Roinn an Taoisigh
Department of the Taoiseach

RIA GUIDELINES

How to conduct a Regulatory Impact Analysis

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Steps of a Screening RIA

1. Description of policy context, objectives and options (for example different forms of regulation)
2. Identification of costs, benefits and other impacts of each option which is being considered
3. Consultation
4. Enforcement and compliance
5. Review

Glossary

Cost-benefit analysis

Cost-benefit analysis (CBA) is an analytical technique that can be used to examine the costs and benefits of a proposed regulation or public policy initiative. All of the relevant costs and benefits, including indirect costs and benefits, are taken into account. The general principle of cost-benefit analysis is that a regulation/policy initiative is desirable if the economic and social benefits are greater than the economic and social costs.

Multi-criteria analysis

Multi-criteria analysis (MCA) is an analytical technique that can be used to assess a variety of policy options on the basis of a number of set criteria. The policy options are compared to ascertain which best meets the criteria identified and is therefore the most likely to achieve overall objectives.

Regulation

In this document we generally use "regulation" to mean primary legislation enacted by the Oireachtas and secondary legislation enacted by Ministers empowered under primary legislation.

Depending on the context, it can also mean "to regulate" in the economic and social sense of the word.

Regulation can also be used in a more specific sense to mean an EU "Regulation", as opposed to a Directive. This is a particular class of legal instrument made by the Council, Parliament or Commission and binding on Member States and their citizens. It will be made clear in the document where these meanings are intended.

Regulatory Impact Analysis

Regulatory Impact Analysis (RIA) is a tool used to assess the likely effects of a proposed new regulation or regulatory change. It involves a detailed analysis to ascertain whether or not the new regulation would have the desired impact. It helps to identify any possible side effects or hidden costs associated with regulation and to quantify the likely costs of compliance on the individual citizen or business. It also helps to clarify the costs of enforcement for the State.

Scenario analysis

Scenario analysis is an analytical technique that can be useful where there are a number of uncertainties or risks associated with a particular regulatory proposal/policy initiative. It involves assessing and comparing the likely outcomes of a regulatory proposal/policy initiative when the values of a number of variables or factors are changed simultaneously.

Sensitivity analysis

Sensitivity analysis is an analytical technique that assesses how the outcome of a regulatory proposal/policy initiative is likely to be affected when the value of one variable or factor is changed.

Sunsetting

Sunsetting is when at the time a regulation is made, a specific date is set on which that regulation will expire unless it is re-made. This ensures that a regulation is formally reviewed at an agreed date in the future, to establish whether or not it still valid or if it could be improved, reduced or even revoked.

White Paper principles of Better Regulation

The Government White Paper on Better Regulation, *Regulating Better* (2004), sets out six principles of Better Regulation. These are: necessity, effectiveness, proportionality, transparency, accountability and consistency.

- Necessity – is the regulation necessary? Can we reduce red tape in this area? Are the rules and structures that govern this area still valid?
- Effectiveness – is the regulation properly targeted? Is it going to be properly complied with and enforced?
- Proportionality – are we satisfied that the advantages outweigh the disadvantages of the regulation? Is there a smarter way of achieving the same goal?
- Transparency – have we consulted with stakeholders prior to regulating? Is the regulation in this area clear and accessible to all? Is it supported by good explanatory material?
- Accountability – is it clear under the regulation precisely who is responsible to whom and for what? Is there an effective appeals process?
- Consistency – will the regulation give rise to anomalies and inconsistencies given the other regulations that are already in place in this area? Are we applying best practice developed in one area when regulating other areas?

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1: Introduction and Background

Purpose of Guidelines

1.1 On the 21 June 2005, the Government decided that Regulatory Impact Analysis (RIA) should be introduced across all Government Departments and Offices. It will apply to:
(i) all proposals for primary legislation involving changes to the regulatory framework (subject to some exceptions)
(ii) significant Statutory Instruments
(iii) proposals for EU Directives and significant EU Regulations when they are published by the European Commission

1.2 The piloting of RIA which took place over 2004 and 2005 demonstrated significant benefits of RIA and gave rise to a range of recommendations in relation to how the pilot RIA model and approach should be amended and improved in advance of its general introduction across Departments and Offices. Further information on the piloting experience and the background to the introduction of RIA is available in the *Report on the Introduction of Regulatory Impact Analysis* (Department of the Taoiseach, 2005a).

1.3 These Guidelines are intended to provide assistance to officials in conducting RIAs. They may be amended at a future stage based on Departments' practical experience of conducting RIAs.

What is RIA?

1.4 **Regulatory Impact Analysis is a tool used to assess the likely effects of a proposed new regulation or regulatory change.** It involves a detailed analysis to ascertain whether or not the new

regulation would have the desired impact. It helps to identify any possible side effects or hidden costs associated with regulation and to quantify the likely costs of compliance on the individual citizen or business. It also helps to clarify the costs of enforcement for the State.

1.5 There is no single generic model of RIA used internationally but RIAs tend to include a clear identification of objectives, structured consultation with stakeholders, detailed examination of impacts and consideration of the use of alternatives to regulation. The model approved by Government in June 2005 has been specifically tailored to the Irish context and will be outlined in detail in Chapter 3 of these Guidelines.

1.6 It is important to note that RIA is not a substitute for decision-making. Instead, RIA is best used as a guide to improve the quality of political and administrative decision-making, while also serving the important values of openness, public involvement and accountability.

Benefits of RIA

1.7 The benefits of RIA can be summarised under three headings:

- Performance of the economy and consumer welfare
- Quality of governance
- Efficiency and effectiveness of the public service

1.8 RIA can contribute to economic efficiency by highlighting aspects of regulation which limit consumer choice and the level of competition in an economy. RIA can also identify potentially anti-

competitive or protectionist regulations before these are enacted. Because it includes consultation with a wide range of stakeholders, it also provides an opportunity for those potentially affected by regulations to highlight any unforeseen consequences that may not previously have been considered.

1.9 RIA is also a means of improving the quality of governance by increasing the transparency and legitimacy of the regulatory process. The inclusion of consultation ensures that the interests of citizens are more systematically included within the regulatory process and the focus on enforcement and review encourages a more strategic approach to the monitoring and enforcement of regulations. This should increase the accountability of the regulatory process.

1.10 Furthermore, RIA will increase the efficiency and effectiveness of the public service. It will improve the quality of policy advice given to Ministers through promoting increased use of evidence in policy-making and providing more information on the likely implications of regulatory proposals. RIA should also contribute to achieving value for money and efficiency by generating more detailed information in relation to cost and allowing more extensive analysis of alternative options for achieving policy objectives.

1.11 Finally, and significantly, RIA should contribute to achieving the six principles of Better Regulation identified in the Government White Paper, *Regulating Better* (Department of the Taoiseach, 2004). These are necessity, proportionality, consistency, effectiveness, transparency and accountability. These principles should be used as a guide when evaluating proposed regulations.

2: When is a RIA Required?

Introduction

2.1 One of the fundamental goals of the RIA process is to reduce the unnecessary use of regulation through an examination of the possible use of alternatives. This requires that RIA must be conducted at an early stage and before a decision to regulate has been taken. This means that it is at least possible to consider the use of alternatives to regulation or lighter forms of regulation, even if they are not necessarily considered to be the most appropriate approach in the long run.

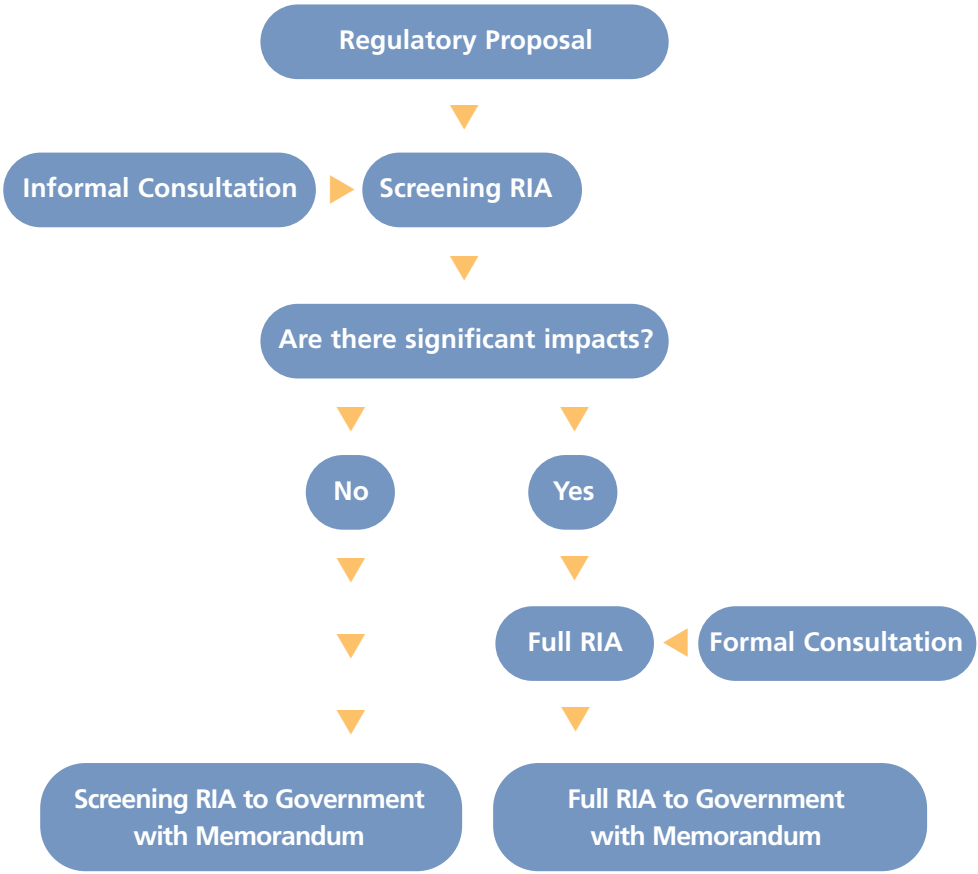
2.2 By its very name 'Regulatory Impact Analysis' implies a focus on the regulatory framework i.e. primary and secondary regulation. The process by which regulations develop varies from one case to another. Commitments to regulate can occur in a variety of circumstances such as through Government programmes or Partnership Agreements. Some are signalled well in advance whereas others may be introduced at short notice. Therefore, the timing of RIAs must vary to some degree depending on the context of the particular proposals and where regulations originate.

Primary legislation

2.3 Where primary legislation (a Bill) is proposed, a Memorandum is brought to Government seeking approval for the General Scheme of the Bill (also known as the Heads of a Bill). RIA should be conducted before this Memorandum goes to Government seeking permission to regulate. The Memorandum and Scheme/Heads must

be accompanied by either a Screening or Full RIA (depending on the significance of the proposal, see Chapter 3). The RIA must be summarised in the Memorandum and the full RIA document included as an attachment to the Memorandum. This process is summarised in Figure 2.1 below.

Figure 2.1: The RIA process



2.4 Although RIA can potentially benefit all policy areas/regulations, it is not compulsory to apply RIA to the Finance Bill and some emergency, criminal or security legislation. In addition, the RIA approach may not be appropriate in the case of tax law/regulations or the imposition of charges because of their sensitivity and the need to guard against possible evasion or avoidance.

Where primary legislation is proposed, conduct RIA in advance of the Memorandum which is brought to Government seeking permission to regulate. Summarise the RIA within the Memorandum and include the RIA as an attachment.

EU Directives/Regulations

2.5 RIAs must be applied to all draft EU Directives and certain significant EU Regulations. Section 3.3 provides guidance as to what should be considered significant in this regard. **RIAs must be conducted on Directives/significant Regulations before they are agreed so that the information that they generate can inform Ireland's negotiating position and minimise potentially negative implications for Ireland.** This is particularly crucial because EU Commission Impact Assessments take account only of cross-national impacts and do not reflect differential impacts on individual member states. Therefore, apply RIAs to draft Directives (and draft Regulations where appropriate) after the Commission has published the proposed Directive (or Regulation) and its own impact assessment, but before negotiations have been completed.

Conduct RIAs on proposed EU Directives/significant Regulations before they are agreed.

2.6 Currently it is required under the European Union (Scrutiny) Act 2002 that Departments/Offices prepare an information note on draft EU measures[1] within four weeks of formal circulation by the General Secretariat of the Council. This information note must outline the nature and purpose of the proposal and should contain an initial indication of possible implications for Ireland (Guidelines for Oireachtas Scrutiny of EU Business). Departments should take account of the RIA model in preparing these information notes. For instance, the requirements of Step 1 of the RIA (see paragraphs 4.1-4.6) could be taken into account when completing Section 9 of the information note, "Short summary and aim of the proposal". The inclusion of some information on cost, benefits and impacts should be considered within section 14 of the information note which deals with "Implications for Ireland". RIA can also inform a Department's further briefing of an Oireachtas Committee, where the draft EU proposal has been referred to a specific sectoral Oireachtas Committee for further scrutiny.

2.7 Once the information note has been completed a Screening RIA must then be conducted on the Directive/significant Regulation. Where significant impacts are identified in the Screening RIA, a Full RIA must be conducted (see Chapter 3 for more details on the content of Screening/Full RIAs and when Full RIAs are required). The RIA(s) should be completed in time to influence the negotiations on the Directive. The RIA must also be updated as required during the negotiation process and transposition into Irish law, to take account of significant changes. The RIA could be used to influence decisions in relation to whether to avail of a derogation or exemption from provisions of an EU Directive/ Regulation in the rare cases where this arises.

[1] Regulations, Directives, joint actions and common positions under Article 15 of the Treaty of the European Union or measures requiring prior approval of both Houses of the Oireachtas pursuant to Article 29.4.6 of the Constitution.

Take account of the RIA model in preparing information notes under the European Union (Scrutiny) Act 2002.

Statutory Instruments/Secondary Legislation (SIs)

2.8 There are a variety of forms of Statutory Instruments: Orders, Regulations and Rules, Schemes and Bye-laws. Many policy measures are given effect by SIs and the RIA process must reflect this. Overall, between 600-750 SIs are introduced in Ireland each year. However, many SIs are relatively minor in their scope and impact so to ensure proportionality, only significant Statutory Instruments are to be subject to RIA at least in the early stages of its introduction (section 3.3 gives guidance as to what should be considered significant in this context).

2.9 Statutory Instruments are often used to transpose EU Directives in Ireland. The RIA requirements in relation to EU Directives detailed in sections 2.5-2.7 above mean that SIs which transpose EU Directives will have already been subject to the RIA process before they reach the national regulatory system. In such cases, the assessment previously conducted could then be updated and attached to the transposing SI when it is laid before the Houses of the Oireachtas.

2.10 A second method of triggering a RIA on an SI is that when Government approves the drafting of a Bill, it may provide that secondary regulations to give effect to aspects of the Act which

are of particular significance be subject to a RIA (again section 3.3 provides guidance on significance for this purpose). Individual Ministers may also decide that SIs are sufficiently significant to warrant a RIA.

