risks to estimating the cost-effectiveness of reducing risks.

Furthermore, risk analysis is of use in answering two important questions. First, whether the risks that regulation is intended to address are of significant magnitude compared with other risks. Second, the extent to which regulation reduces the initial risk problem.

What is risk?

Risk is the probability of an undesirable event occurring. Much regulatory activity, for example in the areas of health and safety, is concerned with the risk of persons being harmed by engaging in a particular activity (for example, by consuming a product or by working in a factory). The notion of harm encompasses fatality, injury or illness.

Risks can be viewed in several ways. It is possible to look at societal risk or individual risk. The former averages out individual risk and measures the risk to society as a whole or to a large group of people. Individual risk, on the other hand, varies from person to person. In addition, voluntary risk can be distinguished from involuntary risk. Voluntary risk occurs where an individual can choose to undertake or avoid the risk-causing activity and is fully aware of the consequences (for example, playing sport).

Conversely, involuntary risk occurs where there is no choice or inadequate information about the consequences. As discussed earlier, incomplete information is one of the main form of market failure. An analysis should also make a distinction between perceived risks and actual risks. Perceived risks occur where individuals overstate the importance of relatively improbable events or discount the importance of highly probable events.

An important distinction to make when conducting risk analysis is that between risk and uncertainty. Risk involves a situation where the probabilities of the various outcomes are reasonably well known. In statistical terms, a probability distribution can be attached to the cost or benefit in question. Uncertainty involves a situation where, while the values the costs or benefits may take may be known, the probabilities of the outcomes are not known.

What is risk analysis?

Risk assessment is a means of analysing the risk of an undesirable event occurring and the consequences that are liable to arise if does occur. An integral part of the assessment process, following on from those first two steps, is determining what action may be necessary to reduce or eliminate the risk and/or its consequences.

Risk analysis is commonly used by policy analysts as a means of assessing individual and societal risks and proposing possible regulatory and non-regulatory solutions to an identified problem. It is most commonly used to analyse regulatory interventions in the health and safety field. However it can also be applied in other public policy fields.

Content of a risk analysis

The following issues can be addressed in the risk assessment of regulation:

- an appraisal of the current level of risk to the exposed population from an identifiable source;
- the reduction in risk which will result from the introduction of the proposed measures;
- consideration of whether the proposed measures are the most effective available to deal with the risk; and
- whether there is an alternative use of available resources which will result in greater overall benefit to the community.

Limitations of risk analysis

There are a number of ways of assessing risk and the impact it is liable to have. They tend to be relatively arbitrary and non-empirical, so that a set of results can be easily interpreted by different persons in different ways. Risk assessment does not normally involve an assessment of the costs likely to be incurred by the affected parties (whether humans, plants, animals or the environment) if the undesirable event does happen. Nor does it take into account the costs and benefits associated with the measures proposed to reduce or eliminate the risk and /or its consequences.

Risk analysis should therefore not be used as the sole basis for deciding whether to take action to correct an undesirable situation or for determining the type of action to be taken.

The analysis process

Risk analysis involves three distinct but inter-linked steps (see Figure 2):

- defining the risk;
- selecting the appropriate response; and
- monitoring the situation and reviewing the effectiveness of the response that was selected and implemented.

Defining the risk

The following questions should be answered to ensure that the risk is defined as accurately as possible:

1. What is the hazard? It is necessary to define exactly what the hazard is.

2. What is the risk? It is important to distinguish between commercial risks and physical risks. Commercial risks can, and probably should, be borne by the company or industry involved and resolved at that level. On the other hand, a physical risk (and this ranges from a direct personal threat to life to environmental pollution) is a problem that is likely to affect individuals and society as a whole and therefore is best addressed at the appropriate government level.

3. How widespread is the risk? Is the risk local only, is it state-wide, national or international? Obviously, the extent of measures to be considered to combat the risk will depend on this assessment, and may the include the need for international co-operation.

4. Is the risk transmittable? In the case of medical risks, for example (such as a contagious disease), the transmitability of the risk is crucial to this assessment, as is the means of transmission and its avoidability. This will also involve identification of the source of the risk and whether transmission occurs across boundaries, for example, from plants to insects to animals to humans, or between different geographical locations.

5. In what circumstances will the risk arise? Is the risk continuous, or will it arise only in particular circumstances (eg if a product is used only in a specific way; or only if a particular chemical is used).

6. Who or what is most at risk? Identification of the at-risk groups is crucial. It is necessary to determine for instance whether children of certain ages are most at risk, whether it is the population as a whole, whether the risk is confined to a particular group (eg, only plants, or male children below the age of 10, or women over 45).

7. Is harm or injury liable to occur? Having gone through the above steps, it is important to determine whether any actual harm (eg, to the environment) or injury is liable to occur. This necessarily involves assessing not only the immediate effects but also the longer term effects. If no actual harm or injury is liable to occur, then any question of intervention probably becomes almost superfluous.

Selecting the response

This is the second step in the risk analysis process. It is dependent on the accuracy and completeness of having defined the hazard.

