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A Good Practices Handbook for Managing Regulatory Impact Analyses

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"Having a GPH for RIA is an excellent idea. I think this could be a very valuable document – not only for government but for others (including folks like me who could use it in teaching). I suspect something like this could be as popular as EPA's guide to economic analysis."
– Prof. Vic Adamowicz, University of Alberta

Canada

Preface

Over the last 20 years, the art of regulatory impact analysis (RIA) has evolved quite substantially. RIA is a multidisciplinary approach consisting of natural and social assessments, legal and policy considerations, communications, public consultation, economic impacts, and decision analysis tools. RIA allows senior public servants and Canadians to fully appreciate the potential implications and uncertainties of a proposal, thereby ensuring the "best" possible course of action given the available information. Of course, the approach can also apply to any public policy decision that demands society to consider complicated tradeoffs.

Application of techniques used in RIA, such as risk assessment, benefit-cost analysis, cost-effectiveness and stakeholder engagement processes, while applied to large infrastructure projects since the fifties, began in earnest in the eighties for transportation, natural resources, agriculture, health protection and promotion, food safety and environmental protection, and conservation proposals. As practitioners applied these tools and techniques in more and more complex scenarios, refinements were made to the approaches requiring specialized manuals to be developed that provided guidance to practitioners and decision-makers. Countries and international organizations have produced a plethora of guidance documents over the years that help with the execution of the individual disciplines involved in RIA.

The challenge facing regulatory, policy, and program managers, however, is to appreciate the linkages and individual contributions that the various disciplines provide to a decision choice in a manner that would facilitate the completion of a defensible and comprehensive analysis. Considerations such as planning an impact analysis, including the scope and depth of the effort required, are important first steps. Determining the skill sets of the analytical team and promoting collaboration among them is also an equally important consideration. Ensuring the integrity of the analysis and disclosing uncertainties are practices more commensurate with art than with science as is communicating results fairly to decision-makers and stakeholders.

This handbook is an attempt to bridge the gaps among the numerous and varied technical guides available in the public domain. This document draws upon the unique experiences of the practical challenges of applying RIA by managers and practitioners located in government departments in Canada, abroad, and at the Policy Research Initiative (now Policy Horizons Canada). This handbook is intended to complement the available technical materials and minimize duplication. The hope is that *A Good Practices Handbook for Managing Regulatory Impact Analyses* will help practitioners and managers to navigate through the sometimes daunting process of RIA.

Paul De Civita
Director General
Policy Horizons Canada

Avant-propos

Au cours de vingt dernières années, les règles de l'art en matière d'études d'impact de la réglementation (ÉIR) ont beaucoup évolué. Ces études reposent en effet sur une approche multidisciplinaire qui comprend des évaluations naturelles et sociales, une réflexion sur la législation et les politiques publiques, des communications, la consultation de la population, l'analyse des conséquences économiques du projet réglementaire considéré et des outils d'analyse décisionnelle. Les ÉIR permettent aux cadres supérieurs de la fonction publique et aux Canadiens d'apprécier pleinement les retombées probables et les inconnues associées à une proposition réglementaire et d'adopter la meilleure voie en fonction de l'information disponible. Évidemment, une telle approche s'applique à toute décision de politique publique requérant que la société se penche sur des compromis compliqués.

L'application des techniques utilisées dans l'ÉIR, telles que l'évaluation du risque, l'analyse coûts-avantages, le rapport coût-efficacité et les processus d'engagement des parties intéressées, ont été appliqués aux grands projets d'infrastructures dès les années 1950. Pourtant, leur mise en pratique dans les secteurs des transports, des ressources naturelles, de l'agriculture, de la protection et la promotion de la santé, de la sécurité des aliments, de la protection de l'environnement et des propositions de conservation n'a véritablement commencé que dans les années 1980. Ces outils et méthodes étant appliqués à des scénarios de plus en plus complexes, les approches exigeant que des manuels spécialisés soient rédigés – pour fournir des orientations aux exécutants et décisionnaires – ont été raffinées. Au fil des ans, les pays et organisations internationales ont produit un très grand nombre de documents d'orientation facilitant la mise en œuvre des disciplines respectives de l'ÉIR.