Conduct RIAs on significant Statutory Instruments.

Policy Review Groups

2.11 Regulations are sometimes initiated in response to the recommendations of a particular Policy Review Group. When these Groups have reported, the expectation tends to be that their recommendations will be accepted and this means that subsequent scope for the use of alternatives is limited. Therefore, when any Policy Review Group is formed its terms of reference must include a requirement to take account of the principles of Better Regulation (see *Regulating Better*, Department of the Taoiseach, 2004 for details of these principles). In particular, its terms of reference must specify that consideration be given to the potential for the use of alternatives to regulation prior to recommending regulatory solutions. Any Reports or Reviews produced by the Group should then indicate how it took account of the Better Regulation principles in conducting its work. Where primary regulations or significant regulatory change are being proposed, consideration should be given to conducting a RIA as part of the work of the Review Group. The Group's final Report would then include a Screening or Full RIA, as appropriate.

Include a requirement to take account of the principles of Better Regulation in the terms of reference of all Policy Review Groups.

2.12 Regulatory Impact Analysis must be applied to regulations before they are enacted (an *ex ante* approach). However, it should also be noted that the review of existing regulations (i.e. *ex post* evaluation) is an important and related priority in the Government White Paper, *Regulating Better*. Where ex post reviews are concerned these should include an assessment of whether regulations are still necessary, whether they are achieving their objectives as simply and efficiently as possible, and whether there is a need for any changes to regulations or administrative requirements.

2.13 The Government decision in relation to RIA applies only to Government Departments and Offices. However other regulators may consider using RIA as a regulatory tool to assist in identifying the costs, benefits and impacts of their regulations since these can have significant impacts.

3: Introduction to RIA Model

3.1 To ensure that RIA is proportionate and does not become overly burdensome, the RIA model involves a two-phase approach. Regulations with relatively low impact are subject to a *Screening RIA*, a preliminary less detailed analysis. A *Full RIA* involving more extensive and detailed evaluation is applied to more significant regulations.

3.2 The steps of a Screening RIA are summarised below. Detailed guidance on conducting each step of the Screening RIA is provided in chapter 4. A Screening RIA will be sufficient in many cases and only where the Screening RIA suggests significant impacts (see paragraphs 3.3 –3.4 below) should a Full RIA be conducted.

Steps of a Screening RIA

1. **Description of policy context, objectives and options (for example different forms of regulation)**
2. **Identification of costs, benefits and other impacts of each option which is being considered**
3. **Consultation**
4. **Enforcement and compliance**
5. **Review.**

3.3 These Guidelines provide detailed information in relation to applying the various stages of both the Screening and Full RIA approach. As a general rule however, a common sense and proportionate approach should apply and, where regulations involve low costs or minor impacts, a light approach should be taken for the Screening RIA.

3.4 Step 2 of the Screening RIA includes an analysis of impacts in the following areas/categories:

- National competitiveness
- Consumers
- The socially excluded and vulnerable groups
- The environment
- Whether there is a significant policy change in an economic market, including consumer and competition impacts
- The rights of citizens
- Compliance burden
- Other economic, social and environmental costs and benefits.

Where significant impacts are identified under any of these headings, a Full RIA must be conducted.

3.5 Given the wide range of policy areas where RIA will apply, it is not possible to specify a definition of "significant" which will cover all types of impacts/policy areas. In general, however, significant impacts are those which have substantial and observable effects either on the economy, on a sector of society or on the environment. Further guidance on impacts under the individual headings specified above is supplied in paragraphs 4.26 to 4.44.

A Full RIA should be conducted where the Screening RIA suggests that any one of the following applies:

(a) There will be significant negative impacts on national competitiveness

(b) There will be significant negative impacts on the socially excluded or vulnerable groups

(c) There will be significant environmental damage

(d) The proposals involve a significant policy change in an economic market or will have a significant impact on competition or consumers

(e) The proposals will disproportionately impinge on the rights of citizens

(f) The proposals will impose a disproportionate compliance burden

(g) The costs to the Exchequer or third parties are significant, or are disproportionately borne by one group or sector. Initial costs of €10 million or cumulative costs of €50 million over ten years (to include both costs to the Exchequer and third parties) should be considered significant in this context.

3.6 In addition, the Government may, in some circumstances, request a Full RIA where it considers regulatory proposals to be politically significant or where convincing submissions on the matter have been received from stakeholders.

3.7 The Full RIA is essentially a more detailed version of the Screening RIA. A summary of the steps of a Full RIA are set out below. More details on the requirements of a Full RIA are contained in Chapter 5.

Steps of a Full RIA

1. **Statement of policy problem and objective**
2. **Identification and description of options**
3. **Impact analysis including costs and benefits of each option**
4. **Consultation**
5. **Enforcement and compliance for each option**
6. **Review**
7. **Summary of merits/drawbacks of each option and identification of recommended option where appropriate.**

4: Conducting a Screening RIA

Description of policy context, objectives and options

4.1 The first step of the Screening RIA has three main elements:
(i) A brief description of the policy context
(ii) An explicit statement of the objectives that are being pursued
(iii) An identification of the various policy options or choices which are under consideration to achieve these objectives.

(i) Policy context

4.2 The RIA should begin by describing the policy context. This is the background to the issue, what the particular policy problem or challenge is, and the conditions/imperatives that mean it must be addressed at this particular time. This should include a brief (1-2 pages at most) summary of the existing regulatory framework and its drawbacks and may necessitate reference to relevant EU or international obligations.

> Describe the policy context i.e. the background to the issue, the policy problem and why it must be addressed now.

4.3 Although there is likely to be a large amount of background material and a lengthy historical context for most issues, only include the key and most relevant information within the RIA. The purpose of this part of the RIA is to give readers who are

unfamiliar with the policy area a brief background to the issue rather than to overload them with facts, figures and historical detail. If it is considered necessary to provide additional background information on the issue, include this as an Appendix to the RIA.

Include only key and relevant information. Where necessary, additional background material can be provided as an Appendix to the RIA.

Example 1: The Policy context

Extract from Canadian Regulatory Impact Analysis on proposed Cigarette Ignition Propensity Regulations

The Department of Health is proposing regulations to address the public health problem resulting from cigarette-started fires. Smokers' materials are the leading cause of residential fires and fire-related losses in Canada each year. From an analysis of Canadian fire statistics for the years 1995 to 1999, the Canadian Association of Fire Chiefs reported that at least 14,030 fires were started by smokers' materials (including cigarettes, cigars and pipes). These fires killed 356 people, injured 1,615 people and cost more than $200 million in property damage. The victims of these fires are often among society's most vulnerable: children, the elderly and the financially poor.

Cigarette fires typically result from lit cigarettes left unattended, smoking in bed, or smoking while under the influence of alcohol, illicit drugs or medication. When a lit cigarette comes into contact with flammable products such as mattresses, bedding or

upholstered furniture, it can start a smouldering process that can continue undetected for some time before bursting into flame. Smoke from the smouldering materials can render people in the vicinity unconscious, thus putting them at greater risk of injury or death from the ensuing fire. Given these facts, it is not surprising that residential fires started by smokers' materials result in a much higher fatality rate than fires started by other ignition sources.

The Department of Health has taken a number of steps to prevent such fires, including educating the public about the dangers of smokers' materials, establishing fire safety standards for consumer products such as mattresses and bedding, regulating ignition sources such as matches and lighters pursuant to the provisions of the *Hazardous Products Act*, and working with the Canadian Council of Furniture Manufacturers to implement voluntary flammability standards for upholstered furniture. Despite these efforts, fires started by smokers' materials continue to exact a significant toll on Canadian society by causing about 70 fatalities and 300 injuries every year. It is estimated that manufactured cigarettes are responsible for about 82 percent of these fires.

After reviewing more than 20 years of research, the Department of Health believes it is possible to reduce cigarette ignition propensity by altering certain design characteristics of manufactured cigarettes. Design alterations to reduce the amount of heat generated could include decreasing circumference, decreasing tobacco density and decreasing paper porosity. Decreasing the tobacco density and cigarette circumference would affect the amount of fuel (tobacco) available and decreasing paper porosity would restrict the flow of oxygen to the fuel. It is likely that a combination of these design changes would be required to meet the ignition propensity standard proposed in these Regulations.

Source: Health Canada 2002

(ii) Statement of objectives

4.4 Once the context has been provided, the objectives of the proposed action should be identified. In other words, what are the regulations or alternative policy tool intended to achieve? Here, it is important to recognise the difference between *general* or *ultimate* objectives and *immediate* objectives. Both should be included in the RIA. General/ultimate objectives are the overall strategic policy objectives while more immediate objectives can be directly linked to the policy intervention. For example, it could be said that an ultimate objective of the Irish smoking ban was to reduce the levels of smoking related illnesses and death. However, the ban was just one contributory measure to achieve this. A more immediate objective was to protect workers from second-hand smoke by eliminating smoking from the workplace. Although ultimate objectives may be referenced in the RIA, the key emphasis must be on immediate objectives – what specifically the particular policy action or regulation is seeking to achieve.

Explicitly state the objectives. Differentiate between ultimate objectives and immediate objectives and focus on immediate objectives.

4.5 International guidance also stresses that objectives should be:

- **S**pecific
- **M**easurable
- **A**ccepted
- **R**ealistic
- **T**ime-dependent

The objectives should be clearly and specifically linked to the policy context described at the outset of the RIA and vice versa.

Ensure that the objectives are SMART and clearly related to the policy context already described.

4.6 There will be some cases where the main imperative behind enacting regulations is to transpose EU Directives or meet international obligations. In these circumstances, transposing or meeting the international obligations should not be framed as the objective behind the policy action although these might be its drivers. The objectives behind the particular EU Directive/Regulation or international action should be framed as the objectives in such cases. An example of clear statement of policy objectives is set out below.

Example 2: Statement of policy objectives

UK RIA: High Hedge: Implementing Part 8 of the Anti-Social Behaviour Act 2003

Objective

1. It is estimated that thousands of people could be adversely affected by overgrown garden hedges. If neighbours are unwilling to co-operate, there is little the person affected by the hedge can currently do to obtain relief.

2. The aim is to minimise hedge disputes by establishing a clear and transparent process for resolving these matters, including a formal role for local authorities.

Source: Office of the Deputy Prime Minister, 2002.

(iii) Identification of options/choices

4.7 Once the context and objectives have been detailed, then the policy options for achieving the objectives must be described. International best practice indicates that the 'do nothing' or 'no policy change' option should be included as an option for consideration. Even where doing nothing is not a viable option in practice, it can serve as a useful benchmark against which other options can be compared. However, particularly for the purpose of the more limited analysis of the Screening RIA, it may be disproportionate to analyse the no policy change option in detail. In such cases, state clearly the approach being taken e.g.:
(For an EU draft Directive) *"The do nothing option is primarily*

being included for benchmarking purposes. Therefore it will not be examined in great detail as part of this RIA because it is not envisaged that this option will be pursued in practice. To take no action would mean a failure to comply with our EU obligations and could result in prosecution by the European Commission."

Having said this, there is often a variety of options available to fulfill the requirements of EU Directives/Regulations. In such cases, the full range of options should be examined.

Include the 'no policy change' option as a benchmark for comparison.

4.8 Depending on the policy context and objectives, there are a number of classes of alternatives or options. Some of the most common are summarised below. Further detail on alternatives to regulation and alternative models of regulation are set out in Appendix A. All policy/regulatory proposals should facilitate the consideration of options under at least one of the headings identified. As is indicated below, even where the Government has committed to regulate and to introduce certain measures, there are usually a number of different options/models available for implementing these measures. Sometimes it may be most appropriate to compare these options/measures (see Example 3 below).

All Screening RIAs must include an analysis of options. These may be alternatives to regulation, alternative forms of regulation or alternative implementation options.

Examples of regulatory options/alternatives

ALTERNATIVES TO REGULATIONS	
Types	**Example(s)**
Taxes	Plastic bag tax (Irl)
Subsidies	Capital depreciation allowances for abatement technologies (US)
Information campaigns	Road Safety advertisements (Irl)
Emissions trading	CO2 Trading Scheme (EU)
ALTERNATIVE FORMS OF REGULATION	
'Command-and-control' – regulations which prescribe/ proscribe certain action	Most regulations
Self-regulation – Control of activities by the private parties concerned without the direct involvement of public authorities	Advertising Standards Authority (Irl)
Co-regulation – Control of activities by a combination of action from private parties and public authorities	Medical Council (Irl) Law Society
Performance-based regulation – where the Regulator sets standards and leaves it to the regulated entity to determine how best to meet these standards	Regulations which set emission standards for vehicle manufacturers but leave it to the manufacturer to determine how best to meet these standards (US)
ALTERNATIVE OPTIONS WITHIN REGULATIONS	
The State decides to regulate and introduce a particular measure but there are different options for implementing the particular measure	Many EU Directives

Source: Definitions from Mandelkern Report 2001 82-83;OECD 2002 Annex 2

Example 3: Identification of options for pilot RIA on Medical Practitioners Bill

One of the pilot RIAs was conducted on the Medical Practitioners Bill. In this case, the Government had already committed to introducing statutory competence assurance for medical practitioners but there were a variety of models of competence assurance which could be used. The RIA therefore identified three alternative competence assurance models and compared their performance.

Source: Department of the Taoiseach 2005a

Example 4: Identification of Options

EU Impact Assessment on a Directive to provide for Equal Treatment in Access to Goods and Services

An EU Impact Assessment was conducted on proposals to provide women and men across the Union with a common set of minimum standards of protection against sex discrimination in access to goods and services.

The following options were identified:

- Option 1 – Do nothing
- Option 2 – Reliance on incentive measures and soft law (e.g. Community Action Programme for Equality between Women and Men)
- Option 3 – Limited legislative intervention in the field of goods and services
- Option 4 – Broader legislative intervention in the fields of goods and services, education, taxation, social assistance and stereotyping in the media.

Source: Commission of the European Communities 2003 p. 12

Identification of costs, benefits and impacts

4.9 Once the options have been outlined, the cost, benefits and impacts of these options should be identified and described. For the purpose of the Screening RIA, formal cost-benefit analysis is unnecessary but where possible monetise cost/benefits and impacts (place a monetary value on them) and/or quantify them (express them numerically e.g. number/proportion of lives saved, reduction in traffic volumes etc). As stated in paragraph 3.3, the level of detail included should be proportionate to the significance and likely impact of the proposal.

> Identify costs, benefits and other impacts. Where possible quantify or monetise these impacts.