The first question to be asked is whether there is any realistic, viable action that the government can take to correct or ameliorate the situation. If the answer is no, or if the costs of any action are likely to outweigh the benefits, then serious consideration should be given to not taking any action at all. An explanation must be given as to what actions were considered, why they are impractical and the consequence (if any) of no action being taken.

Monitor the situation and review the effectiveness of the response

Whether the selected response is no action, introduction of a tax or subsidy, or a voluntary code of practice or a mandatory regulation, it is essential that both the situation and the effectiveness of the response be closely monitored. Monitoring will determine whether:

- the risk was under- or over-estimated and the response is adequate in the circumstances;
- the risk has changed and the response no longer applies to new circumstances; and
- those at which the action was directed are responding.

The monitoring and assessment process requires determination of:

- whether the risk has been eliminated. In which case, can the response be removed altogether or should it be retained in place to prevent a recurrence of the risk?;
- whether the risk has been reduced but not eliminated. It may be unrealistic to expect complete elimination of the risk to occur. In that case, what level of reduction in the risk leaves a situation which, whilst not necessarily ideal, is acceptable?; and
- how much longer the response should be left in place. If any reduction in the level of risk is not sufficient to justify considering the situation to be acceptable, how much longer should the response stay in place to reach an acceptable level of reduction?

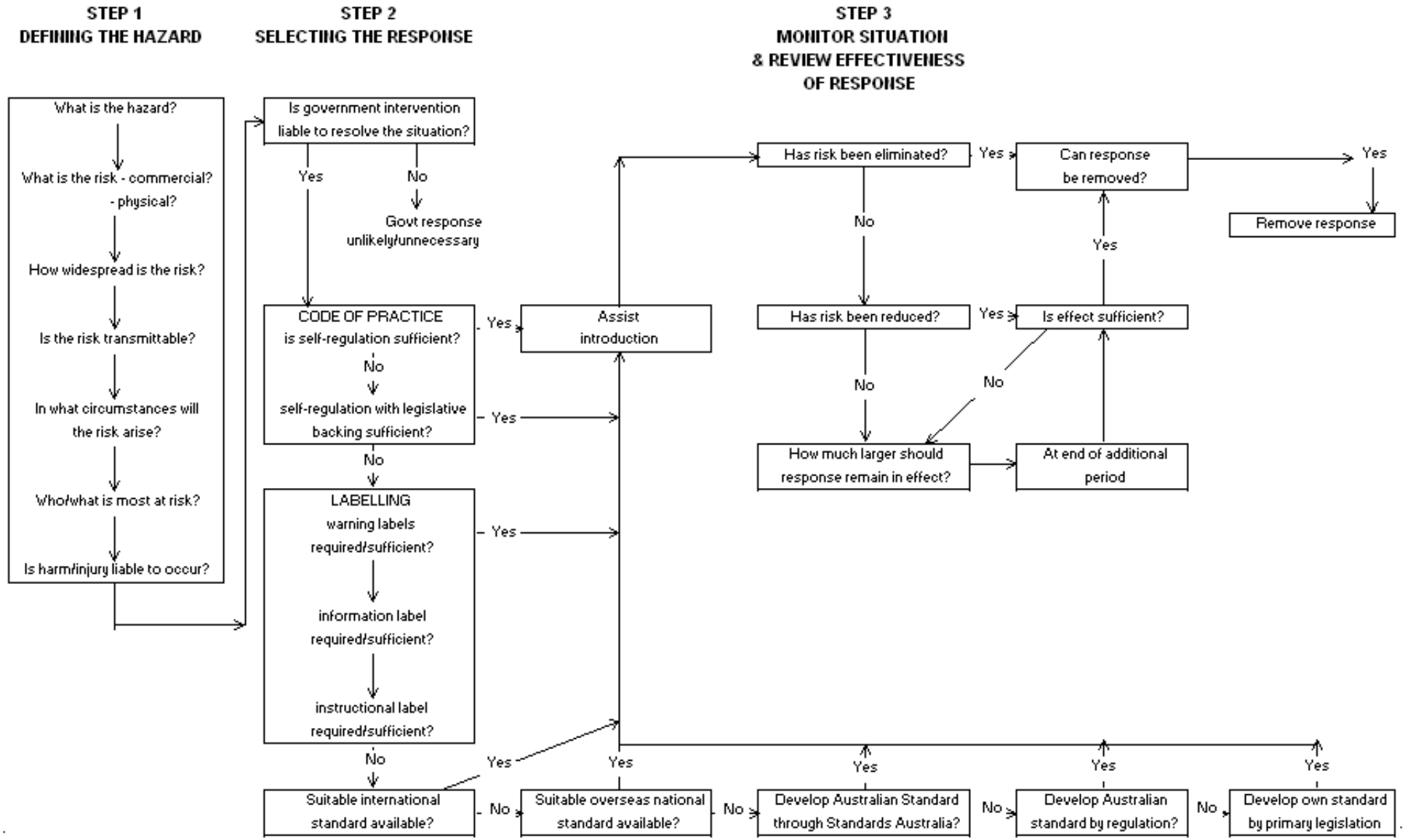
Extending risk analysis

Risk analysis can extend beyond the particular risks targeted by government action. Risk-risk analysis addresses the net effect of intervention on all risks and involves examination of risk trade-offs. This type of analysis arose largely from concerns that some regulations intended to reduce particular risks actually increased the total risk. For example, while fuel economy standards designed to promote the production of smaller and more fuel efficient cars may reduce health risks associated with environmental pollution other things being equal, it does this at a greater risk of harm to passengers from accidents.