Cependant, le défi auquel les gestionnaires de la réglementation, des politiques et des programmes sont confrontés consiste à déterminer les liens et les apports des diverses disciplines au processus de décision, lorsqu'il s'agit d'effectuer une analyse défendable et complète. Dans un premier temps, il est important de planifier, par exemple, une étude d'impact incluant la portée et l'intensité de l'effort requis; déterminer les compétences cumulées par les membres de l'équipe d'étude et promouvoir la collaboration au sein de cette équipe l'est tout autant. Veiller à l'intégrité de l'analyse, révéler les inconnues et communiquer fidèlement les résultats aux décisionnaires et autres parties concernées sont des pratiques qui relèvent davantage des règles de l'art que des sciences.

Le présent manuel vise à bâtir des ponts au-dessus des vides laissés par les guides techniques – nombreux et variés – consultables dans le domaine public. Il s'inspire de l'expérience unique des gestionnaires et exécutants des ministères canadiens, de l'étranger et du Projet de recherche sur les politiques (aujourd'hui Horizons de politiques Canada) qui, en effectuant leurs ÉIR, se sont heurtés aux problèmes concrets associés à la tâche. Ce manuel se pose donc en complément des documents techniques déjà diffusés, afin d'éviter autant que possible les chevauchements et redites. Les rédacteurs du présent *Manuel des pratiques exemplaires en matière de gestion des études d'impact de la réglementation* espèrent que le fruit de leur travail aidera les gestionnaires et autres responsables d'ÉIR à mener à bien le processus parfois redoutable d'analyse!

Paul De Civita
Directeur général
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- Health Canada;
- Environment Canada;
- Fisheries and Oceans Canada;
- Canadian Food Inspection Agency; and
- Transport Canada.

We greatly appreciate their assistance.

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Exhibits

List of Acronyms and Abbreviations

BCA	benefit-cost analysis
CEA	cost-effectiveness analyses
EVRI	Environmental Valuation Reference Inventory
IQ	intelligence quotient
MAC	maximum acceptable concentration
MTBE	methyl tertiary butyl ether
PRI	Government of Canada's Policy Research Initiative
PV	present value
RIA	regulatory impact analysis
RIAS	Regulatory Impact Analysis Statement
SOW	statement of work
USEPA	US Environmental Protection Agency
VSL	value of a statistical life
WTP	willingness to pay

S. Executive Summary

Canadian policymakers seek to alleviate a wide range of public safety, human health, and environmental problems that negatively affect the Canadian population. However, any policy action has some beneficial and some adverse impacts and policymakers must decide which policy actions are worthwhile to undertake. A regulatory impact analysis (RIA) is a tool that is used to develop, organize, analyze, and present information on the impacts of different policy options to help decision-makers identify policy options that do the most good with the least harm.

The Government of Canada has used some form of impact analysis as part of their regulatory process for many years. Most recently, the *Cabinet Directive on Streamlining Regulation* (Government of Canada, 2007) spells out goals for the analysis of a proposed regulation. The Directive specifically states that the regulatory process should ascertain that the benefits of intervention justify the costs and to select policy options that maximize net benefits. Additionally, the Directive states that, "the analysis of these impacts provides useful information to decision-makers, even when economic efficiency is not the only or the overriding public policy objective" (Government of Canada, 2007, p. 8).

This handbook is directed to the RIA manager. It presents a process for conducting a successful RIA. It also provides clear and concise guidance on "good practice" processes for conducting well-integrated, technically credible, and policy-informative RIAs for policy options that impact public safety, human health, and the environment in a number of domains such as agriculture, transportation, the environment, and natural resource management (e.g., fisheries, mining, exploration).