(i) Risks and assumptions

4.10 For most, if not all RIAs, the nature and magnitude of impacts cannot be predicted with certainty. They can depend on other policy actions, unforeseen future events and how actors or stakeholders behave in response to regulations or policy initiatives. For example, the success of road safety campaigns is dependent on road users assimilating the road safety message and changing their behaviour. The impact of transport policy will be affected by factors such as housing policy and industrial development while international developments such as oil prices may affect the success of industrial policy. There may also be risks associated with certain policy areas. These risks will vary in the likelihood of their occurring and in the damage they might cause.

4.11 Although it is impossible to predict costs, benefits and impacts with certainty, the analysis and examination of available statistics and information should help in achieving the most accurate picture possible. Consultation with stakeholders will also assist in identifying impacts and their magnitude. However, there are also specific techniques which can be used to ensure that uncertainty and risks are specifically taken into account in analysing impacts. These include sensitivity analysis, scenario analysis and the use of ranges (more details on these techniques are available in Appendix B).

4.12 Sensitivity analysis involves changing the value of one variable or factor which is likely to affect the outcome of the regulations/policy initiative. For example, the costs and benefits of health and safety regulations in a particular sector may depend on the future growth of that sector. Impacts could be estimated using a variety of figures for the number of employees or firms in that sector.

4.13 Scenario analysis is a similar technique but involves changing the value of a number of variables or factors simultaneously rather than just one. This approach may be useful for an area where there are a number of uncertainties or risks.

4.14 A third possible approach to uncertainty is to use ranges when presenting estimated benefits and costs. In other words, a RIA might state that costs are likely to be in the range of €1 million to €3 million. Ranges may be broader or narrower depending on the level of uncertainty. When using ranges it is useful to explain the variables or factors which might influence whether a value ends up being at the higher or lower end of the range.

(ii) Costs

4.15 All costs generated by each option should be identified and where possible estimated and set out in a table. It may be necessary to prepare both a short summary table for inclusion within the RIA document and a more detailed cost breakdown which could be presented in an Appendix to the RIA (see the following example). **The distribution of costs (i.e. who bears them) should be described** i.e. costs to the Exchequer (State) or to third parties, business, consumers etc. **Initial (start-up costs) and recurring or annual costs should also be differentiated.**

Table 4.1: Sample cost summary table

	Option A					Total
Year	Initial costs to Exchequer	Initial costs to third parties	Staff costs (Industry)	Compliance costs (Industry)	Costs to consumers	
0						
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
Total						

4.16 One of the key drivers behind the introduction of RIA was to reduce the burden of red tape on business and to ensure that regulations are not imposing disproportionate compliance costs on third parties such as consumers, industry etc. The Screening RIA must therefore identify and where possible estimate the costs of complying with regulatory proposals and specify who will bear these costs. Compliance costs in this context are not merely the direct charges or fees imposed by a proposal. They are any costs which arise from the necessity of having to comply with the regulations in question.

Include compliance costs under the costs section of the Screening RIA. Specify who will bear these compliance costs.

4.17 The RIA should differentiate between one-off and on-going compliance costs (see Box below). In some cases, the estimation of compliance costs will necessitate consultation with those likely to be affected. Where the cost estimates involve particular assumptions, these should be explicitly stated and explained.

Examples of compliance costs

One-off costs	• information costs (identifying and understanding the new regulatory requirement) • upgrading production processes/equipment/ buildings/software etc • buying-in of specialist services (e.g. accounting, IT, legal etc.)
On-going costs	• individual or staff costs or time • inspection fees/ enforcement • licence application process (application form, writing letter, running advertisements etc.) • form filling/administration/paperwork (compiling necessary information, time taken etc.)

Source: New Zealand Ministry of Economic Development 2004

4.18 Quantification of costs can be difficult and particularly so when the cost data comes from those affected by the regulations. Those who may be negatively affected by such regulations may have an incentive to overstate the level of cost, particularly in the case of estimating the cost of compliance. This should be taken into account when estimating costs by, for example, verifying data through the use of other independent sources. Sensitivity analysis or ranges may also be used to take account of different cost estimates (see paragraph 4.13).

4.19 Where a Screening RIA indicates that the proposal may involve initial costs of over €10 million or cumulative costs of greater than €50 million over ten years (including both enforcement costs borne by the State and compliance costs on business, consumers etc) conduct a Full RIA.

Example 5: Cost analysis

Extract from UK Impact Assessment on amendment to firearms legislation aimed at reducing misuse of air weapons and imitation weapons

Note: This cost analysis is strong in setting out assumptions and in covering business and public costs. However, public costs for options 1 & 2 should also have been included.

Three options were identified:

Option 1: Do nothing and rely on current legislation
Option 2: Legislate to make air weapons subject to a certification of registration scheme and to ban imitation weapons
Option 3: Introduce the proposed legislation

Business sectors affected

The affected business sectors would include the manufacturers of air weapons, importers, registered firearms dealers, sporting goods shops, hardware and ironmonger shops, mail order companies, and other retail outlets.

Assumptions

The following assumptions have been made:

- The new offence of possessing of airguns/imitation guns in a public place without reasonable excuse is likely to have a very minimal effect on the sale of such weapons. Sale of these items will not be banned.
- 200,000 new air weapons are sold every year. These figures were provided by the Gun Trade Association (GTA) and cover the year 2001.
- The trade in second-hand air weapons is not quantifiable but the GTA estimates 80% of this trade is carried out privately.
- 10% of new purchases are made by adults, usually parents, for the use of 14 to 17 year olds (20,000).

- 14 to 17 year olds will no longer be able to own an air weapon but will be able to use an air weapon owned by adults if supervised. We estimate that purchases of air weapons intended for use of 14 to 17 year olds will remain mostly unchanged with a fall off in business of only 2% of overall trade (4,000 weapons).
- Average cost of air weapons sold for use by 14 to 17 year olds is £125 bearing in mind that such guns are likely to be at the lower end of the market. (It should be noted, however, that many air weapons can cost several thousand pounds.) This cost would include a sighting scope for the weapon. This estimate has been provided by the GTA.

Costs
There are no costs to business in pursuing Option 1.

Option 2 would result in massive costs to business.
Part prohibition (all air pistols would be likely to become prohibited) estimated at 50% of total sales of new air weapons which would range from £12.5m (100,000 x £125) for standard entry weapons to £100m (100,000 x £1000) for the more expensive weapons.

Loss of business from need for registration estimated at 10% which would range from £2.5m (20,000 x £125) to £20m (20,000 x £1000). This would mean a total loss to business of between £15m to £120m.

Option 3 would result in a loss of business on new purchases for the use of 14 to 17 year olds of £600,000 (4,000 x £125). There is no discernible costs issue here as we believe the proposals will create no greater burden than already exists. Neither air weapons nor imitation firearms will be banned and will still be available for sale/trade

Firearms dealers are small businesses and will not, we believe, be unduly affected by these changes, as it is already illegal to purchase an air weapon under the age of 17.

Public costs
(Note: only the costs of Option 3 are identified. The Irish RIA model specifies that the costs of all options identified should be examined.)

In 2001-02 there were 173 convictions of young people under the age of 17 in connection with air weapon offences. The caution rate for these offences is approximately 75%. As a result 44 people appeared in court. It is likely that the new offence will mean more arrests but its deterrent effect should keep these to a minimum. We are therefore making an estimate of 250 arrests. We will make an assumption (based on 2001-02's records) that 75% will accept a caution. This will mean that 70 will proceed to a court hearing. These cases would be heard at Magistrates and Youth Courts. The cost for this has been assessed at £173.25 per case. Lord Chancellor's Department (LCD) have assessed the Legal Aid costs for arrests and prosecutions to be £47,190.

- Court costs = 70 cases x £173.25 = £12,127.50 p.a.
- Police costs = 250 cases x £32 (2 hours at £16 per hour) = £8000 p.a.
- CPS costs = 250 cases x £366 = £25,620.
- Legal Aid costs = £47,190.
- Total costs = £92,937.50.
- Rounded Up = £93,000.

With regard to the offences relating to possession of an air weapon or an imitation air weapon in a public place we have received information from the police that shows there were 11,000 deployments of Armed Response Vehicles (ARV) during 2000-01. These figures cover only English and Welsh forces. We have therefore estimated a further 2000 call-outs for Scottish forces. We have worked on 70% of these call-outs being for air weapons and imitation weapons.

This equates to 9,100 call-outs. We estimate that 50% of these cases would immediately show the suspect to have a clear reasonable excuse for possession of the weapon. Of the remaining 4,550 many would not be charged or would be charged with other, more serious offences and others would be able to prove a reasonable excuse in due course. We would expect 1,000 cases to result in charges. We are likely to see the

same caution rate of 75%. The cost for each case in a Magistrates court is £74.25 and LCD estimate Legal Aid costs for arrests/prosecutions and appeals to amount to £192,050. We assume 32 appeals.

- Police costs: 1,000 cases x £32 = £32,000.
- Court costs: LCD estimate £16,600.
- Legal Aid costs: £192,050.
- Appeal costs: not identified.
- CPS costs: 250 cases x £366 = £25,620.
- Total Costs = £266,270.

We expect there to be some initial training costs for the police to enable them to enact this legislation, but this should be offset by reduced costs in investigating the more serious incidents of criminal damage and injury caused by the misuse of air weapons. Unfortunately it is impossible to quantify any gains or losses in this area. The same situation also applies to downstream costs such as court cases. There will be cases that relate to this new offence but they are likely to be less costly than those cases involving actual misuse of a weapon.

(iii) Benefits

4.20 Once the costs associated with each option have been identified, these must be compared with their relative benefits. The benefits of a regulation or other policy initiative are likely to be closely related to its objectives. For example, if the objective of a regulation is to reduce air pollution, a successful regulation in this context would be one which achieves the benefits of cleaner air or a reduction in pollution. When comparing options, one area of focus must therefore be the extent to which each option will achieve the desired benefits (in this example the likely reduction in pollution).

> Identify the benefits of each option. Take into account both tangible and intangible benefits.

4.21 Many regulations or policy goals involve the achievement of non-tangible benefits such as protecting public safety, improving public health, increasing the accountability of Regulators etc. It is often mistakenly assumed that because it is difficult, if not impossible, to monetise these benefits that they cannot be analysed. While it is true that assigning monetary values to the intended benefits of a project is the most difficult element of assessing costs and benefits, there are a variety of analytical techniques which are available to analyse benefits, some of which are relatively non-technical.

4.22 One technique which is often used is multi-criteria analysis (MCA). This involves the identification of the objectives behind a policy proposal as well as criteria which would indicate the achievement

of these objectives. The various policy options are then compared as to which best meets the criteria identified and therefore is most likely to achieve the overall objectives. Table 4.2 sets out a hypothetical multi-criteria framework. (For further details on MCA, Cost-Benefit Analysis [CBA] and other analytical techniques, see Appendix B and the further guidance section in Chapter 6.)

Table 4.2: Hypothetical multi-criteria framework for social regulations[2]

	Option A	Option B	Option C
Objective 1: Protect the public from harm			
Comprehensive	1.7	3.0	2.6
Independent	2.1	1.7	1.2
Responsive	2.1	1.3	2.7
Average standardised score	1.9	2.0	2.2
Objective 2: Provide a means of redress			
Transparent			
Equally accessible to all socio-economic groups			
Consistent			
Fair			
Well publicised			
Average standardised score			
Objective 3: Operate efficiently			
Value for money			
Leadership			
Quality assurance			
Average standardised score			

[2] In this case, respondents are offered the rankings of low, medium or high which are then assigned scores of 1,2 or 3. However, rankings could be represented in the form of symbols e.g. √, √√ or √√√. Further guidance on MCA is available in a document published by the UK Office of the Deputy Prime Minister, 2001.

4.23 All Screening RIAs should include a structured analysis of benefits. At a very minimum, the anticipated benefits of each option should be stated. The level of benefits which each option is likely to achieve should also be stated. Where this involves specific assumptions, these should be explicitly stated. Where possible, use multi-criteria analysis or a similarly structured approach.

> A Screening RIA must include a structured analysis of benefits. Where possible, estimate the magnitude/level of benefits associated with each option.

4.24 The distribution of benefits must also be examined i.e. which individuals/groups/regions/sectors will reap the benefits associated with each option. This is important because observers such as the OECD have suggested that in the past Irish regulation has been biased towards producers at the expense of consumers. It is also important in achieving overarching principles such as equality and social inclusion. Different options will achieve a different distribution of costs and benefits. This must be highlighted so that the final policy choice is based on a full picture of the benefits and their distribution.

4.25 Table 4.3 is an example of a summary benefit table from an EU Impact Assessment. This is an example of best practice because it examines the performance of each option in achieving a series of explicitly identified benefits. The Impact Assessment also contains more detailed text explaining the benefits achieved and why certain options are likely to achieve more benefits than others.

Table 4.3: Example of summary of benefits[3]

Example 6: EU Impact Assessment of Regulation on Visa Information System (VIS) and the Exchange of data between member states on short-stay visas

Benefits	Efficiencies in implementing of Common Visa Policy	Reductions in fraud and visa shopping	Increased efficiency of border checks	Reduction in illegal immigration	Facilitates the Dublin Regulation	Contribution towards internal security	Increased efficiencies for bona fide travellers	Other spin offs
No VIS	-	√	√	√	-	√	-	-
Entry-exit system	√√√	√√√	√√√	√√√	√√√	√√	√√√	√√√
VIS without biometrics	√√	√√	√√	√	-	√	√√	√
VIS with biometrics	√√√	√√√	√√√	√√	√√√	√√	√√√	√√√

(iv) Other impacts

4.26 A number of other impacts are required to be examined as part of a Screening RIA. Six areas which must be examined and described are listed below. Where significant impacts under any of these headings are identified as part of the Screening RIA, a Full RIA must be conducted. Specific guidance on each one is provided in this section.

[3] The options identified were (i) no visa information system (ii) an entry-exit system to be examined and for appropriate information to be gathered relevant to immigration and residence status (iii) visa information system without biometrics (iv) a visa system with biometrics.
√ - small impact √√ - medium impact √√√ very significant impact √√√√ exorbitant impact

Impacts which must be analysed

(a) Impacts on national competitiveness
(b) Impacts on the socially excluded or vulnerable groups
(c) Impacts on the environment
(d) Whether the proposals involve a significant policy change in an economic market including an examination of the impacts on consumers and competition
(e) Impacts on the rights of citizens
(f) Whether the proposal involves a significant compliance burden.

WHERE THERE ARE SIGNIFICANT IMPACTS UNDER ANY OF THESE HEADINGS CONDUCT A FULL RIA

National competitiveness

4.27 Competitiveness is such a multi-dimensional concept that it is difficult to precisely define it. In fact various stakeholders often have completely different definitions for competitiveness. However, the National Competitiveness Council (NCC) uses a very comprehensive definition of competitiveness defining it as:

"the ability to achieve success in international markets leading to better standards of living for all. It stems from a number of factors, notably firm level strategies and a business environment that support innovation and investment, which combined lead to strong productivity growth, real income gains and sustainable development."