Information about risk levels and their associated costs are available to a limited extent from insurance markets associated with particular risks, for example, motor vehicle use. There are some risks for which there may be no market information, for example, the risks associated with bungee jumping. Methodologies have, however, evolved to evaluate such risks. One such methodology is willingness-to-pay. That is, what will individuals be prepared to spend to reduce or eliminate the chances of risk.

A further extension of risk analysis is that of risk-benefit analysis. This involves evaluating the benefits associated with a proposal in comparison with its risks. Risk analysis can also be incorporated into cost-benefit and cost-effectiveness analysis.

Figure 2: RISK ANALYSIS FRAMEWORK



Cost-Benefit Analysis

What is cost-benefit analysis; and how and where can it be used?

Cost-benefit analysis (CBA) is a procedure that can be used to measure the economic and social impact of government action by reference to the 'net social benefits' that action might produce. As such, it can be a valuable aid to decision making. Its power as an analytical tool rests in two main features:

- costs and benefits are each as far as possible expressed in money terms and hence are directly comparable with one another; and
- costs and benefits are valued in terms of the economy as a whole, so the perspective is 'global'. This contrasts with, for example, a financial evaluation, which is conducted from the vantage point of an individual, a firm, an organisation or group.

Decisions about the overall effectiveness of regulatory action should not be made on the basis only of its effect on particular groups in society. Public policy makers are expected to make judgements based on what is best for the community as a whole. By measuring 'social', as opposed to only private, market-based costs and benefits, CBA is a valuable tool when developing good policy responses to economic and social problems. When undertaking CBA as part of the evaluation of the regulatory action being considered, TTRMA Principles should be adequately considered.

The term 'net social benefits' refers to the difference between social benefits and social costs. According to the cost-benefit rule, government action is only justified where, subject to budget constraints, there are positive net social benefits expected to be gained from intervention, such as imposing regulations on the community. Benefits and costs are 'social' rather than private or individual, in the sense that they are measured irrespective of the people to whom they accrue and are not confined to formal market transactions. If there are non-market implications from regulatory activities or market prices are distorted, CBA proceeds as if the correct market prices existed. These are referred to as shadow prices.

Inevitably, some costs and benefits resist the assignment of dollar values. Known as 'intangibles', these are separately presented to decision-makers for assessment in conjunction with those that can be quantified.

A major advantage of CBA is that costs and benefits occurring at different points in time can be explicitly compared. The 'factoring down' of benefits and costs that will occur in the future into present values is known as 'discounting' [. In the same way interest rates are used to calculate the present value of a given amount of money in, say, 10 years time, discount rates are used to determine equivalence between the current value of a dollar and the dollar value of costs and benefits occurring in the past or future.] . Since a dollar in the future is usually worth less than a dollar today, future costs and benefits need to be discounted to their equivalent 'present value'. Conversely, in a retrospective analysis, past costs and benefits are compounded forward to their present value.

Under the net present value rule, a regulatory activity should only be undertaken if its net present value (ie benefits minus costs) is positive. Accordingly, CBA is a valuable tool for decision makers when assessing the issue of whether a particular proposal is appropriate. If comparing a number of options, the alternative with the highest positive net present value would be preferred.

CBA can provide guidance on the implications of regulatory activity, where there are grounds for mistrusting the signals provided by market prices or where no markets exist. CBA is also helpful where regulations impose 'spillover' costs or benefits on third parties. Often these do not receive due recognition because no formal market transactions take place. Through the use of shadow prices, values can be placed on non-market 'spillover' effects (eg pollution, safety) and compared with market transactions.

Examples where the signals that market prices normally provide are either absent or fail to reflect the true costs of regulatory action arise when valuing:

- intermediate goods - such as savings in travel time resulting from transport regulations;
- 'externalities' - or unmarketed positive or negative spillover effects such as arise from pollution, vaccination programs or banning a dangerous product;
- goods affected by taxes and subsidies; and
- labour in the presence of unemployment.

Cost-benefit analysis is employed in various ways, for example, when deciding:

- whether a regulatory proposal should be undertaken;
- if an existing regulation should be maintained; or
- between alternative regulatory proposals (usually aimed at similar objectives).