The RIA process involves a number of steps that are essential to the goals described in the Directive. The process, outlined in Exhibit S.1, starts by clearly defining the problem to be addressed. Without a clear understanding of the problem, why it has arisen, and its anticipated future path, it will be impossible to identify policy options that will improve conditions over time. The problem definition should include the following elements: identification of the government's outcome of direct interest; the causes or drivers of that outcome; a discussion of the anticipated trends related to the problem without further policy intervention; and the economic, social, environmental, health and safety, and public security significance of the problem.

Before determining the scope, depth, and timing suitable for the RIA being developed for the policy problem being addressed, it is necessary to determine the objectives. The specific objectives of the intervention need to be defined in terms that can be quantified and measured. The objectives must be well articulated because the consequences of all the policy options are ultimately evaluated relative to these objectives. The objectives are defined in terms of the change in public welfare that is being sought, such as reductions in accidental deaths, rather than in intermediate results, such as improved traffic signals. Defining specific objectives of a policy action also helps to meet the need

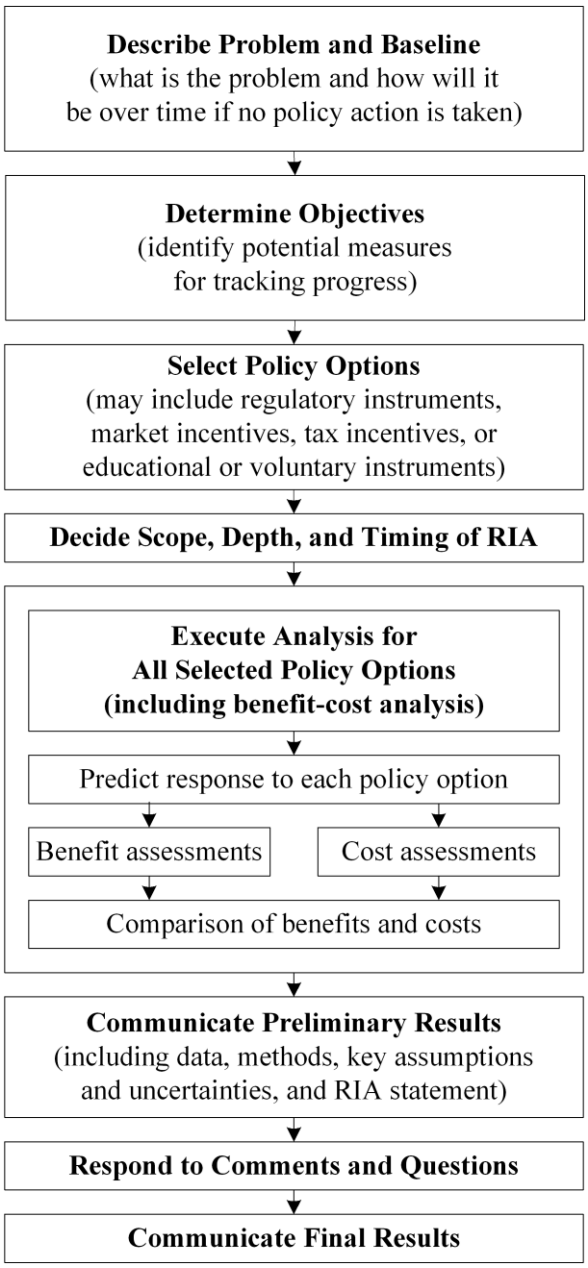

Exhibit S.1. Flow chart of the RIA process.

for future assessments of policy effectiveness. The RIA manager must understand what the decision-makers expect in terms of how the results of an impact analysis will be used in the decision-making process. At a minimum, the RIA should respond to questions seen as policy relevant by decision-makers. For example, there may be an expectation that some action will be taken and that the primary purpose of the RIA is to help in selecting a policy option. Alternatively, the focus may be on deciding whether or not to take action.