4.28 Examples of the factors that influence competitiveness include investment in science and technology and the use of this knowledge in new and existing industries, the quality of infrastructure and the public service, the education system and skills of the workforce, competition policy, the incentives and support services provided to the enterprise sector, the adoption of advanced work practices and the quality of management.

4.29 The NCC analyse Ireland's competitiveness according to a competitiveness pyramid, which distinguishes between the inputs into national competitiveness (where policy-makers can have the most influence on Ireland's competitiveness) and the outputs, which are not within the direct control of policy-makers.

Figure 4.1: National Competitiveness Pyramid

Source: NCC 2003 National Competitiveness Challenge

4.30 All proposed regulations must therefore be examined as to whether they could negatively impact on:

- Ireland's business and work environment
- Economic and technological infrastructure
- Education and skills
- Entrepreneurship and enterprise development
- Innovation and creativity.

If it is considered that there will be significant impacts under any of these headings and therefore on national competitiveness, conduct a Full RIA (see Chapter 5 for guidance on the Full RIA approach). A significant impact constitutes an impact that will have a material adverse effect on relevant stakeholders. To determine whether or not there will be significant impacts and to competitiveness test the proposed regulation, it is strongly recommended that a detailed consultation with the relevant stakeholders be carried out. The relevant stakeholders are usually best placed to outline both the direct and indirect consequences of implementing a proposed regulation.

Examine the effects of the regulation on national competitiveness.

Impacts on the socially excluded or vulnerable groups

4.31 Government Departments and Offices have been required to proof impacts on poverty and on vulnerable groups since 1998. The revised National Anti Poverty Strategy *Building an Inclusive Society* (Government of Ireland 2002) and Ireland's *National Action Plan Against Poverty and Social Exclusion* (Government of Ireland 2003) stress the cross-cutting nature of poverty and exclusion and identify a number of policy areas relevant to tackling social exclusion such as employment, income maintenance, education, health and housing policy. They also identify several groups which are vulnerable to poverty and social exclusion: women, children and young people, older people, people with disabilities, Travellers, prisoners and ex-prisoners, migrants and ethnic minorities. Reducing urban poverty and rural disadvantage are also key national priorities.

4.32 The Government is also committed to promoting equality in terms of access to employment, and access to goods, facilities and services. Ireland's equality legislation prohibits discrimination on nine grounds: gender, marital status, family status, sexual orientation, religion, age, disability, race and membership of the Traveller community.

4.33 The National Health Strategy, *Quality and Fairness- A Health System For You*, states that *"Health Impact Assessment (HIA) will be introduced as part of the public policy development process"* and indicates that HIA is to be carried out on all new relevant Government policies. A Screening RIA should therefore, where appropriate, examine the potential impact on health with

particular reference to health inequalities. Further guidance is available from the Social Inclusion Unit in the Department of Health and Children and the Institute of Public Health in Ireland. (www.publichealth.ie)

4.34 The Screening RIA should examine and identify potential impacts on social inclusion or vulnerable groups, taking account of the policy areas and groups identified above. In doing this the likely impact of the policy or regulation on poverty and on the inequalities which are likely to lead to poverty should be considered. Where significant impacts under any of these headings are identified, a Full RIA must be conducted. Appendix C sets out more details as to how poverty impact assessment should be conducted. Further guidance on social inclusion and equality issues may be obtained from the Office for Social Inclusion in the Department of Social and Family Affairs (www.socialinclusion.ie), and the Equality Division in the Department of Justice, Equality and Law Reform.

> Examine the impacts of regulations on social inclusion and vulnerable groups.

Environmental Impacts

4.35 A Screening RIA must also examine and identify potential impacts of proposed regulations on the environment. National policy in relation to the environment includes *Sustainable Development: A Strategy for Ireland; Making Ireland's Development Sustainable;*

Waste Management: Changing Our Ways; Waste Management: Taking Stock and Moving Forward; National Climate Change Strategy and *the National Biodiversity Plan.* (These documents are all Department of the Environment, Heritage and Local Government publications. See reference list for full details).

4.36 The Environmental Protection Agency publishes periodic reports on the state of Ireland's environment, which identify pressures and impacts on the environment from various economic sectors, as well as highlighting trends across the range of environmental media. The Environmental Protection Agency has also identified a number of environmental issues which should be examined when conducting environmental impact assessments and provides information sources to guide analysis under each heading:

- Air quality
- Water quality and resources
- Soil quality
- Climate Change
- Environment and Human Health
- Natural Heritage and Biodiversity
- Waste
- Noise
- Landscape and Land-use change
- Material Assets (such as water supply and management, infrastructure, housing, transport, industry etc.)
- Cultural Heritage, including architectural & archaeological aspects.

(See http://www.epa.ie/TechnicalGuidanceandAdvice/StrategicEnvironmentalAssessment/)

4.37 Where significant negative environmental impacts are identified under any of these headings, a Full RIA must be conducted. In determining the significance of impacts, consideration should be given to:

- The overall risks to environment and human health
- The probability, duration, frequency and reversibility of the impacts
- The magnitude and spatial extent of the impacts (geographical area and size of population affected)
- The cumulative nature of the impacts
- Transboundary pollution risks
- The effects on areas, landscapes or species which have a recognised national or international protection status.

> Examine the impacts of regulations on the environment.

Significant Policy Change in an Economic Market/Impact on consumers and competition

4.38 The Screening RIA must assess whether the regulatory proposals involve a significant policy change in an economic market. Officials will in general be best placed to determine what is a significant change in a particular policy area under their aegis. However, in general terms there are a number of policy changes which are likely to be significant in a particular economic market or sector. For example, changes to the regulatory framework such as the transfer of power to an Independent Sectoral Regulator, or a significant change to a Regulator's powers and functions are likely to be significant in their impacts. Other regulations which might fall under this heading include the removal or addition of

restrictions on producers in a market or the liberalisation of the provision of a particular product or service.

4.39 It is also necessary that impacts on consumers and competition be examined under this section of the Screening RIA. Greater competition stimulates innovation and efficiency among businesses; contributes to lower prices of goods and services for consumers and enhances overall national competitiveness. Regulation can impact on competition in a number of ways. For example, regulations can create barriers to entry such as limiting the number of suppliers in a market e.g. capping the number of licences; it can restrict the supply of certain services e.g. the restriction on the provision of services by persons other than a particular group.

4.40 In analysing the impact of a regulation on competition the following questions might be useful:

- Is it introducing higher switching costs for consumers?
- Will there be restrictions on consumers' choice?
- Will there be restrictions on firms' choice?
- Is the regulation likely to restrict entry to the market?
- Is the regulation likely to alter market structure?
- Is the regulation likely to increase some firms' market power?
- Is the regulation likely to reduce the competitive position of small enterprise relative to large?
- Would set-up costs be higher for new producers?
- Would ongoing costs be higher for new producers?
- Are some firms affected substantially more than others?

Where significant changes are identified under any of these headings, a Full RIA must be conducted.

Establish whether the regulations will involve a significant policy change in an economic market. This should include an examination of the impacts on competition and consumers.

The rights of citizens

4.41 Assess whether the proposals impinge disproportionately on the rights of citizens. Although it is the role of the Courts to adjudicate on cases of human rights breaches, officials should examine proposed regulations from this perspective and conduct a Full RIA where significant human rights impacts are identified. There is often a balance to be achieved between protecting individual freedoms and promoting the welfare of society. Judgements in relation to the appropriate balance in each case will be made by the relevant Minister based on the advice of officials, legal obligations and other factors.

4.42 In examining such impacts, consideration should be given to the personal rights defined in the Irish Constitution as well as to international agreements to which Ireland is a party. These include United Nations Treaties such as the *Universal Declaration of Human Rights* and Council of Europe Treaties like the E*uropean Convention for the Protection of Human Rights and Fundamental Freedoms.* Examples of such rights are the right to life, liberty and security of person, the right to equal protection before the law,

freedom of movement and the right to own property. Further information and publications on Human Rights can be obtained from the website of the Irish Human Rights Commission.

Examine the impacts on the rights of citizens.

Compliance burden

4.43 The level of compliance costs and who will bear them will have been detailed under the costs section of the RIA. At this point in the RIA these costs should be re-examined from the point of view of their proportionality and distribution. Where the Screening RIA suggests that there will be a disproportionate compliance burden generated by the regulations (i.e. where the compliance costs are not accompanied by sufficient benefits), a Full RIA must be conducted.

(v) Summary of costs, benefits and impacts

4.44 To complete Step 2 of the Screening RIA summarise the costs, benefits and impacts of each option being considered. Any significant impacts under the headings discussed in the previous section should also be summarised.

4.45 In some cases, it will be appropriate at this stage to identify a preferred option based on the costs/benefits and impact analysis. In other circumstances there may be other factors influencing the decision so that the RIA should only summarise the pros and cons of each option.

Summarise the costs, benefits and impacts specifying the cost-benefit ratio where possible. Select a preferred option where appropriate.

Consultation

4.46 Informal consultation must be conducted as part of a Screening RIA. Although reporting on consultations is the third section of the Screening RIA document, consultation with key stakeholders should take place as early as possible in the RIA process so that it can feed into the analysis of costs, benefits and impacts. There are a variety of mechanisms for consultation and these are summarised in more detail in Appendix D. Detailed guidance on consultation can also be found in *Reaching Out: Guidelines on Consultation for Public Sector Bodies* (Department of the Taoiseach, 2005b).

4.47 What is meant by *informal* in this context is that the consultation is not necessarily publicly advertised or all-inclusive. It might not necessarily involve formal consultation documents or fixed time-frames for responses. However, it is important that even informal consultation should be balanced in terms of seeking views from different interests in the process. At the very least, consumer interests and all Government Departments and Offices must be consulted as part of a Screening RIA. In general, it is desirable that all affected parties should also be consulted including the Social Partners and relevant industry groups. Consultation with the National Consumer Agency which represents the interests of consumers should be considered. Consideration should also be

given to informally consulting the Competition Authority as part of the Screening RIA. One of the Authority's statutory functions is to advise the Government and individual Ministers about the implications of legislative proposals (including any statutory instruments) for competition in markets for goods and services. Some of these implications can be subtle, and not readily apparent or identifiable at first sight.

4.48 A summary of views conveyed through the consultation process should be provided as part of the Screening RIA. The RIA should also contain a response to the views expressed. Where the final regulatory proposals do not take on board points/issues raised during the consultation process, this should be explained where possible. In general, the wider the consultation that takes place, the more buy-in there is likely to be from those affected by regulation and the lower the likelihood of unforeseen impacts of regulatory proposals.

> Conduct consultation as early as possible in the RIA process. Consult all key stakeholders. Summarise all views expressed within the RIA document and respond to these views.

Enforcement and compliance

4.49 Compliance costs will already have been detailed as part of Step 2 of the RIA. The RIA should also include specific information as to how enforcement of the regulations is to be achieved. Regulations which are not enforced will not achieve their objectives. A key question that must be addressed within the RIA is whether the

regulations are enforceable within the budget and constraints available. Where the answer to this question is no, an alternative policy option must be considered.

4.50 Other questions that should be addressed in relation to enforcement include the following:

- Will enforcement be carried out by an existing body/authority?
- If so, will it have the resources to take on board these new functions?
- If a new enforcement agency/office is to be created, the costs of establishing and running this new body must be included under the costs section of the RIA.

It should be noted in this context that the White Paper *Regulating Better* (2004, 44) commits that

"where new regulators are proposed, they will be established only if the requirement for a regulator can be clearly demonstrated and if responsibility for the sector in question cannot be assigned to an existing regulator."

4.51 RIA must also clarify where any new body created will fit within the existing regulatory landscape, who it will report to and how accountability will be achieved. If an existing body is to be charged with enforcement, this body should be consulted at an early stage to ensure that any specific issues or difficulties are identified and addressed. Where more than one body is charged with enforcement in a sector, consideration must be given as to how to ensure co-ordination and consistency amongst the bodies/agencies involved.

Describe the enforcement arrangements. What agency/body is to be charged with enforcement? Detail how the Better Regulation principles of consistency and accountability are to be achieved under the enforcement regime.

4.52 Achieving full compliance may not always be possible. Some thought must be given as to what levels of compliance are necessary for the regulations to achieve their objectives. As a general rule of thumb, the higher the level of risk associated with a policy area, the higher the necessary level of compliance. Compliance targets should be set out within the RIA and the RIA should also examine how best to ensure that these levels of compliance are achieved. Where risks are lower, less costly and bureaucratic methods of enforcement should be considered such as spot-testing for compliance, risk-based inspection or using self-assessment mechanisms.

What are the compliance targets?
How are these best achieved?

Review

4.53 The final step in the Screening RIA is to identify mechanisms for periodically reviewing the regulations to evaluate the extent to which they are achieving the objectives/intended benefits. Possible review mechanisms include reporting on performance within Annual Reports, consulting with stakeholders and establishing Review Groups. Sunsetting should also be considered. This is where at the time a regulation is made, a specific date is set on which the regulation will expire unless it is remade. This ensures that the regulation will be formally reviewed in the future to establish whether or not it is still valid, or if it could be improved, reduced or even revoked.

4.54 Performance indicators should be identified to indicate the extent to which the regulations are meeting their objectives. These might include compliance targets, levels of satisfaction amongst stakeholders or the achievement of particular goals or targets. For example, road safety policies specify indicators such as the number of lives lost in accidents, the number of serious injuries caused through accidents, the number of road accidents etc.

4.55 Once performance indicators have been identified, consideration should be given as to how information/data on these performance indicators will be obtained. This may involve the commissioning of research, the establishment of consumer or stakeholder feedback mechanisms or the collection of new statistics. Details of the data which will be used to measure performance should be stated.

Specify performance indicators. Identify the mechanisms for measuring these and the data which will be used.

4.56 **The Screening RIA is now complete!** Where a Full RIA is not required, summarise the Screening RIA in the Memorandum for Government. The Screening RIA should be attached to the Memorandum for Government (or proposed Directive/significant EU Regulations if applicable) and the usual legislative and Cabinet procedures should be applied. Publish the Screening RIA along with the draft legislation, Directive or SI, taking account where necessary of relevant exemptions under the Freedom of Information Act. Where the Screening RIA indicates significant impacts or costs, begin the process of conducting a Full RIA.

WHEN CONDUCTING RIAS:

DO

Apply RIA as early as possible in the policy development process	✔
Consult at an early stage	✔
Remember that readers may not be familiar with the policy area	✔
Use clear accessible language	✔
Summarise the most salient and relevant points	✔
Detail any assumptions made in evaluating impacts	✔
Remember the principle of proportionate analysis	✔

DO NOT

Use technical jargon or acronyms without explaining them	✘
Limit the analysis to just one option	✘
Base cost estimates on a best-case scenario	✘
Neglect social, environmental and other intangible impacts	✘

5: Conducting a Full RIA

Introduction

5.1 The Full RIA involves a more detailed analysis than the Screening RIA. However, the guidance for conducting a Screening RIA contained in the previous chapter is relevant for a Full RIA also. To avoid repetition, the information in the last chapter will not be reproduced again. Rather, this Chapter will detail the additional requirements and considerations involved in completing a Full RIA. Additional relevant information is also contained in the Appendices.