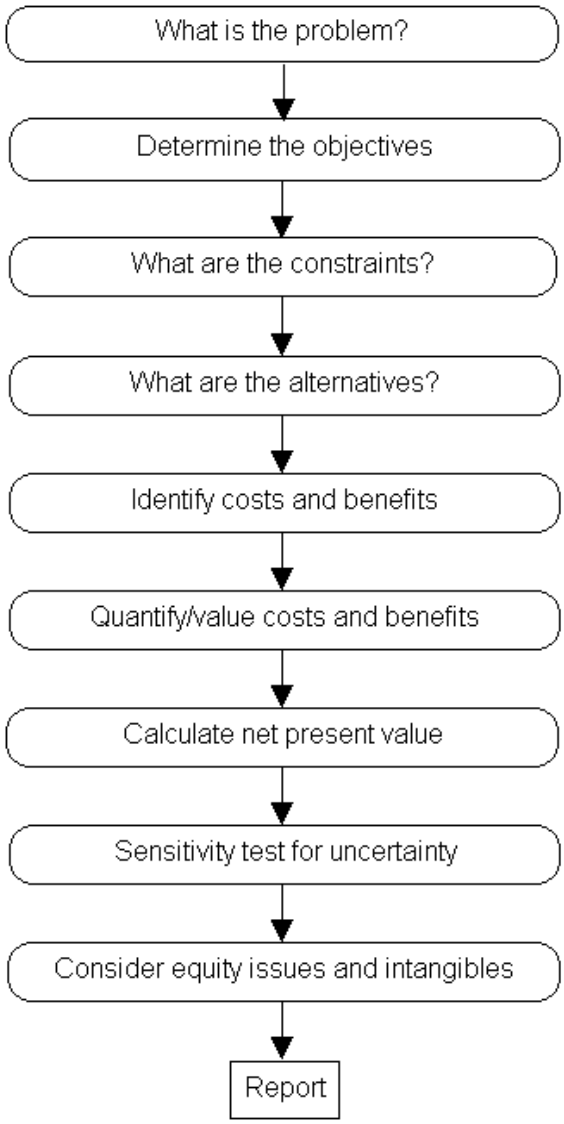
CBA can be applied to a broad range of government activities from investing in infrastructure projects, to mandatory product standards, occupational registration requirements or health and education policies.

The main practical constraint to using CBA is the feasibility and appropriateness of assigning money values to the costs and benefits generated by government action. In circumstances where these constraints are overwhelming, cost-effectiveness analysis is frequently a viable alternative approach.

The key steps in the CBA process

There is a logical sequence of steps to take when undertaking a cost-benefit analysis prior to deciding on a standard or regulation. A diagram of the steps outlined below is shown in Figure 3.

Figure 3: Key steps in the cost-benefit process



1. What is the problem?

The first step entails an investigation and assessment of the problem, its context and its background. A proposal to intervene with regulation or standard will be based on an assessment that the status quo is undesirable. That assessment needs to be described to define the problem. This is an opportunity to place the proposal for intervention in its broader context, before narrowing the focus to its specific details. The market failure framework described earlier can be used for the purpose of identifying the problem.

2. What are the objectives?

This step includes a definition of the objectives to be achieved and who the intended beneficiaries are.

3. What are the constraints?

Public policy makers face various constraints on government action. Examples of such constraints are:

- financial - for example, budgetary limitations and price ceilings;
- distributional - for example, a perverse distribution of benefits among individuals or groups (eg from the less well off to the wealthy);
- managerial - for example, limits on the staff;
- environmental - for example, compliance with environmental protection requirements; and
- policy - for example, is the proposal consistent with broad government policy?

Before options are identified for further consideration, any practical constraints on the feasibility of such alternative options should be examined and documented in the RIS. In some cases the nature and extent of these constraints may be unclear or difficult to measure. In which case, any uncertainties and risks should also be acknowledged and documented in the RIS.

When analysing all alternatives consideration should be given to the principles contained in the Competition Principles Agreement of 11 April 1995, in particular clause 1 (3), which includes reference to consideration of the environmental, social and economic aspects.[1]

4. What are the alternatives?

While each alternative to the proposal for intervention that is identified will require a considerable amount of subsequent analysis if it is to be fully incorporated into a CBA, the number of alternatives generated should be sufficient to provide the decision-makers with real scope for exercising choice. To facilitate this, alternatives should be clearly distinguished.

Furthermore, a 'do nothing' alternative should always be identified, implicitly if not explicitly. This will be the base case against which alternatives can be compared. Then costs and benefits would be incremental to what would have happened in the absence of regulatory action.

5. What are the benefits?

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[1] Without limiting the matters that may be taken into account, where this agreement calls:

(a) for the benefits of a particular policy or course of action to be balanced against the costs of the policy or course of action; or
(b) for the merits or appropriateness of a particular policy or course of action to be determined; or
(c) for an assessment of the most effective means of achieving a policy objective;
the following matters shall, where relevant, be taken into account:
(d) government legislation and policies relating to ecologically sustainable development;
(e) social welfare and equity considerations, including community service obligations;
(f) government legislation and policies relating to matters such as occupational health and safety, industrial relations and access and equity;
(g) economic and regional development , including employment and investment growth;
(h) the interests of consumers generally or of a class of consumers;
(i) the competitiveness of Australian businesses; and
(j) the efficient allocation of resources.