The scoping effort is intended to determine the range of policy options and impacts that will be considered. It is also necessary to determine the depth of the impact analysis including which selected impacts need to be quantified and monetized. The RIA manager then needs to determine the timeframe for the analysis in the context of the decision-making process. This will include the time required for the initial analysis, comment periods, and consultations on preliminary and draft methods and results of the RIA.

Many factors determine the level of effort required for the RIA. The most important factors for the RIA manager to assess in determining the level of effort required include:

- The potential costs of regulatory compliance to Canadians;
- The potential benefits of compliance to Canadians; and
- The level of public acceptance for the proposed regulations.

The center of the RIA process is the impact analysis, which often includes a benefit-cost analysis (BCA). The level of quantitative detail in the analysis varies depending on what is needed to support decision-making, what data and information are available, and whether impacts are all expected to be low or whether some are expected to be medium or high. Sometimes cost-effectiveness analyses, breakeven analyses, or simply descriptive analyses are used to evaluate the policy options when a full BCA is not needed or is not feasible.

The first step in conducting the impact analysis is to develop a detailed plan for the analysis. This plan should identify major components of the analysis and how they will fit together. The plan should include what will be quantified, what will be monetized, and what will be left in qualitative terms. A key element of the plan is the approach for integrating all the steps of the analysis because individual steps of the analysis are often conducted by RIA team members with different technical expertise.

No matter how carefully an RIA is conducted, uncertainty in the conclusions is inevitable, because forecasts of what to expect in the future are never fully certain. Assessment of uncertainty is best incorporated at every step of the analysis, and key sources of uncertainty should be identified and communicated to decision-makers. This should be balanced with what the analysts are most confident about. The presentation of uncertainty can be done so that the conclusions of the RIA are not unnecessarily undercut, but are put in a realistic context.

It is important to note that quality assurance cuts across all aspects of the impact analysis and is an important factor in how the results of the impact analysis are presented. Quality assurance begins at the first step in the RIA development and continues through the checking of results. A key to a quality assurance program's success is to have the RIA manager and team approach the task with an openness and willingness to seek, receive, and incorporate constructive feedback and criticism offered to improve the analysis.

Consultation and review are important parts of the process for developing policy proposals. Consultation with stakeholders is necessary at the beginning of the RIA process to help identify the impacts and results that can be expected with various policy options. Consultation and review are also necessary before finalizing the RIA. These are all parts of the quality assurance process. It is also important for decision-makers to know the concerns and comments of various stakeholders who would be affected by the policy actions. The RIA team summarizes comments received and responses made in the analyses and conclusions as part of the final reporting on the RIA.

Communication of the results of the RIA is important in providing an analysis that is useful for decision-makers and other interested parties who will use the RIA to make choices about the future of Canada. These results are typically presented in a technical report that documents all the data sources, analysis methods, underlying scientific study results, key assumptions, and any sensitivity or uncertainty analyses that have potentially important implications for the conclusions of the RIA. The guiding principles of transparency and replicability apply here in that there should be sufficient information provided that another analyst, with the appropriate technical background, could replicate the analysis.

Properly conducted RIAs can serve a number of purposes that promote safety and economic prosperity. Contents of the technical RIA report can be used for the creation of a Regulatory Impact Analysis Statement (RIAS), which summarizes the RIA methods and results and presents the policy implications.

1. Introduction

Policy actions to address public safety, human health, and environmental problems generate a range of impacts, some beneficial and some adverse. A regulatory impact analysis (RIA) is a tool that is used to develop, organize, analyze, and present information on the impacts of different policy options to help decision-makers identify the options that do the most good with the least harm.

The Government of Canada has used some form of impact analysis as part of its regulatory process for many years. Most recently, the *Cabinet Directive on Streamlining Regulation* (Government of Canada, 2007) spells out goals for the analysis of a proposed regulation. The Directive specifically states that the regulatory process should ascertain that the benefits of intervention justify the costs and to select policy options that maximize net benefits. However, the Directive clarifies that maximization of net benefits is not the only decision-making criterion by noting, "the analysis of these impacts provides useful information to decision-makers, even when economic efficiency is not the only or the overriding public policy objective."