Statement of policy problem and objectives

5.2 The statement of the policy problem should follow a similar format to the first Step of the Screening RIA. Details should be supplied on the background to the issue and why it has to be addressed at this particular time. Where necessary, details of the existing regulatory framework should be provided as well as any relevant international obligations. The objectives behind the policy intervention should be identified, taking account of the distinctions set out in paragraphs 4.4 - 4.7 between ultimate and immediate objectives, and ensuring that objectives fulfil the SMART criteria. The extract from the Australian RIA which follows is a good example of a succinct account of the background to the issue and clearly stated objectives.

> Clearly and succinctly set out the background to the policy issue. Identify the objectives behind the regulation/policy measure.

Example 7: Extract from Australian Regulatory Impact Statement on the Broadcasting Services Amendment (Media Ownership) Bill 2002

PROBLEM

Technological progress and globalisation are combining to change the structure of the Australian media market, and patterns of media consumption. While industry participants have responded to these changes by investing in new technology enterprises, and forming broader strategic partnerships, regulation of ownership and control of Australian media has been largely static. This has created tension between the tendency towards convergence in the communications market, and legislative provisions based on sector-specific regulation and an assumption that influential sources of news and opinion are limited to traditional domestic media outlets.

Restrictions on cross-media and foreign ownership and control are no longer relevant to the current media environment. The Government's election policy notes that *"without reform, the current media ownership laws will consign the Australian media sector to an outdated structure, little or no capacity for new players, an absence of further competition, and an inability to respond to a rapidly evolving and converging international media environment."* The ownership and control regime gives rise to potential organisational inefficiencies and restrictions on competition. The restrictions also hinder the Broadcasting Services Act's (BSA) objective, under section 3(e), *"to promote the role of broadcasting services in developing and reflecting a sense of Australian identity, character and cultural diversity".*

The cross-media restrictions on ownership and control contained in the BSA are inflexible and tightly focussed. They do not provide scope to reflect the changing influence of technologies, and the evolution of the communications market, over a period of time.

The application of restrictions on foreign ownership and control of commercial free-to-air and subscription television similarly limits investment and innovation. The foreign ownership restrictions are inconsistent with the regulation of other areas of the media.

OBJECTIVES

The objective of the proposed amendments to the BSA is to improve competition in the media sector while supporting the objects of the BSA.

For foreign ownership and control specifically, an objective is to allow greater access to capital together with continuing general foreign investment safeguards.

In the case of cross-media reform, the proposals seek to allow increased scope for commercial opportunities whilst preserving a diversity of opinion and information which is of relevance to local communities.

A second general objective is to ensure that the legislative framework has sufficient flexibility to accommodate changing conditions within the communications environment, and that the objectives of the BSA are applied consistently across the media sector.

Source: The Parliament of the Commonwealth of Australia 2002

Identification and description of options

5.3 A Full RIA requires a more detailed analysis of options than the Screening RIA. The do–nothing/no policy change approach should be included since it provides a useful benchmark against which to compare all other options. An alternative to regulation or alternative form of regulation to command-and-control must also be included (see paragraph 4.9 and Appendix A.) This may include alternatives to regulation such as an economic instrument or information campaign or involve an alternative model of regulation such as self-regulation, co-regulation or performance-based regulation.

5.4 Each option should be clearly described and explained. Where an option has a number of components, detail each one. An extract from a UK RIA is supplied below where the options are clearly set out and described[4].

> Examine at least three options. Include the 'no policy change' option and at least one regulatory alternative

[4] This RIA does not however examine the costs and benefits of all these options, as the Irish model specifies

Example 8: Extract from UK Sub-RIA[5] on Recovery of NHS Treatment and Ambulance Costs

Options
This is not a regulatory measure in the sense of one which is intended to adjust a system to work correctly through the imposition of rules. It has more in common with a non-regulatory economic instrument but does bring with it responsibilities for business. Those responsibilities are meeting the cost of the NHS treatment plus the administrative costs associated with payment.

Four options have been identified:

Option 1
Do nothing. Doing nothing does not address the issue raised by the Law Commission that by providing healthcare free of charge the NHS in effect discharges part of a wrongdoer's liability.

Option 2
Withdraw NHS services where liability accepted. Withdrawing NHS services once a person or institution had accepted liability would not reduce the costs of immediate/short term care to the NHS as liability would be unknown at that stage. At a later stage, whilst it would remove the cost from the NHS it would place an equal or, more likely, greater burden on the compensator of having to pay for private sector treatment. It is not known if there would be sufficient capacity available outside the NHS to provide the needed treatment or whether people entitled to use the NHS would be willing to be transferred to the private sector.

Option 3
Improve health and safety regulation. Health and safety regulation is already comprehensive in the UK and whilst continuous efforts are

[5] The UK Health and Social Care (Community Health and Standards) Bill involved a number of different policy measures. The approach taken was to break down the Full RIA into a number of discrete mini or sub-RIAs – one of which was on the Recovery of NHS Treatment and Ambulance Costs where people claim and receive personal injury compensation. The Full RIA is available @ http://www.dh.gov.uk

made to improve regulation, it is unlikely that this would reduce the burden to the NHS in either the short or medium term.

Option 4
Introduce, through primary legislation, the recovery of NHS charges following payment of compensation, with the intention that this is based on a simple tariff system of NHS charges with central collection by Compensation Recovery Unit (CRU).

Impact Analysis including costs and benefits of each option

5.5 The basic principles outlined in Chapter 4 in relation to the analysis of costs, benefits and impacts also apply in conducting a Full RIA. However, a Full RIA involves a more detailed and rigorous analysis of impacts, costs and benefits. It should examine and measure costs and benefits under all the key headings previously specified i.e.

(a) National competitiveness
(b) The socially excluded or vulnerable groups
(c) The environment
(d) Changes to an economic market including competition and consumer impacts
(e) Impacts on the rights of citizens
(f) Compliance burden on third parties.

The analysis should however involve more detailed and accurate quantification and in some cases full Cost-Benefit Analysis will be necessary (see Appendix B).

5.6 The analysis of benefits and costs is the central analytical element of the RIA . It necessitates an analysis of all the costs and benefits which are likely to result from a regulation/policy proposal. The costs and benefits must then be compared. **Where the costs exceed the predicted benefits, the proposal should be refined or in certain circumstances abandoned.**

Conduct a robust and structured analysis of costs, benefits and impacts. Use formal Cost-Benefit Analysis where possible. CBA must be considered where costs of €50 million over ten years are likely.

5.7 In principle this sounds like a relatively straightforward process. However, the analysis of costs and benefits can be extremely complex. A number of categories of costs and benefits exist as well as a variety of analytical techniques for evaluating them. These will briefly be outlined in this section and referred to in more detail in Appendix B. Some key issues that should be considered in analysing costs and benefits are set out below.

Tips for analysing costs and benefits

- The information and analysis on the costs and benefits in the RIA should be proportionate to the likely impact. But the analysis should always be rigorous in order to inform decision-making to the greatest degree
- You should spell out and test any assumptions, and provide a reference to any data sources or data analysing methodologies used
- Quantify where possible and provide detailed qualitative analysis for the few cases where quantification is not possible. Use broad orders of magnitude or ranges where there is uncertainty
- Think about who benefits and who bears the costs
- What sort of costs are there (policy or implementation)?
- What are the distributional impacts of the policy?
- What are the risks associated with implementation and how will these affect the costs and benefits?

Source: UK Cabinet Office 2003 Better Policy-Making : A Guide to Regulatory Impact Assessments Annex 4

(i) Types of costs and benefits

5.8 There are a variety of types of costs and benefits including *tangible* and *intangible*, *direct* and *indirect*, *real* and *pecuniary* (Mulreany 2002, 6-7). These are defined below and examples of each are provided in Table 5.1 which follows.

Types of costs and benefits

- **Tangible** costs and benefits are those which can be valued by the market. In other words, they can be monetised
- **Intangible** costs and benefits cannot be valued by the market. They cannot be monetised
- **Direct** costs and benefits are those which are related to the primary objective of the regulations
- **Indirect** costs and benefits are secondary outcomes of the regulations and are not related to its primary objectives
- **Real** costs and benefits are those derived by the final consumer and add or subtract from the overall welfare of society
- **Pecuniary** costs arise when the costs borne by one sector of society are matched by a similar level of benefits received by another group. There is no change in the overall welfare of society. Pecuniary costs should not be counted in cost-benefit analysis but should be taken into account in evaluating options.

Table 5.1: Examples of types of costs/benefits of irrigation project

Irrigation project			
Real		**Benefits**	**Costs**
Direct	Tangible	Increased farm output	Cost of pipes
	Intangible	Beautification of an area	Loss of wilderness
Indirect	Tangible	Reduced soil erosion	Diversion of water
	Intangible	Preservation of rural society	Destruction of wildlife
Pecuniary		Relative improvement in farm equipment industry	

Source: Mulreany 2002 p. 6

(ii) Analytical techniques

5.9 There are a number of techniques which can be used for the analysis of costs and benefits. These include **cost-effectiveness analysis**, **multi-criteria analysis** and **cost-benefit analysis**. CBA is the most robust approach to examining costs and benefits. More detail on applying these techniques is provided in Appendix B.

5.10 There is no specific rule as to which approach should be used when conducting a Full RIA. This will depend on the policy area, the time and resources available and the level of costs involved. Crucially however, it depends on whether it is possible to monetise (put a monetary value) on the costs and benefits of a regulatory proposal. Where this can be achieved, full Cost-Benefit Analysis should be considered and in particular **where it is expected that the regulations will generate costs of €50 million over ten years** (see Appendix B). This includes costs borne by the State as well as costs of compliance on consumers, business etc. This threshold is drawn from the Department of Finance *Capital Appraisal Guidelines* (2005) which are a useful resource when embarking on detailed analysis and evaluation.

5.11 Where monetisation is possible, the benefit-cost ratio (i.e. benefits divided by costs) should be estimated or at a minimum the level of costs relative to the benefits of each option should be summarised (see sample Table 5.2 below). There are a number of decision rules which can influence the choice of option but as a general rule the greater the ratio of benefits to costs the better.

Table 5.2: Summary of costs and benefits

	€ million			
Project	**Costs**	**Benefits**	**Net benefits**	**Benefit-cost ratio**
A	145	175	30	1.2
B	50	125	75	2.5
C	125	100	-25	0.8

Analytical techniques which can be used as part of RIA

Cost-Effectiveness Analysis: This is a less demanding alternative to formal Cost-Benefit Analysis. It compares the costs of different options for achieving a particular policy objective and it may be used where significant costs or benefits associated with a regulation cannot be monetised. Its drawbacks are that it does not provide any insights into the level of benefits which should be sought, or whether the desired benefits are worthwhile. Nor does it identify unanticipated or secondary impacts.

Cost-Benefit Analysis: In Cost-Benefit Analysis all of the relevant costs and benefits, including indirect costs and benefits, are taken into account. Cash values, based on market prices (or shadow prices, where no appropriate market price exists) are placed on all costs and benefits and the time at which these costs/benefits occur is identified.

The general principle of Cost-Benefit Analysis is that a regulation is desirable if the economic and social benefits are greater than economic and social costs.

Multi-criteria Analysis: This involves the assessment of policy options according to how well they achieve an explicit set of objectives. It involves the development of measurable criteria to assess the extent to which the objectives have been achieved. The relative performance of each option in achieving the objectives can then be compared with the relative costs of each option. MCA often involves the development of weightings for each criterion to achieve an overall ranking of options since one option may score well on one criterion while an alternative option may score better against another.

(iii) General rules and principles in analysing costs and benefits within CBA

5.12 Key rules in analysing costs and benefits as part of a CBA are to exclude transfers and to avoid double-counting. Some costs or benefits resulting from policy measures are simply transfers from one section of society to another (i.e. pecuniary costs and benefits). For example, the revenue from taxes and social security benefits or grants constitute transfers. Such revenue should not be included in the calculation of net costs and benefits within a RIA. They should however be taken into account when the distributional impacts of the regulations are being examined as part of this Step. They may also be relevant to impacts on the socially excluded or vulnerable groups. Care also needs to be taken to avoid any double-counting of costs and benefits. If a cost is incurred by one group or sector and passed on to another through, for example, increased prices, this cost should only be counted once. These costs should be included instead in the analysis of distributional effects.

When quantifying net costs and benefits, do not include transfers and avoid double-counting. Discount costs and benefits to reflect the time value of money.

(iv) Discounting

5.13 The value placed on costs and benefits depends on when they occur. Most policy options result in costs and benefits that arise at different times and the value placed on costs and benefits depends on when they occur. For example, building a road has an immediate cost, but generates benefits over a long period. When a constant amount of money is received over a set period of time, this sum will be worth more in the early years compared with later years. Conversely, costs to be paid in the future are less onerous. The discount rate is a correction factor reflecting these facts. A Full RIA should take account of the time value of money through the use of discounting.

5.14 Discounting allows the direct comparison of costs and benefits occurring at different points in time, valuing immediate costs and benefits more highly than those that occur later. When discounting is used, it should be applied to both costs and benefits. The total of the discounted costs and benefits of a policy option is called its *net present value*. When conducting formal CBA, the preferred option is generally the one with the highest net present value. Before discounting costs and benefits, you should seek advice from the Department of Finance as to the most appropriate discount rate. More information and examples of discounting can be found in publications by the Commission of the European Communities (2005, 39-41) and in the Department of Finance (2005, 34-35).

5.15 Where benefits and costs are being measured over time, the analysis should be conducted at constant prices, except where there is a significant change in the relative prices of an input or output (e.g. an anticipated large increase in oil prices over time).

(v) Alternatives to monetisation

5.16 There are many policy areas where costs and impacts are significant but where full monetisation of benefits is not possible. This may particularly arise in the context of environmental or social costs and benefits. In some cases, it may be possible to quantify (place some numerical value) on these benefits. For example, it might be possible to estimate the number of consumers likely to benefit from a regulation without putting a financial value on the benefit which each consumer would receive. In other cases, it may only be possible or proportionate to describe or analyse benefits qualtitatively. For example, in evaluating the benefits of three models of regulatory structure appropriate text might be:

"Data from stakeholders and experts in the field suggests that Option A will score highly in terms of accountability. Option B would score only averagely in achieving accountability because it does not involve formal reporting requirements. Option C is not expected to enhance accountability at all because it continues with the current structures which are no longer in keeping with modern governance and accountability requirements."