(Source: pp 14-15 Compendium of National Policy Agreements , Second Edition, June 1998, National Competition Council)

A list of the benefits that are expected to flow from the proposals should be drawn up. To identify benefits (and costs), a clear account of the chain of causation from the proposal is needed. This should be available from the policy analysis undertaken in formulating the proposal. The list of benefits might include such items as:

- an increase in the value of economic output as a result of a particular action;
- avoided costs - costs which would have been incurred in the 'do nothing' situation;
- productivity savings - ie, producing more with less; and
- health, environmental and other social benefits, which are often not marketed or are characterised by prices which reflect less than the full value of the benefits.

6. What are the costs?

Similarly, for each alternative a list of costs should be drawn up. Examples of costs are:

- increases in expenditure by governments to establish and/or maintain regulation and enforcement regimes;
- increased costs on business and the broader community from higher input costs and regulatory compliance costs. A Regulatory Impact Statement should provide quantitative data on regulatory compliance costs, including information about the number and type of businesses or individuals affected, and the likely financial (and other) impacts on those affected. Compliance costs can include additional paper burden costs, additional staffing, licence fees or charges, external advice, transport and/or restrictions on competition. Regulatory Impact Statements should also give full consideration to ways of minimising such costs. Where quantitative data about such costs are unavailable, a qualitative assessment should be provided;
- increased costs on consumers from higher prices for goods and services; and
- externalities or spillover effects on other parties, both positive and negative. For example, environmental costs such as air, water and noise pollution.

Particular attention should be given to the likely impacts on small business, especially where regulatory compliance costs could have a disproportionate impact on small business..

7. How can costs and benefits be quantified?

Cost-benefit analysis compares costs and benefits using a common measure, usually dollars. Therefore, dollar values must be assigned to as many of the costs and benefits as possible. Market prices, where they exist, provide a great deal of information concerning the magnitude of costs and benefits. However, actual prices sometimes have to be adjusted to convert private costs and benefits into social ones, that is, costs and benefits which reflect gains and losses to the economy as a whole, rather than to individuals or groups.

8. How should net present value be assessed?

The values assigned to costs and benefits should be based on an explicit assumption about price inflation; normally, costs and benefits will be valued in real terms with the base being that of the current year. Total costs in each year of the project's life are subtracted from total benefits in that year to yield net benefits in each year. Annual net benefits are then

discounted back to today's dollars. The stream of discounted net benefits is then summed to yield the net present value. The formula for the net present value is:

$$NPV = \sum_{t=0}^{n} \frac{(B_t - C_t)}{(1+r)^t}$$

where B denotes the value of the benefits received in any future year, C refers to the costs incurred in any future year, r is the discount rate and t refers to the year (where the current year is denoted year zero).

Subject to a consideration of budget constraints, intangibles and distributional issues, a CBA will support a proposal if the net present value is equal to or greater than zero. Similarly, if there are a number of ways of achieving the desired outcome, a CBA will support the alternative with the highest net present value, where that is equal to or greater than zero.

9. How should uncertainty be dealt with?

The values included in a CBA are the 'most likely' or 'best' estimates. Sensitivity analysis is a simple procedure for providing the decision-maker with information about the impact of estimation errors on the viability of the proposal. The first step in a sensitivity analysis is to substitute the most pessimistic estimates for each variable simultaneously, and see how much the net present value is affected. If the result is still greater or equal to zero, then we are able to say that even under worst case assumptions, the CBA supports the proposal.

The second step is to try to assess how risky the proposal is, that is, which variables significantly affect the net present value and which do not. This can be established by varying each variable one at a time, holding all other variables unchanged.

How should the report be structured?

The final step in the cost-benefit process is the writing-up of the analysis, which includes the recommendation to the decision-maker. The report should include:

- a summary of the results of the analysis;
- an introduction describing the considerations which led to the decision to undertake a CBA;
- a statement of the 'problem' the proposal is designed to redress;
- the objectives of the regulatory proposal;
- a description of the alternatives considered;
- the constraints considered in conducting the analysis and the alternatives selected;
- the time profiles of costs, benefits and net benefits, together with information on the sensitivity of those profiles to alternative assumptions;
- information on intangible costs and benefits;
- a list of assumptions made in performing the analysis, and information on how benefits and costs were estimated;
- a description of distributional effects;

- a conclusion discussing the results of the analysis; and
- an outline of an evaluation mechanism.

To what level or depth should the analysis be conducted?

The steps outlined are recommended for every CBA. However, obtaining and analysing information also incurs costs. Hence, there are important choices to make regarding the level or depth to which the analysis is conducted. The more significant a proposal and the greater the likely economic and social implications, the more expenditure on a CBA can be justified. The viability of smaller proposals can be threatened by investing too much in analysis. This possibility should set obvious limits on the level and depth of the analysis required.

The likely benefits of obtaining and analysing additional information should always exceed the costs of so doing. Better information often reduces the uncertainty surrounding estimates, however, if a proposal is already known to be clearly viable or unviable, the pay-off from obtaining extra information may be negligible. Detail and complexity are not the same as rigour - which is ultimately more important. An elaborate and detailed analysis of a problem that has been wrongly conceptualised may well be worthless. But a 'back of the envelope' analysis of a problem that has been thought through correctly will, at the very least, be a helpful first step.