This handbook is directed to the RIA manager. It presents a process for conducting a successful RIA. It also provides clear and concise guidance on "good practice" processes for conducting well-integrated, technically credible, and policy-informative RIAs for policy options that impact public safety, human health, and the environment. The following issues are addressed:

- ***Framing the problem:*** The RIA starts by clearly articulating the origin, nature, and magnitude of the problem.

- ***Policy options:*** A range of policy options are identified to address the problem. An important consideration is whether nonregulatory methods can be used to achieve the desired impact. Policy options selected for consideration should reflect the full range of potential interventions that could be used to address the identified problem.

- ***RIA purpose:*** The RIA's primary purpose is to assist the decision-maker in selecting a policy option to pursue. As a result, its depth, scope, and timing should consider what information the decision-maker needs and when the information is needed.

- ***Participants in the analysis and review process:*** Many individuals need to be involved in the RIA process given the technical issues and stakeholder interests. The RIA manager determines how and when different parties are involved.

- ***Integrated assessment:*** Integration means that the basic framework, method, and parameters of the analysis are set to ensure that results produced by one group are best suited for use by others in a sequential analysis.

- ***Technical quality:*** An RIA needs a technically robust and informative analysis (i.e., appropriate depth, documentation, and expert review), but it must be done with available resources.

- ***Effective communication:*** Effective communication is essential, including accurate communication of the methods, results, and uncertainty.

This handbook focuses on the processes of planning, organizing, and conducting an RIA, rather than on the technical content of the analysis. A premise of this handbook is that the RIA manager is aware of the relevant technical issues that need to be addressed in different components of the analysis. As a result, detailed discussions of these technical issues are not provided, although there are references to critical research and technical guidance documents in a number of areas. Several guides are available that describe technical aspects for how to conduct benefit-cost analysis (BCA), including one from the Treasury Board of Canada Secretariat (2007b). Most developed countries have incorporated some type of RIA in their regulatory development process. Guidance documents developed by and for these entities provide useful resources (e.g., OMB, 2003; Australian Government, 2006; European Commission, 2009; OECD, 2009; USEPA, 2010). In particular, the guidance document prepared by the U.S. Environmental Protection Agency (USEPA, 2010), is recommended as an excellent resource because of its comprehensive discussions of critical topics and illustrative examples.

This process-oriented handbook is organized as follows:

- ***Chapter 2:*** Describes how to define the problem and baseline, determine objectives, select policy options, and how to determine the scope, depth, and timing of the impact analysis;

- ***Chapter 3:*** Provides a process for executing and integrating the impact analyses for the selected policy options under consideration;

- ***Chapter 4:*** Describes issues associated with the quality assurance of the RIA, including the treatment of uncertainty in the analysis and the presentation of results; and

- ***Chapter 5:*** Addresses the communication of RIA results and conclusions to decision-makers and others.

2. The RIA Planning Process

This chapter describes a process that the RIA manager can follow to determine the appropriate scope, depth, and timing for an impact analysis, which is the central component of an RIA.

Exhibit 2.1 shows the main steps in designing and conducting an RIA. These steps are planned and implemented according to the scope, depth, and timing suitable for the policy problem being addressed. The process begins by describing the problem and the baseline. Then potential policy objectives are determined and policy options are selected. These steps are essential in order to prioritize topics the RIA will address with available resources.

As shown in Exhibit 2.1, this preliminary process is described in the first three steps. The fourth step is to decide on the RIA's scope, depth, and timing. As used in this chapter and the rest of the handbook, these terms are defined as follows:

- ***Scope:*** The anticipated impacts from the policy option that the impact analysis will examine in detail. These impacts are usually divided into negative impacts (costs) and positive impacts (benefits).