5.17 Multi-Criteria Analysis can incorporate both quantifiable and non-quantifiable benefits. So what would a multi-criteria approach look like? A typical approach is to summarise the costs in a table/spreadsheet(s). The benefits would be presented separately in another matrix or table. This benefit table is essentially a more detailed version of Table 4.1 and could include the objectives/benefits associated with the regulations as well as an assessment of how well each option performs in achieving each benefit. This would summarise all benefits whether they are analysed quantitatively or qualitatatively (an example of such a table follows).

Table 5.3: Example of summary of benefits table for a Full RIA (where CBA not possible)

		Option		
Objectives	**Type of impact assessment**	**A**	**B**	**C**
1: Save lives	Qualitative	-	-	-
	Quantitative/monetary	400 lives saved	230 lives saved	270 lives saved
2: Operate efficiently	Qualitative	√√	√	√√
	Quantitative/ monetary	6 months before operational	1 year before operational	2 years before operational
3. Improve quality of life	Qualitative	√√√	√√	√√
	Quantitative/monetary	Will affect 500,000 citizens	Will affect 450,000 citizens	Will affect 330,000 citizens

(vi) Distributional analysis

5.18 The RIA should involve more than a quantification of the aggregate costs and benefits of various options. Other policy considerations such as equity and fairness are significant in determining policy decisions and should be reflected within the RIA process. RIAs must therefore also examine which groups or individuals within society will bear the costs and receive the benefits of particular regulations. In particular, RIAs should examine the effects of regulatory options on consumers, vulnerable groups, the socially excluded, and business. It is extremely difficult however to quantitatively take account of distributional effects. Most Full RIAs will therefore rely on a qualitative description of the distribution of costs and benefits which the decision-maker can take into account alongside the net present value of the costs and benefits.

Take account of distributional effects.

(vii) Risk and uncertainty

5.19 In the real-world, it is impossible to predict with certainty the impacts associated with a policy option. These will depend on future events, some of which are out of the control of policy-makers. RIAs should reflect these uncertainties by taking account of risk and the various future scenarios which might occur. Cost and benefit estimates should be calculated for a variety or range

of future values or scenarios through the use of techniques such as sensitivity analysis (see Appendix B). For example, the costs and benefits of Health and Safety Regulations may depend on factors such as the levels of employment in particular sectors, changing costs of enforcement and the levels of workplace accidents. In such cases, the assumptions governing each estimate should be clearly stated and calculations should be based on differing assumptions where levels of uncertainty exist.

5.20 Chapter 6 contains details of publications and websites which provide further guidance in techniques for analysing costs, benefits, impacts and risk.

Take account of risk and uncertainty. Calculate costs and benefits under a variety of assumptions and scenarios. Identify ranges of costs and benefits where necessary.

Consultation

5.21 Formal (structured) consultation is a compulsory part of a Full RIA. This should take place at an early stage in the impact analysis so that the views expressed during the consultation process can be taken into account in identifying impacts and selecting the preferred option. Formal consultation differs from informal consultation in a number of ways. It is usually based on a written document, it encompasses a wider population and it involves a specific time period for responses. It should be widely publicised

through appropriate channels such as advertisements in the national media, on government websites etc. For very specialist policy issues, it may not be appropriate to publicly advertise the consultation process. However, where only a sub-section of the population is being informed about the process, it is important to ensure that this includes all relevant interested parties including consumers and representatives of the public interest and specialist Agencies such as the Competition Authority and the National Consumer Agency.

5.22 Potential respondents should be given sufficient time to respond to the consultation process. For example, the EU Commission has set a period of eight weeks for a written consultation while in the United Kingdom consultation periods must be twelve weeks at minimum. Steps must also be taken to ensure that less resourced groups are in a position to respond to the consultation and that consultation methods take account of the fact that some parties may not have access to internet facilities. Care should also be taken to ensure that the views of vulnerable groups such as the elderly and disabled and those with literacy problems are reflected in the consultation process. This may necessitate the use of particular consultation methods such as public meetings, focus groups etc.

5.23 Formal consultation as part of RIA should generally encompass the following steps:

- Identify the stakeholder groups and individuals to be consulted
- Consider the most appropriate and inclusive methods of consulting these stakeholders
- Decide whether the consultation should be publicly advertised
- Prepare a consultation document setting out the policy problem, the objectives of the proposed regulations, the options which are being considered and any other issues on which views are being sought. (Where possible the Screening RIA should be used as the basis for the consultation document)
- Publish and publicise the consultation document and invite written comments within a specific time-frame
- Where necessary, devise and apply additional consultation methods to include other affected parties
- Evaluate the policy options in light of the views expressed as part of the consultation
- Include a synopsis of the views expressed and a response to these views within the Full RIA document.

Include structured, open consultation as part of a Full RIA. This should be publicly advertised for most issues and a reasonable time-frame should be provided for responses. Ensure that the consultation is inclusive and accessible.

5.24 Additional guidance on how to conduct a consultation process is available in Appendix C and in Reaching Out: *Guidelines on Consultation for Public Sector Bodies* (Department of the Taoiseach 2005b). The following example from an EU Commission Impact Assessment document may also be of assistance.

Example 9: Extract from section on consultation in EU Commission Impact Assessment on Regulations in relation to Medicinal Products for Paediatric Use

(commentary in italics)

CONSULTATION PROCESS
The Commission has consulted extensively on the issue of medicines for children and on its proposals for a draft paediatric regulation. This consultation has included:

- Workshops and roundtable meetings
- Stakeholder interviews by Rand Europe
- Public consultation.

Workshops and roundtable meetings
The Commission has held a series of workshops and bilateral meeting with stakeholders on the issue of medicines for children and on its proposals for a draft paediatric regulation. Annex 2 of the Full RIA provides a summary list of the workshops and bilateral meetings held *(see http://europea.eu.int/comm/secretariat_general/impact/docs for the Full RIA.)*

Stakeholder interviews by Rand Europe
In the course of conducting the Rand Study interviews took place with representatives of the following organizations….
17 organisations from a number of member states are then listed….

Public consultation
The Commission's public consultation was split into two halves. Between 28 February 2002 and 30 April 2002, the public consultation focussed on the key elements to be included in a regulation. Between 8 March 2004 and 9 April 2004 the public consultation was based on the draft legislative text. For the latter part of the consultation, the consultation document was placed prominently on the Commission website (http://pharmacos.eudra.org) and sent by email to the following organisations:

- Member States via the Pharmaceutical Committee (and its ad-hoc group on paediatrics)…
  30 other organisations/ bodies are listed…

The 2004 part of the public consultation was limited in duration because:

1. it was the second time the public had been consulted by the Commission on this issue, and,
2. it was considered that the public health issues of insufficient medicines for children needed to be dealt with in a timely manner.

Consultation results

A summary of the results of the 2002 part of the consultation is provided In Annexes to the RIA.

In the 2004 part of the public consultation the Commission received 69 contributions. Many of them, in particular the ones from regulators, patients associations, or the industry, were the result of wider consultation by specific stakeholder organisations. A full listing of all parties providing comments is provided at Annex 4 (of the Full RIA). The vast majority of the comments welcomed the Commission's draft legislative proposal and explicitly supported the outlined objectives. As already revealed by the 2002 part of the consultation, all respondents recognised the need to take specific regulatory measures in order to achieve the objectives. Broadly speaking, most of the contributors agree with the key principles and concepts underlying the Commission's proposal.

Many of the comments on details of the draft paediatric regulation have been taken on board for the final proposal. Two key issues that were amended as a result of the consultation response (and the extended impact assessment) were rewards/incentives for orphan medicines and the strength of the incentive for off-patent medicines, and these are briefly explored below…

Stakeholders concerns in relation to two key issues are then outlined and the EU Commission explains how it amended its proposals to reflect these concerns…

Appendices to the IA (i) list all workshops and meetings held (ii) summarise responses to the various public consultation phases as well as providing a full list of respondents.

Source: Commission of the European Communities 2004b.

Enforcement and compliance

5.25 The Full RIA should involve a detailed examination of enforcement and compliance issues for each option being considered. Many of these issues are already addressed in Chapter 4, paragraphs 4.33-4.36 The Box below sets out some questions which the Full RIA must address for each option.

Issues to be addressed in relation to enforcement and compliance

- What are the necessary compliance targets for the policy option to achieve the desired objective? Here account should be taken of the risk associated with the policy area
- Is it realistic to assume this level of compliance?
- How is compliance with the regulatory proposal to be enforced?
- Is enforcement to be carried out by an existing or new body?
- If additional enforcement functions are to be carried out by an existing body, detail any additional resources that will be necessary to ensure successful enforcement
- If a new enforcement body is to be created, detail the initial and ongoing costs of the establishment and operation of this body
- If there is more than one body involved in implementing or enforcing the regulations, how will consistency and communication between these bodies be ensured?
- How will accountability and independence of the enforcement body/(ies) be ensured?

5.26 Enforcement and compliance issues are rarely addressed comprehensively as part of international approaches to RIA. An example has therefore been created below. This is adapted from a draft RIA on the *Health and Social Care Professionals Bill* conducted by the RIA Working Group in 2002 (see Department of the Taoiseach 2002).

Example 10: Example of enforcement and compliance analysis

Objective: In 2002 the Department of Health and Children was developing legislation to introduce a system of statutory registration for health and social care professionals in Ireland. This was the subject of a draft RIA conducted by a cross-Departmental Working Group. It should be noted that this RIA was not based on the current Bill which is passing through the Houses of the Oireachtas.

The draft RIA identified the objective of the proposals as follows: to ensure that members of the public are protected and informed so that they can be confident that the professional providing the service is properly qualified, competent and of good standing. The proposed system also aimed to ensure professional conduct and the promotion of high standards of professional education and training among health and social care professionals.

The draft RIA identified three options:

Option A: Maintain the status quo
Option B: Self-regulation by professional bodies
Option C: Establishment of a system of Statutory Regulation.

Enforcement and compliance

In general, this is an area where there is potential for a significant degree of risk to public health and safety. Compliance targets for these

regulations must therefore be close to 100% to ensure that they meet their objectives of protecting the public.

Option A: This option involves no changes to the enforcement and compliance regime since the current system would continue. The onus is on the patient/client to protect their own safety through ensuring the professional they attend is suitably qualified, competent and of good standing. No enforcement or compliance costs or changes to the institutional framework are generated by this option.

Option B: Under this option, each profession would be regulated by its own professional body. A number of drawbacks of this approach have already been identified in this RIA. Specifically, in relation to enforcement and compliance, it should be noted that membership of a professional organisation cannot be made compulsory. Without a statutory basis for membership, this scheme would not be effective as only those who voluntarily join would come under the remit of the professional body. This limits the scope for enforcement and implies that compliance could be low amongst those who pose most danger to the public.

Another difficulty is that there is no single national representative body for each profession. It is therefore unlikely that agreement would be reached as to which body would assume the new regulatory role. The operation of a number of regulatory bodies in parallel would lead to overlapping responsibilities, a lack of clarity as to respective roles and the risk of inconsistent enforcement.

Furthermore, the professional bodies for different professions are at varying stages of development. This leads to the potential for stronger enforcement for some professions and weaker enforcement for others. These differences in enforcement would be unrelated to the level of risk posed to the public.

Compliance costs under this option would mainly fall to the professions and to the State (see identification of costs under previous step on

impact analysis). These costs are unlikely to be significantly lower than under Option C and, as already outlined in the impact analysis, are likely to be considerably less effective.

Option C: Under this option, a new body – the Health and Social Care Professionals Council - is being created to enforce the regulations. It is responsible for registration, fitness to practice and other regulatory functions. All members of the professions covered by the regulations must register with the Council. Therefore, all members will be subject to its regulations and comprehensive enforcement will be possible. Members of the profession who breach the regulations will be subject to disciplinary procedures and could potentially be subject to a number of sanctions including a fine and removal from the professional register.

To ensure accountability of the Council, its Accounts must be submitted to the Comptroller and Auditor General and will subsequently be published. The Council must also present a Report to the Minister not later than three months after the end of each financial year. Any proposed rules must be published and public submissions sought prior to their enactment. The participation of public interest representatives on the Council will also assist in ensuring accountability to the public.

Twelve registration boards (one for each profession) will be established and will regulate their procedure where the Council decides not to do so. Any bye-laws proposed by the Registration Boards must be submitted to the Council for approval and be published. The registers must also be made available to the public.

The costs of compliance are primarily borne by the professions who will fund the Council through registration fees. These costs are detailed within the impact analysis section of the RIA. There is a risk that the cost of these fees will be passed on to the public in terms of an increase in charges and this is explored further under the cost section of the RIA. There are no significant costs to the State of this legislation.

Address compliance and enforcement issues for each option. In particular, describe the enforcement arrangements for each option and identify compliance targets.

Review

5.27 For each policy option, mechanisms for review must be identified. The analysis within the RIA will be based on certain assumptions. These may not hold in reality. Furthermore, the experience of those subject to regulations may indicate problems with the operation of the regulations after they are enacted. As time goes on, changes in the particular policy area may mean that the regulations become out of date or are no longer meeting their objectives.

5.28 Regulations must therefore be reviewed regularly and RIAs should detail the mechanisms by which the regulations/regulatory alternatives will be reviewed. These might include the establishment of new reporting mechanisms such as dedicated sections on regulations within Annual Reports or regular appearances of the relevant Minister or Regulator before Oireachtas Committees. A commitment to comprehensively review the operation of the regulations after a given period of time might also be included. For example, the Government has agreed that the Department of the Taoiseach should review the operation of RIA after two years.

5.29 Consideration must be given to the basis for any review i.e. how the reviewer will evaluate the performance of the regulations. Appropriate performance indicators should be developed to measure the extent to which the regulations achieve their objectives as well as to identify any drawbacks or problems. These might include compliance targets, degree of satisfaction of stakeholders or the level of achievement of desired outputs.

5.30 Attention must also be paid to identifying the kind of data which must be available to ensure effective review. Where there are data gaps, it may be necessary to identify methods of collecting such data e.g. stakeholder surveys, the commissioning of new data from the Central Statistics Office and so on. There should also be a mechanism for stakeholders to report on their experience with the new regulatory regime so that problems can be detected and addressed. The Australian example which follows is relatively unusual in setting out definite and clear commitments in relation to review.

Identify mechanisms for review for each option under analysis. Develop performance indicators for each option. Outline the data sources which will be used to report on these indicators.

Example 11: Section on review from Australian Regulatory Impact Statement on the Fisheries Legislation Amendment Bill 1999

Four years after the date of entry into force of the UN Fish Stocks Agreement, the Secretary-General of the United Nations must convene a conference with a view to assessing the effectiveness of the Agreement in securing the conservation and management of straddling fish stocks and highly migratory fish stocks. The conference will review and assess the adequacy of the provisions of the Agreement and, if necessary, propose means of strengthening the substance and methods of implementation of those provisions in order to better address any continuing problems in the conservation of straddling and highly migratory stocks.