Letting decision-makers decide

Distributional implications can be obscured by the aggregating character of the cost-benefit process. Analyses should include all the information available to ensure that decision-makers are aware both of the identity of the groups likely to gain and to lose as a result of government action, and of the nature and size of the gains and losses. This information should be carefully presented, most usefully in the form of a distributional incidence chart or matrix.

Distributional judgements are properly made at the political level. In the interests of avoiding subjective bias, analysts should, by and large, refrain from attaching distributional weights to cost and benefit streams. Exceptions might be where there are unambiguous government policy objectives to assist specific groups in the community, and where the justification for special assistance to these groups relative to other groups is clearly established. However, for reasons of transparency, decision-makers and the public should be made fully aware of the costs of government action aimed at benefiting particular individuals or groups in the community.

Cost-Effectiveness Analysis

What is cost-effectiveness analysis; how and where can it be used?

Cost-effectiveness analysis (CEA) is a technique that can be used to compare the costs of different options with the same or similar outputs or benefits. Because CEA expresses benefits in physical units (eg lives saved, tonnes of coal) rather than in dollars, CEA is particularly useful in assessing proposals where it is easier to identify benefits than to value them. CEA can often be a viable alternative to cost-benefit analysis where using CBA is not feasible because of difficulty in assigning money values to the costs and benefits generated by Government action.

What cost-effectiveness offers is a priority ranking of proposals on the basis of comparative 'cost per unit of effectiveness', or alternatively, of 'units of effectiveness per dollar'. Sometimes analyses which compare only the costs of alternatives are described as cost-effectiveness analyses. For the description to be valid, however, the value of output of the alternatives must be the same, that is, the alternatives must be equally effective.

Cost-effectiveness analysis is widely used in health, safety and education fields where there are, at the least, some difficulties in expressing in money terms the benefits of output values such as reduced mortality, morbidity or improved educational outcomes.

One advantage of CEA as an analytical technique is that it eliminates more costly options from consideration. Another is that it provides an index of the relative efficacy of options, allowing a ready comparison of alternatives.

There are at least three contexts in which cost-effectiveness analysis is appropriate and useful. However, in each it is a precondition that the alternatives being compared should have a common predominant effect.

First, cost-effectiveness is useful when the issue at hand is the optimal use of a fixed (or substantially fixed) quantity of resources. That is, where it is necessary to set priorities between alternative expenditure options but where the more fundamental questions of whether the government should be involved in the activity at all, or of how much the government should be willing to spend, are not at issue.

Second, the method is applicable when projects or programs are already in place and are expected to continue, but not necessarily in their current form. That is, where there is an interest in improving the allocation of resources within a framework of set policy objectives.

Third, cost-effectiveness analysis is a powerful tool when a particularly large number of alternatives are under consideration. Because cost-benefit analysis is oriented towards comprehensiveness in measuring costs and benefits, there is usually a low limit (in practice, if not in theory) on the number of alternatives which can be compared. This is not an impediment in cost-effectiveness analysis where the benefit categories that are analysed are restricted in number. Cost-effectiveness rankings are also very readily intelligible for purposes of comparison.

The limitations of cost effectiveness analysis

Unlike cost-benefit analysis, cost-effectiveness analysis provides no absolute criterion for accepting or rejecting projects. In CBA, a proposed regulation would be acceptable (subject to budget constraints) if its net present value is equal to or greater than zero. In cost-effectiveness analysis, however, we have only a self-referencing ranking of projects. Because of this difference, cost-effectiveness analysis should as far as possible be avoided when decision-makers are seeking information to aid a decision on the level of resources to allocate to a particular area. In some cases it is possible to introduce an 'external' monetary benchmark, in effect superimposing a rough and ready cost-benefit framework on the cost-effectiveness analysis.