- ***Depth:*** The extent to which impacts from a policy option need to be quantified and monetized.

- ***Timing:*** The schedule required to complete the consultation, data collection, and analysis, as well as the review and reporting of results.

2.1 Overview of the Planning Process

An RIA includes assessment of the anticipated beneficial and adverse impacts of the policy options. These impacts are then compared with a future scenario where no new action is taken to address a problem. This comparison usually takes the form of a BCA that is intended to help decision-makers select the preferred policy option. In some cases, a full BCA is not needed because expected costs are minimal. In other cases, a full BCA is not feasible because of data limitations. Alternatives such as a cost-effectiveness analysis or a break-even analysis can provide useful information. In any case, an RIA cannot be used to comprehensively analyze all potential impacts attributable to a single policy option, let alone a suite of policy options. The analysis must simplify real-world complexities in order to demonstrate the potential impacts of different policy options. It must also consider the needs of decision-makers and the constraints of available resources, including data and time.

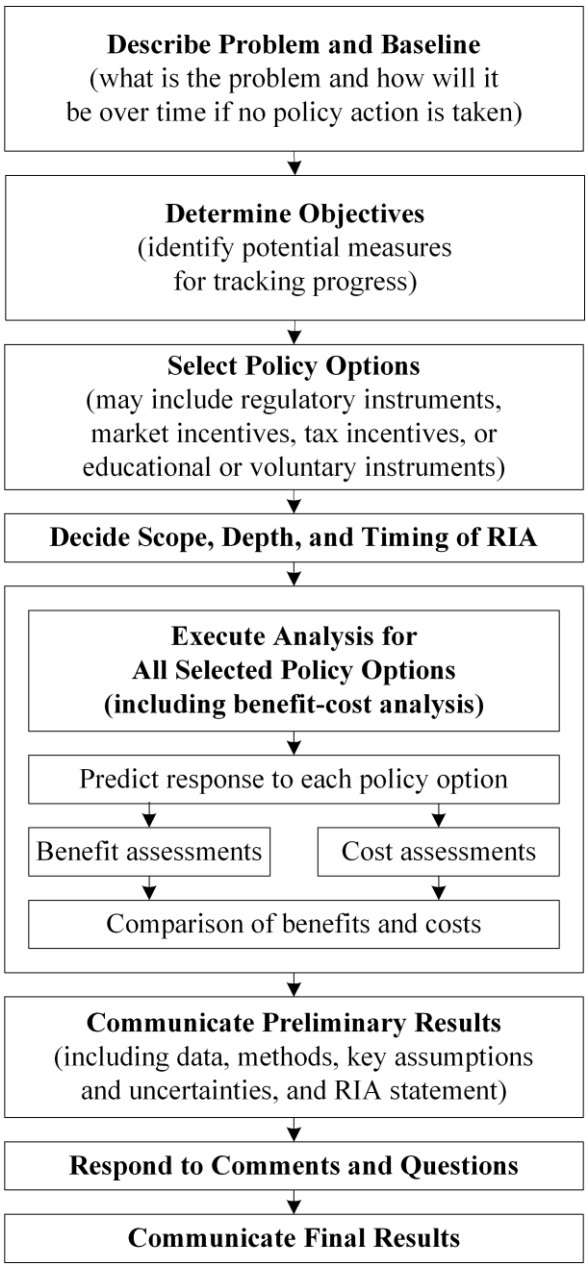

Exhibit 2.1. Flow chart of the RIA process.

In determining the RIA's scope, the RIA manager must understand what the decision-makers expect in terms of how the results of an impact analysis will be used in the decision-making process. At a minimum, the RIA should respond to questions seen as policy relevant by decision-makers. For example, there may be an expectation that some action will be taken and that the primary purpose of the RIA is to help in selecting a policy option. Alternatively, the focus may be on deciding whether or not to take action. Everyone may assume that the analysis will help to justify the decision they want to make. However, the RIA analyst should not avoid options or hide information that is not supportive of a specific policy option. The RIA should be an objective and neutral assessment, not an effort to arrive at predetermined conclusions or to market a preferred policy option.