The preferred option for implementing the UN Fish Stocks Agreement is the minimum approach determined to be effective. The effectiveness of the approach will be reviewed in preparation for the United Nations review conference and in light of any recommendations of the conference.

Many of the obligations of the UN Fish Stocks may be implemented administratively through plans of management determined under the FMA. The plans of management set out objectives; measures by which the objectives are to be attained; and performance criteria against which the measures taken may be assessed.

Other options for monitoring progress may include:

- Monitoring incidents of IUU fishing
- The Resources Assessments of Commonwealth Fisheries carried out by the Bureau of Rural Sciences
- Examination of the annual Australian fisheries statistics complied by the Australian Bureau of Agricultural and Resource Economics

Summary of performance of options/recommended option

5.30 International best practice suggests that the final step of a RIA should be a recommendation to proceed with one of the options analysed. In some RIAs there may be an obvious preferred option and so a recommendation will be appropriate. In other policy areas, it may be necessary to reflect other considerations so that the final step should simply be to summarise the pros and cons of each option. The key decision-maker (usually the relevant Minister) will then decide which of the options to implement.

5.31 Where an option is being recommended, a short paragraph should be supplied justifying the choice of option. This should be based on the information and analysis contained in the earlier stages of the RIA. Where it is decided that a summary of all options is most appropriate, this should consist of one or two paragraphs summarising the information and analysis relating to each option in the RIA.

> Finish by selecting a preferred option based on the RIA. Where this is inappropriate, summarise the pros and cons of each option.

5.32 **The Full RIA is now complete!** It should be summarised in the Memorandum to Government (for primary legislation). The Full RIA should also be attached as an Appendix to the Memorandum (or draft EU Directive if applicable) and the usual legislative and Cabinet procedures followed. The RIA should be published at the same time as the legislation/Directive and should be updated to reflect any changes made as the regulations are being enacted/transposed.

6: Further Guidance

6.1 This Guidance reflects current best practice and the latest information available. However, it will be updated periodically based on experience with RIA and any future changes in RIA requirements. In addition, the Department of Enterprise, Trade and Employment has indicated its intention to develop additional material in relation to business and competitiveness impacts. This will be included in future editions of the manual.

6.2 Given that use of the Irish RIA model has only just commenced, there are no examples of its application available for publication as yet. The examples supplied for each step of the RIA are mainly taken from other countries. However, RIA models vary from country to country with regard to the steps within them, the precise impacts to be tested etc. It would be potentially confusing for readers to present an example of a RIA based on a different model than the Irish one. However, as RIAs are completed, examples will be circulated to Departments and case studies will be used for the purpose of RIA training.

6.3 Further guidance and advice in applying RIA can be obtained from the Better Regulation Unit, Department of the Taoiseach (e-mail: betterregulation@taoiseach.gov.ie). The Department of Finance should be consulted in relation to the selection of analysis techniques and an appropriate discount rate. Queries on examining the various impacts referenced in the model should be directed to the appropriate Government Departments/Agencies.

6.4 In addition, the following websites and publications may be of assistance (full references are provided after the Appendices.)

Website	Topic
www.betterregulation.ie Ireland	Further information on better regulation in Ireland
http://www.europa.eu.int/comm/secretariat_general/impact/	Further information on impact assessment at EU level
http://www.cpmr.gov.ie	The Committee for Public Management Research includes a useful Report on the Irish RIA piloting process and other reports on regulatory reform and consultation
http://www.pc.gov.au/orr/ris/examples/	Examples of Australian RIAs
http://www.cabinetoffice.gov.uk/regulation	Lists of UK RIAs and guidance on a number of better regulation themes
http://www.oecd.org	General material on regulatory reform in OECD countries

Publications	
Department of the Taoiseach 2005a: *A Report on the Introduction of Regulatory Impact Analysis*	Report on the RIA pilot process and outline of Irish RIA model
Department of the Taoiseach 2005b: *Reaching Out: Guidelines on Consultation for Public Sector Bodies*	Irish Guidelines on consultation
Committee for Public Management Research: *Regulatory Impact Analysis: Lessons from the Pilot process*	Report by the CPMR on the Irish RIA pilot process
Department of Finance: *Guidelines for the Appraisal and Management of Capital Expenditure Proposals*	Department of Finance guide on approaches to appraisal
HM Treasury Green Book: Appraisal and Evaluation in Central Government	UK Guide on appraisal and analytical techniques
Office of Management and Budget: *Circular A-4: Regulatory Analysis*	US guide which is likely to be of assistance in conducting a Full RIA
Better Regulation Taskforce: *Alternatives to State Regulation Imaginative Thinking for Better Regulation*	UK reports on alternatives to regulation
European Commission: *Impact Assessment Guidelines*	EU Guidance on Impact Assessment including Annex on methods and techniques
UK Office of the Deputy Prime Minister: Multi-criteria analysis manual	UK Guide to conducting multi-criteria analysis

Appendix A: Alternatives to Regulation and Alternative Models of Regulation

The OECD (2002, 52) states: "efficient and effective policy action is only possible if all available instruments are considered." Step 2 of the RIA involves considering a range of options or alternatives to achieving a policy objective. When identifying options, it is useful to bear in mind that there is a distinction between alternatives to regulation and alternative models of regulation.

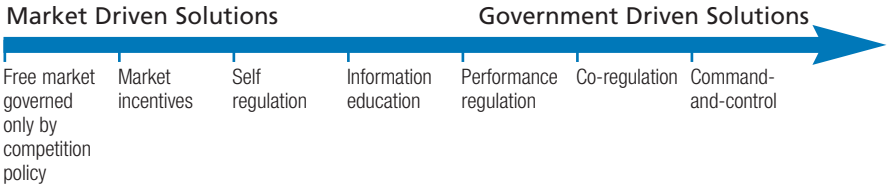
Alternatives to regulation include:

- No intervention/do nothing
- Information and education
- Incentive/market-based structures

Alternative models of regulation include:

- Classic command-and-control regulation
- Self-regulation/Co-regulation
- Performance-based regulation

These are represented on the spectrum below which classifies alternatives according to the degree to which they involve market-driven solutions or increased levels of Government intervention.



Source: adapted from OECD 2002,52

Alternatives to regulation

No intervention/maintaining the status quo

Some policy challenges may be addressed by improving enforcement of existing legislation. In other cases any form of intervention might involve more costs than benefits or might generate unintended impacts. No intervention should therefore be considered as a possibility. Even where it is not a viable option, it can be useful to compare the costs and benefits of regulations and other policy tools with the costs and benefits of not intervening.

Information and education campaigns

Information campaigns are the most widely used alternative to traditional regulation in OECD countries (OECD 2002, 54). Such campaigns are used to address information asymmetries and enable consumers to make informed choices and assess risk. While many information campaigns simply seek to inform citizens and enhance consumer choice, some information campaigns are more explicit in seeking to change behaviour. This form of campaign is generally found where the behaviours sought to be modified have substantial effects on society as a whole e.g. smoking, road safety etc. There are information campaigns on both these issues in Ireland. Another example is the *Race Against Waste* campaign to encourage recycling and more sustainable waste disposal and management.

Information/education campaigns	
Advantages	**Disadvantages**
• Less intrusive than regulation • Allows individuals/businesses to make informed decisions • Can be useful where regulations would be too costly/difficult to enforce	• Can be expensive to develop and run campaigns • Can be costly for citizens/consumers to process information • Difficult to identify specific causal link between campaigns, heightened awareness and behaviour • Information/risks may not be understood • Information supplied may be disputed or inaccurate

Incentive based structures/economic instruments

There are a variety of economic instruments which can be used as alternatives to command-and-control regulation. These include, *inter alia,* charges, taxes, subsidies and tradeable permit systems. From an economic perspective, these market incentives or economic instruments are the preferred alternatives to command-and-control regulation because they avoid the market distorting effects of most forms of regulation yet succeed in better aligning price incentives with the common good.

Market-based mechanisms are particularly useful to achieve environmental objectives. An Irish example is the plastic bag tax introduced in 2002 aimed at reducing consumption of plastic bags and the pollution they cause to the environment. Money garnered from the 15 cent levy goes to the Environment Fund which supports waste management and other environmental initiatives.

Subsidies are used in countries such as the Netherlands to encourage commuting via public transport while in Korea firms which establish facilities to prevent, treat or recycle pollutants can avail of long-term low interest loans (OECD 2002, 138).

Another form of economic instrument is the tradeable permit. A firm/industry is issued with a permit to emit a particular quantity of a pollutant. Firms can sell on some of their allocation if they do not exceed their quota and must purchase additional permits if they exceed their quota. This provides them with incentives to reduce their production of the pollutant. The EU has introduced a pan-European Emissions Trading Scheme for Carbon Dioxide which came into force on 1 January 2005 with the aim of reducing emissions of carbon dioxide and other greenhouse gases.

Economic instruments	
Advantages	**Disadvantages**
• Less costly in achieving policy objectives • More flexible than command & control regulations • Can encourage innovation and technical change • Involve low levels of discretion because penalties or rewards operate mechanically after their introduction. Therefore reduces risks of capture • Provides incentives to meet Government objectives in an efficient manner • Do not impose heavy burdens of information – gathering and provision • Leaves discretion to individuals/firms.	• Can be ineffective if the value of an activity is more than the tax or the cost of reducing it is more than the subsidy • May need highly complex systems of rules to be put into effect e.g. tax systems can involve very complex regulations • May need enforcement mechanisms to reduce tax avoidance or prevent information being withheld • Can often be difficult to predict the effects of an incentive. This may involve costly research and calculations • May be seen as signaling that certain levels of undesirable behaviour are acceptable (e.g. a certain level of pollution).

Source: Baldwin and Cave, 1999 41-47; Better Regulation Taskforce 2004b

Models of regulation

Traditional command-and-control regulation

Command-and-control systems of regulation are essentially "law and state-centred process(es) of legislation action combined with administrative enforcement." (Parker and Braithwaite 2003, 127). Command-and-control regulations are arguably the most pervasive policy tool and have been applied in a wide variety of areas, both economic and social. In the Irish case, the practice has been for regulatory standard to be set by Government Departments through primary or secondary legislation and enforced by regulatory bureaucracies.

Although command-and-control systems have a number of advantages, they have a number of drawbacks (see Table which follows). In particular, regulations can be costly to enact and enforce. OECD (2002, 22) estimates that, in many countries, regulations impose costs of 10% of GDP or above.

Command-and-control regulation	
Advantages	**Disadvantages**
• Fixed standards imposed quickly and actions/goods which do not conform are instantly outlawed • Denotes forceful action by Government and indicates it is taking a stand for/against particular activities • Outlaws behaviour which involves significant danger to public safety • Some people may only comply with regulations when they are strict and strongly enforced.	• Results in overly complex and bureaucratic rules and procedures which can be costly in terms of time and money • Enforcement often expensive and evasion possible through creative compliance • Can increase risk of regulatory capture since relies on industry for information on standards and limits • Can be difficult to determine most appropriate levels of performance • Can be overly dogmatic and intrusive • Can involve more policy risk.

Sources: Baldwin and Cave, 1999, 35-37; Parker and Braithwaite 2003, 127; Parker 2000

Where risks to the public are significant, command-and-control solutions are often the most appropriate. However, where danger to the public is less of an issue, lighter approaches to regulation or alternatives should be considered.

Voluntary approaches – Self-Regulation

Voluntary approaches are arrangements initiated and undertaken by industry and firms, sometimes formally sanctioned or endorsed by Government, in which self-imposed requirements are agreed which go beyond or complement the prevailing regulatory requirements. These include voluntary initiatives, voluntary codes, voluntary agreements, and self-regulation and vary in regard to their enforceability and degree of voluntarism.

There are two motivations which can encourage firms to participate in voluntary approaches. First, companies who take voluntary action to address a policy concern may stave off more onerous Government regulation. A threat by Government of possible future regulation can encourage an industry to deal with the issue itself. Firms are also increasingly recognising that they can enhance their reputation and increase sales via participation in voluntary associations (OECD 2002, 140).

An Irish example of self-regulation is the Advertising Standards Authority of Ireland which is an independent self-regulatory body set up and financed by the advertising industry to monitor and protect certain standards of advertising. This is achieved through the development of and voluntary compliance with a set of advertising standards.

Voluntary approaches/Self-Regulation	
Advantages	**Disadvantages**
• Often cheaper than command-and-control with less direct costs to the State • More adaptable to societal and technical change • Excludes the Courts (cheaper and reduce the case load of the Courts) • Promote interaction in the public interest amongst competitors • Compliance costs lower because they are designed by the industry.	• Can be ineffective since there may not be adequate enforcement • Little action may be taken to curb/change behaviour which generates significant profit • Can be anti-competitive and result in barriers to entry.

Source: UK Better Regulation Taskforce 2004 b, 4

Performance-based regulation

Performance-based regulation involves the specification of required outcomes or objectives, rather than the means by which these must be achieved and may be enforced through self-regulation or co-regulation. The degree of Government intervention is therefore reduced. Firms and individuals are able to choose the process by which they will comply with the law. The focus of regulation is on results or outputs, rather than inputs.

Performance-based regulation	
Advantages	**Disadvantages**
• Firms and individuals can identify efficient and lower cost processes to achieve the particular outcome • Encourage innovation and the more widespread use of technology • Regulations can be simpler and clearer since they involve only the specification of objectives and outputs instead of prescriptive detail and processes.	• Can be difficult to develop since it requires precise and unambiguous specification of objectives and outcomes • Requires operational guidelines to support firms and individuals with compliance. These can then become de facto prescriptive regulations.

Source: OECD 2002, 135

The use of performance-based regulation is rapidly developing in OECD countries. Its use has been increasing significantly in relation to health, safety, consumer protection and environmental regulation in particular. For example, in Canada, the Ontario Ministry for the Environment and Environment Canada negotiated an agreement with a major steel company to advance the prevention and abatement of releases from their steel manufacturing. Targets were set and the company itself could decide how these were met. An evaluation of this programme found that costs were kept low and the targets were met (OECD 2003, 30).

Co-regulation

Co-regulation is where the regulatory role is shared between Government and the particular industry or sector being regulated. In some cases the industry or a large proportion of industry participants formulate a code of practice in consultation with Government, with breaches of the code usually enforceable via sanctions imposed by industry or professional organisations rather than the Government directly. In other cases, the Government can retain control of some aspects of policy and devolve other elements to the industry.

An Irish example is the delegation of the regulation of the medical and legal professions to the Medical Council and the Law Society.

Co-regulation	
Advantages	**Disadvantages**
• Reduces cost to the State because the costs are usually borne by the profession/industry • Encourages greater responsibility within sectors/industry for performance • Harnesses the expertise and knowledge of an industry or professional association • Can increase compliance levels because industry/profession involved in monitoring behaviour.	• Can encourage anti-competitive behaviour and barriers to entry • Higher risk of regulatory capture given the close relationship between the Government and the industry/profession • Enforcement may be weaker due to lack of accountability and self-interest on the part of the profession/industry • Needs careful design based on principles of transparency and accountability to avoid barriers to competition.