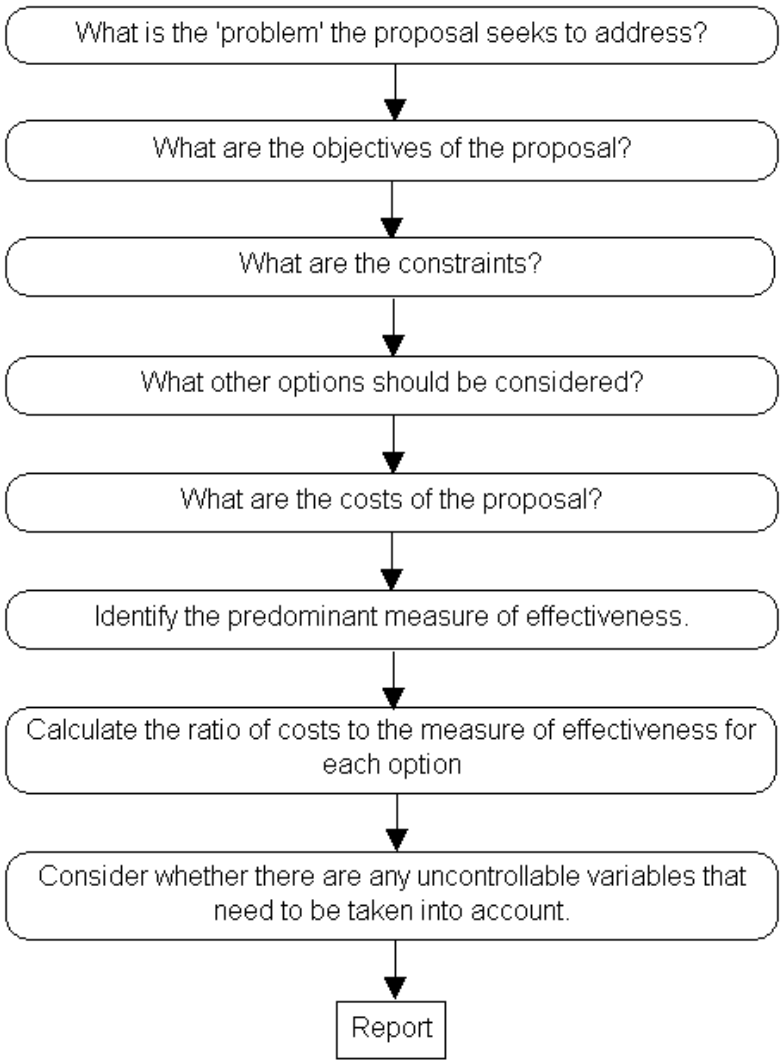
Secondly, cost-effectiveness analysis should not be used when alternatives differ significantly in their predominant effects (output values). Any cost-effectiveness ranking which ignores such differences can only be misleading.

The key steps in the CEA process

There is a high degree of similarity between the steps used in both CBA and CEA.

The key steps in the CEA process are outlined in Figure 4.

Figure 4: Key steps in the cost-effectiveness process



What is the problem?

Consideration needs to be given to the current social or economic problem that the proposed regulation seeks to address.

What are the objectives of the proposal?

A CEA should outline what the objectives of the proposal is and how that relates to they problem that has been identified. Attention should be given to who the beneficiaries are.

What are the constraints?

Constraints on meeting the objectives should be identified to ensure that all alternatives examined in the CEA are feasible. Different types of constraints may include:

- financial;
- distributional;
- managerial;
- environmental; and
- base policy.

What other options should be considered?

Care should be taken to consider all feasible options including a 'do nothing' option. To ensure the analysis is effective. Alternatives should be well-defined and discrete, with a minimum of overlap.

What is the predominant measure of effectiveness?

Considerable care is needed in identifying appropriate measures of effectiveness in CEA. As a general rule, the closer the measure is to the ultimate objective of the activity, the more likely it is to avoid the dangers of overlooking significant forms of benefits from the activity, and of not being comparable with the alternatives under consideration.

The end product of a cost-effectiveness analysis is the ratio of cost to the measure of effectiveness for each alternative being considered. Because cost-effectiveness analysis is well suited to the analysis of measures that have been in place for a period of time, it should usually be possible to obtain a substantial amount of information in both the cost and effectiveness categories. Additionally, a large amount of feedback can be expected from the measure's 'community', that is, those involved in implementation, its supporters, clients and critics. These considerations imply the need for a particularly high standard of care and thoroughness in the collection and analysis of data, and presentation of results.

It is also important in cost-effectiveness studies to try to separate out the impact of the measure from that of other variables.

CEA tends to focus on a single criterion of effectiveness and therefore care must be taken to ensure that the criterion used is the primary output of all the options under consideration. Otherwise, the ranking shown by the CEA may be misleading.

What are the costs?

For each alternative a list of costs should be drawn up. Costs include:

- increases in government expenditure;
- increases in business costs, including compliance costs;
- increased consumer costs form higher prices for goods and services; and
- externalities.

An analysis of costs can be carried out using two main approaches.

Cost savings approach

A cost savings approach is adopted in which the costs of persisting with an existing situation are compared with the costs of introducing a new measure. The comparison yields a net benefit profile - that is, a cost savings profile - of the new system.

To overcome the problem of potential differences in output values of alternative approaches, agencies are required to include in the analysis, supplementary statements which describe those differences (for example, in levels of customer service, levels of performance, or levels of flexibility).

Costs (Existing situation)	-	Costs (New measure)	+	Unquantified output benefits (New measure)	=	Net Benefits (New measure)

This approach is very much akin to the inclusion of intangible effects in a cost-benefit analysis and is considered adequate where the relevant differences are relatively minor. However, in general, the greater the difference in output values between alternatives, the greater the justification for investing time and money in quantifying them as precisely as possible. This is likely to result in a more comprehensive and more accurate analysis and, hence, a better basis for decision-making. To ensure clarity, however, the relevant accompanying statement setting out the assumptions of the analysis would also be required.

Cost effectiveness approach

An alternative approach to the problem of quantifying differences in output values is to undertake a specified cost-effectiveness analysis. This would compare the costs of each option (calculated in present value terms) with a relevant performance measure, or index of performance measures. The cost-effectiveness approach represents a simpler and more practical solution to the problem of taking account of differences in output values than attempting to integrate those differences into the cost savings approach.