Finally, the RIA manager should keep in mind that the RIA is one of many inputs into policy decision-making. Other influential factors may include legislative requirements, political pressures, and equity and fairness considerations. Ideally, the analysts are responsible for obtaining and presenting the available scientific evidence regarding the problem, with interpretation and analysis that assists in decision-making. Some influences on the decision-making process, such as political opposition, are not the responsibility of the RIA analyst. The results of the analysis are unlikely to be, and in most cases should not be, the only factor considered in the decision-making process.

2.2 Describe the Problem and Baseline

The first step in an RIA is to clearly define the problem. Without a clear understanding of the problem, why it has arisen, and its anticipated future path, it will be impossible to identify policy options that will improve conditions over time.

The problem definition is not just a simple statement that a problem exists. Instead, it is a statement with the following elements:

- Identification of the problem and the government's outcome of direct interest;
- The causes or drivers of that problem, including any market forces and existing government interventions affecting the problem;
- A discussion of whether and why the problem is likely to get worse, get better, or stay the same without further policy intervention; and
- The economic, social, environmental, health and safety, and public security significance of the problem (e.g., the number of people affected, the geographic extent of the problem, and the degree of harm or risk that impacts affected individuals).

The problem definition should be sufficiently precise so that all policy options, even those aimed at secondary or tertiary causes, can be clearly related to anticipated changes in the outcome of direct interest. The problem definition should also be precise enough about trends to assist in establishing the baseline projection.

The problem definition will change and become more precise as the RIA proceeds and more is learned. This refinement over time is consistent with the view that all parts of the RIA are iterative with ongoing evaluation and refinement until the RIA is completed.

A description of the expected progression of the problem over time without additional action being taken defines the baseline scenario in the RIA. It is important to note that taking no further action is different than taking no action at all. No further action means that existing agreements and other relevant regulations will continue to be implemented and that new controls will not be enacted. As an example, for an existing regulation, the baseline scenario would foresee continuing with the schedule of activity described in those regulations.

In many cases, a problem may not change without further action. However, it may get worse or get better over time if no new action is taken. For example, existing regulations requiring stringent pollution controls on new power plants may be expected to reduce air pollution emissions over time. Market conditions also may change, and economic and population growth could affect the future path of a current problem. In other cases, different things might be expected to affect a problem, making assessment of future trends more complicated. For example, regulations that require lower exhaust emissions from new cars will result in lower average emissions per mile driven in the future as older model cars are retired. On the other hand, population and economic growth could result in more cars on the road and perhaps increases in vehicle miles traveled per person. This would likely offset, either partially or completely, the effect of a decrease in emissions per mile driven with the newer model cars.

For a full quantitative impact analysis, the baseline must be quantified. However, in the planning process, it is usually sufficient to determine whether the problem is expected to get worse, get better, or stay the same if no action is taken. That is, the qualitative baseline scenario includes a statement of problem trends over the time horizon of the analysis and an explanation of why this is likely, including an explicit statement of important assumptions made.

2.3 Determine Objectives

Related to the problem definition is the determination of the objectives of potential policy options. The specific objectives of the intervention need to be defined. Consider the adverse health effects attributable to air pollution. Regulators tasked with reducing this health burden might describe their problem in terms of the current level of air pollution emissions, recognizing that emissions reductions would be needed to improve ambient air quality. However, this lack of precision in defining the problem may result in a focus on policy options that would not significantly improve

the real problem. For example, if the objectives were defined in terms of reducing total pollution emissions rather than reducing the health impacts of air pollution, the benefits of alternative policy options would not be appropriately evaluated because some types of air pollutants cause more health impacts than others. The objectives must be well articulated because the consequences of all the policy options are ultimately evaluated relative to these objectives.