These are the most common forms of regulatory alternatives/models. Their appropriateness depends on the policy problem which is to be addressed, the prevailing culture and administrative system and a variety of other factors. In the White Paper, *Regulating Better*, the Government has agreed that alternatives to regulations should be used more widely. The evaluation of alternatives as part of RIA can contribute to this goal.

Appendix B:
Methods of Comparing Impacts

(Extract from EU Commission Impact Assessment Guidelines Annex, 42-44)

Cost-benefit analysis

This entails identifying and evaluating expected economic, environmental and social benefits and costs of proposed public initiatives. A measure is considered justified where net benefits can be expected from the intervention.

Advantages	Disadvantages
• Accounts for all (negative and positive) effects of policy measures • Allows comparison of the ordering of costs with the ordering of benefits of the proposal over time • Can also be used to rank alternative (including non-regulatory) proposals in terms of their net social gains (or losses).	• Cannot include impacts for which there exists no quantitative or monetary data • Difficulties in establishing the social discount rate • Usually more expensive and time-consuming than other less broad methods • May lead to distributional issues being overlooked.

Cost-effectiveness analysis

This requires calculating the cost needed to achieve a desired outcome, allowing the costs of different options to be compared. It is an alternative to cost-benefit analysis in cases where it is difficult to value benefits in money terms. Cost-effectiveness analysis offers a ranking of regulatory options based on 'cost per unit of effectiveness' of each measure.

Advantages	Disadvantages
• Offers a more relaxed approach towards benefit measurement than cost-benefit analysis • Useful to compare alternatives that are expected to have more or less the same outcome.	• Does not resolve the choice of the optimal level of benefits • Concentrates on a single type of benefit (the intended effect of the measure), excluding possible side-effects • Provides no assistance as to whether a regulatory proposal would provide net gains to society.

Multi-criteria analysis

This term covers a wide range of techniques that share the aim of combining a range of positive and negative impacts in a single framework to allow easier comparison of scenarios and decision-making. The technique can be useful where there is a large amount of information on a number of different impacts, and that information is in different formats. It allows a variety of impacts to be presented that are qualitative, quantitative and monetary and involve varying degrees of certainty.

Key steps generally include:

- Identifying the objective
- Identifying options to achieve the objective
- Establishing criteria to be used to compare the options (these criteria must be measurable, at least in qualitative terms)
- Scoring how well each option meets the criteria
- Assigning weights to each criterion to reflect its relative importance in the decision, using e.g. participatory techniques, ethical principles, technical grounds or an interactive procedure with the policy-makers
- Ranking the options by combining their respective weights and scores.

Advantages	Disadvantages
• Recognises multi-dimensionality of sustainability • Allows different types of data (monetary, quantitative, qualitative) to be compared and analysed in the same framework with varying degrees of certainty • Provides a transparent presentation of the key issues at stake and allows trade-offs to be outlined clearly; contrary to other approaches such as cost-benefit analysis, it does not allow implicit weighing • Enables distributional issues and trade-offs to be highlighted.	• Includes elements of subjectivity, especially in the weighting stage where the analyst needs to assign relative importance to the criteria • Because of the mix of different types of data, cannot always show whether benefits outweigh costs • Time preferences may not always be reflected.

Risk analysis

This assesses the risk of an undesirable event occurring, and the possible consequences to individuals and to society if it occurs. Risk appraisals can then be used to determine the options available to reduce or eliminate the risk and/or its consequences.

To carry out risk analysis, you need to:

- Identify the risk
- Assess how likely that risk is to happen
- Assess the potential impact to the proposed programme/measure if the risk identified were to occur.

Advantages	Disadvantages
• Scientific assessments of risks make crucial contributions to regulatory decisions, especially in the areas of public health and safety, environmental protection, resource exploitation, wealth creation, innovation and national security indicating whether the policy will be effective in reducing risks in a significant manner.	• Risk impacts may be diverse and not commensurate (that is, brought into a common measure) • Does not normally involve an assessment of the costs likely to occur if the undesirable event does happen • Takes no account of negative and positive impacts other than risks linked with the proposed measures to deal with the risk and/or its consequences • Should not be used as the sole basis for deciding whether to take action or for determining the type of action to be taken.

Variants of these methods exist and can be used when appropriate. Examples are cost assessment, risk-risk assessment, etc. We can also use techniques to value changes in risks of events occurring. This is extremely useful, indeed necessary, when looking at many environmental or health impacts. For example, many policies will try to reduce the risk of illness or death. We cannot – and do not seek to – place a monetary value on our own lives or on other individuals' lives. However, changes in risks are a different matter. While no one would trade their life for a sum of money, most people will be prepared to choose between safety equipment with different prices and offering different levels of safety, or between different ways of crossing a street to save time. We can therefore identify the value individuals place on small changes in risk.

Sensitivity analysis

Sensitivity analysis explores how the outcomes or impacts of a course of action would change in response to variations in key parameters and their interactions. It may be that a single factor is crucial to the decision of whether or not an option is worth implementing. In such cases a useful form of sensitivity analysis is to identify how much the value of the factor would have to fall (if it is a benefit) or rise (if it is a cost) to make it not worth undertaking the option.

To carry out sensitivity analysis, you need to:

- Focus on the most important alternatives
- Search for switching value/point.

Advantages

- It is often the best way to handle the analysis of uncertainties.

Appendix C:
Poverty Impact Assessment

It is a requirement in the Cabinet Handbook (published in October 1998) that Memoranda for the Government: *"indicate clearly the impact of the proposal on groups in poverty or at risk of falling into poverty in the case of significant policy proposals."*

In 1999 the then Department of Social, Community and Family Affairs circulated poverty proofing guidelines to all Government Departments in order to assist them in this regard. The Office for Social Inclusion has recently reviewed this process and new Guidelines for Poverty Impact Assessment will shortly be circulated.

The requirement in RIA to examine the impacts of regulations on social exclusion and vulnerable groups mirrors the requirement which has been in place since 1998. In order to avoid duplication of processes it is important that the procedures followed in the context of carrying out a RIA are in line with those already in place for poverty proofing and those being developed for poverty impact assessment.

In assessing the impact of a policy or programme on poverty and social exclusion, consideration should be given as to who the target groups are and whether there are any differences within the target group (or between the target groups) which could lead them to benefit in different ways. The impact on poverty may be felt in terms of numbers in poverty or the level of poverty experienced. The extent of the impact on each of the vulnerable groups listed in the National Action Plan Against Poverty and Social Exclusion (namely, women, children and young people, older people, people with disabilities, Travellers, prisoners and ex-prisoners, those experiencing rural disadvantage or urban poverty, migrants and members of ethnic minorities) should be identified. Consideration should also be given to measures which could ameliorate any negative effects identified.

The relationship between poverty and inequality is quite a complex one. However, the impact of the programme or policy on the inequalities which may lead to poverty should also be considered.

The stages proposed to be involved in poverty impact assessment are summarised on the following page. Policymakers should refer to the website of the Office for Social Inclusion (www.socialinclusion.ie) in order to access up-to-date information in relation to poverty and social exclusion issues generally and, in particular, to access the latest version of the Poverty Impact Assessment Guidelines.

Poverty Impact Assessment – Stages involved

Stage 1
Screening – this will inform the policy maker as to whether or not it is necessary to carry out a full poverty impact assessment.

Stage 2
Full Poverty Impact Assessment

Step 1: Consultation

Step 2: Define Policy Aims and Target Groups

2.1 What is the primary objective of this policy/programme/ expenditure proposal?

2.2 Who are the target groups and how would the proposal reach those groups?

2.3 What are the differences within the target group/between the target groups which might lead to them benefiting from the policy/programme in different ways and how could these be addressed?

Step 3: Consider Available Data and Research

Step 4: Assess Impacts and Consider Alternatives

4.1 What type of impact on poverty (either in terms of numbers in poverty or level of poverty) would the proposal have on each of the vulnerable groups listed in the National Action Plan Against Poverty and Social Exclusion?

4.2 If the proposal would have no effect on poverty what options might be identified to produce a positive effect?

4.3 If the proposal has a positive effect does it help to prevent people falling into poverty, reduce the level (in terms of numbers and depth) of poverty or ameliorate the effects of poverty? (please specify). Explain how these positive effects are achieved and consider whether the position could be improved upon...

4.4 If the proposal has a negative effect (i.e. it increases either the numbers in poverty or the level of poverty experienced) what options could be considered to ameliorate this effect?

4.5 Would the policy/programme/proposal contribute to the achievement of the NAP/inclusion targets (including subsidiary targets)?
If yes, explain how this is the case and whether the position can be improved further. If no, can anything be done so that it does contribute to the targets?

4.6 Would the programme address the inequalities which may lead to poverty?

Step 5: Make Decision and Arrange Monitoring

5.1 Will this proposal be adopted?

5.2 If the proposal is to be adopted, how will its impact on poverty be monitored?

Step 6: Publish Results

Step 7: Return Summary Sheet to the Department's Social Inclusion Liaison Officer

Appendix D: Consultation

Introduction

Consultation is a key element of RIA. As well as contributing to the framing of regulations, effective quality consultation promotes a greater understanding of proposals and better compliance with legislation. In addition, it guards against the possibility of involving only those who are most vocal or best resourced to express views on particular policies or regulations. This can be important, for example, when it comes to ensuring that consumer interests are also taken into account when economic regulations or regulatory decisions are being made.

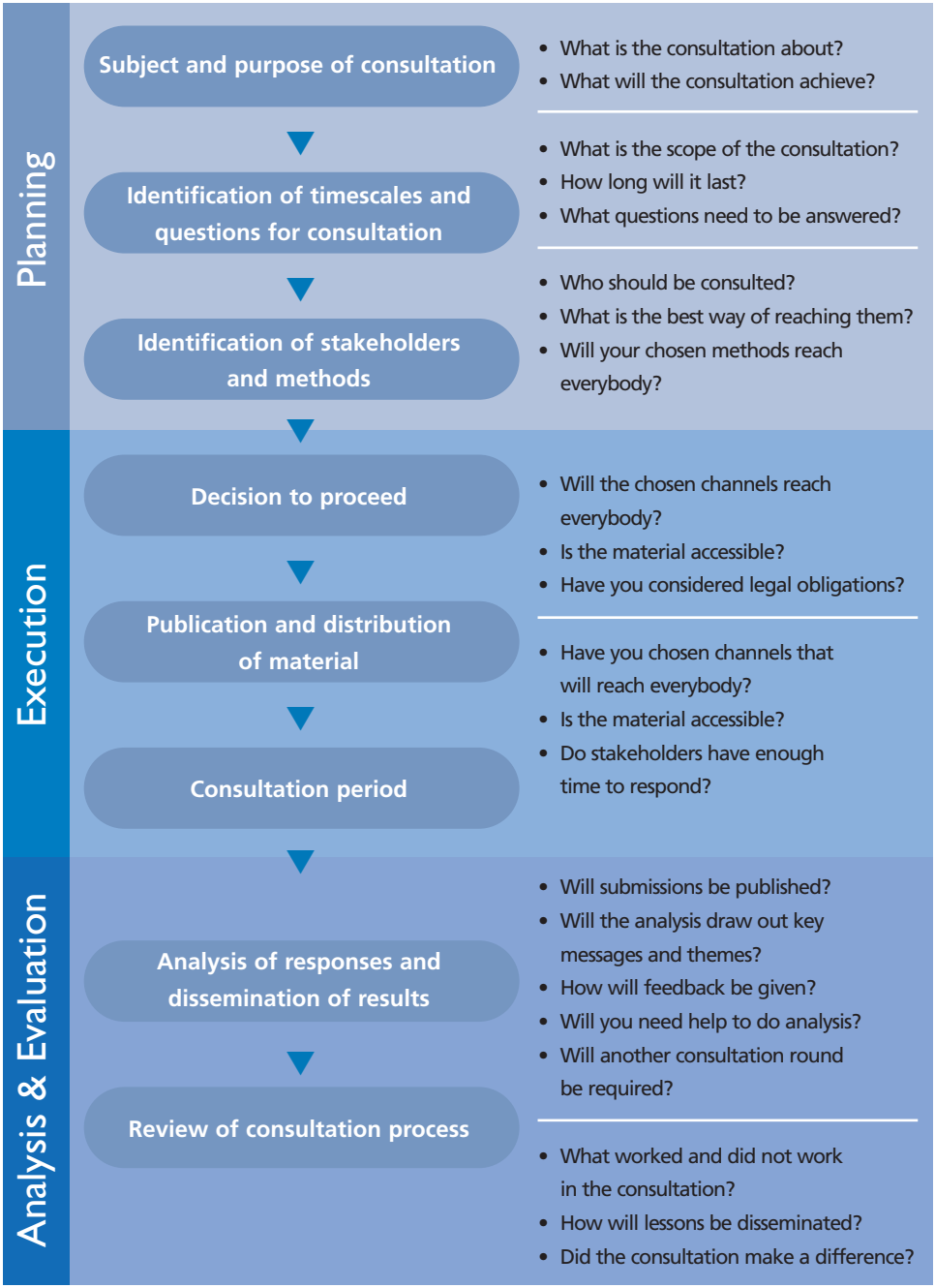
Conducting the Consultation

There are three distinct stages to the consultation process:

1. Planning
2. Execution
3. Analysis and evaluation.

Issues to be considered at each stage of the consultation process are summarised in the Consultation Flowchart that follows.

Consultation flowchart



Checklist for better consultation

The following checklist for better consultation will help to ensure that all the important aspects of organising a consultation have been covered:

- [ ] Are you clear on the purpose and objectives of your consultation?
- [ ] Are you clear on the questions you want to ask in your consultation?
- [ ] Have you identified all of the stakeholder groups and individuals that should be consulted?
- [ ] Have you chosen the most appropriate and inclusive methods of consultation, including those that meet the needs of 'non-traditional' stakeholders?
- [ ] Have you allowed for sufficient resources for the consultation?
- [ ] Have you considered all of your legal obligations?
- [ ] Have you publicised your consultation in online and offline media?
- [ ] Have you allowed sufficient time to give stakeholders an opportunity to consider the issues fully?
- [ ] Have you planned how you will analyse the submissions received during your consultation?
- [ ] Have you planned to evaluate your consultation process and to ensure any lessons learned are taken into account for the future?

A more detailed consideration of these all issues is included in *Reaching Out: Guidelines on Consultation for Public Sector Bodies*. The Guidelines are available online at: www.betterregulation.ie. The Guidelines also provide references to further useful information.

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Steps of a Full RIA

1. Statement of policy problem and objective
2. Identification and description of options
3. Impact analysis including costs and benefits of each option
4. Consultation
5. Enforcement and compliance for each option
6. Review
7. Summary of merits/drawbacks of each option and identification of recommended option where appropriate