Where quantifiable performance differences between options exist, analysts should include with their cost savings analysis a cost-effectiveness analysis of this type.

Provided that a cost-effectiveness analysis is undertaken for the existing situation as well as for the proposed measure, the addition of this further step should provide decision-makers with significantly more information, improving the decision-making process.

To clarify further, a cost saving analysis should be used to determine whether a proposed option or solution is worth pursuing. This applies to all situations where the agency has a choice between the existing situations and a new measure, and where, therefore, any new measure requires fundamental justification. In these situations a cost-effectiveness analysis is also desirable (where quantifiable performance differences exist) both as a way of checking on and throwing additional light on the justification provided by the cost savings analysis.

Finally, in cases where a decision has already been taken to implement a new measure, a cost-effectiveness analysis on its own may be appropriate. However, even in these cases, the additional availability of a cost savings analysis will normally provide a much sounder basis for decision-making.

What is the ratio of cost to the measure of effectiveness for each option?

The end product of a cost-effectiveness analysis is a ratio of cost to the measure of effectiveness for each alternative being considered.

Are there any uncontrollable variables that have to be taken into account?

Have all the variables that might affect the outcome been identified? It is important to try to separate the impact of the proposal on effectiveness from the impact of other variables.

How should the report be structured?

The final step in the cost-effectiveness process is the report which includes recommendations to the decision-maker. The report should include.

- a summary of the results of the analysis;
- an introduction describing the considerations which led to the decision to undertake a CEA;
- a statement of the 'problem' the proposal seeks to solve.
- the objectives of the regulatory proposal;
- a description of the alternatives considered;
- the constraints considered in conducting the analysis and the alternatives selected;
- a list of assumptions made in performing the analysis and information on how measures of effectiveness and costs were estimated;
- a conclusion discussing the results of the analysis; and
- an outline of an evaluation mechanism.

Choosing the Most Appropriate Technique

The three main techniques available to assess the effects flowing from regulation have been outlined. Each has advantages and disadvantages (summarised in Table 1), and some regulatory proposals are better analysed by using one technique rather than another, or by using a combination of them.

With cost-benefit analysis, ideally all the costs and benefits to the whole society of a particular regulatory proposal are valued and compared. Net social gains suggest that the regulation would improve the welfare of society as a whole. Cost-benefit analysis can also be used to rank alternative (including non-regulatory) proposals in terms of their net social gains (or losses).

The main disadvantage of cost-benefit analysis is that difficulties can arise in evaluating costs and benefits for which there are no market prices.

The application of cost-benefit analysis to regulations intended to reduce risk inevitably requires that a value be placed on human life. While this has been done in some of the literature, there is a wide variety of approaches used to arrive at this value as well as a wide range of values. For example, in the United States, one study of various measures showed a variation from $0.1 m per life saved to $125 m per life saved. In a climate of limited

resources, it is probably not difficult to decide which of these two measures it would be preferable to introduce. Such attempts have often been viewed as controversial. In contrast, cost-effectiveness analysis avoids explicitly valuing human life and instead focuses on the costs of a specified output such as that of saving a life (or reducing injury at a specified level).

In general, CBA is appropriate when the costs and benefits can be quantified.

Cost-effectiveness analysis differs from cost-benefit analysis in that benefits are expressed, not in money units, but in physical units. Costs, as in cost-benefit analysis, are expressed in money terms.

In relaxing the approach towards benefits measurement, cost-effectiveness analysis is particularly useful in areas (such as health, accident safety, environmental protection and education) where it is often easier to specify benefits than it is to value them. For example, it is easier to identify the number of lives that a proposed measure may save than to value those lives.

Assuming that adequate, quantitative measures of regulatory effectiveness can be found, the method is very useful in comparing alternative options. However, there are several limitations to cost-effectiveness analysis, particularly compared with cost-benefit analysis.

First, cost-effectiveness analysis focuses on a single type of benefit to the exclusion of others. It is critical that the chosen benefit is predominant for all proposals under consideration and is closely related to the overall policy objective. Otherwise, the ranking that cost-effectiveness analysis achieves may have little validity or be misleading. Even where the condition is substantially met, the cost-effectiveness method is likely to involve some loss of information and simplification relative to a cost benefit approach.

A second limitation is that, unlike cost-benefit analysis, cost-effectiveness analysis provides no guidance as to whether there are net gains to society from implementing a regulatory proposal.

Risk assessment can be used for analysing regulations intended to reduce risk and is commonly used in areas like health and safety. It can vary from assessing the mechanical impact of regulation on risk to estimating the cost-effectiveness of reducing risks. Compared with cost-benefit and cost-effectiveness analyses, simple forms of risk assessment are more limited in scope. Instead of assessing the dollar costs or benefits of reducing risks, risk assessment focuses on questions relating to the impact that regulation has on risk.

More sophisticated forms of risk assessment, such as risk-risk analysis, can be incorporated into cost-benefit and cost-effectiveness analysis. Costs and benefits can be multiplied by probabilities to produce expected costs and expected benefits in dollar terms.