Arsenic in drinking water case study: What is the problem?

More than 10 million Canadians face the risk of arsenic in their drinking water at levels that are higher than the maximum acceptable concentration (MAC) established by Health Canada.

Arsenic occurs naturally in many water supplies. It also may be introduced by human activity (e.g., mining, pesticides, manufacturing emissions).

The significance of the human health problem caused by arsenic in drinking water is a function of the number of people whose drinking water has arsenic concentrations that are high enough to be a health concern and of the nature of the health risk that arsenic causes. Arsenic is a known carcinogen and there is some cancer risk associated with even low levels of exposure, such as at or near the MAC.

Widespread exposure to arsenic in community and private drinking water supplies makes this a potentially significant human health risk by increasing the risk of cancer. Government intervention would, therefore, be assessed against its effect in reducing cancer incidence.

Source: Health Canada, 2006.

Defining specific objectives of a policy action also helps to meet the need for future assessments of policy effectiveness. Ideally, the objectives can be defined such that progress can be tracked with readily available data. For example, for a policy aimed at reducing pollution-related asthma symptoms in children, it would be preferable to define objectives in terms of reducing days missed from school or reducing days with symptoms rather than improving measures of lung function in children. The latter are not routinely collected or reported in available databases or ongoing health surveys, and it would be expensive to set up an ongoing collection of such data that require special measurement equipment and medical supervision.

2.4 Select the Policy Options

The purpose of the RIA is to identify different policy options to consider when addressing a well-defined problem and to provide information to help policymakers choose the best option. Examples of potential policy options include:

- Strict regulatory requirements for specific pollution control equipment, emissions or concentration limits, or a ban on specific chemicals used in various products or processes.

- Consumer education, such as labeling or quality certificates, or release of information, such as performance characteristics.

- Market incentives, such as rebates or tax breaks for certain purchases or actions. Cap and trade emissions control programs are also considered market incentives because they limit total emissions but allow individual producers to decide whether to purchase emissions permits or install emissions controls. This flexibility tends to reduce the total costs of achieving a selected total emissions limit.

- Voluntary approaches, such as public information and education (e.g., a fish advisory in locations where elevated levels of mercury have been found in certain fish species). The public is informed and advised to avoid or limit consumption of fish in these locations in order to reduce exposure to potentially harmful amounts of mercury.

- Design variations of these approaches. Within these basic approaches, the RIA might consider regulations of different stringency or different design. For example, if arsenic in water is a problem, the RIA may consider the costs and benefits of different levels of arsenic control. If labeling is an option, the RIA may consider different label designs or different kinds of information.

As suggested by the *Cabinet Directive on Streamlining Regulation* (Government of Canada, 2007), the best alternative is often a mix of policy options, such as labeling requirements combined with consumer education.

The RIA manager may be presented with a set of policy options to consider. However, the manager should work with the team to determine if additional options should be considered in the RIA planning phase. Because the RIA process will reveal additional information about the potential policy options as the analysis proceeds, the scoping effort can focus on developing a complete set of options to consider while recognizing that specific options can be refined over time.

2.5 Determine the Scope of the Impact Analysis

The scope of what needs to be included in the impact analysis varies depending on the expected impacts the proposed policy options will have on society. A first step in the process of determining the scope of the impact analysis is a preliminary assessment of the expected beneficial and detrimental impacts of the policy options under consideration. Consultations with experts, government entities, and stakeholders are needed to identify all the potential impacts and to decide on the scope of the impact analysis.

Many factors determine the level of effort required for the RIA. The most important factors for the RIA manager to assess in determining the level of effort required include:

- The potential costs of regulatory compliance to Canadians;
- The potential benefits of regulatory compliance to Canadians; and
- The level of public acceptance for the proposed regulations.

For the purposes of scoping, the RIA manager should conduct an initial brainstorming session with other team members in order to identify all possible impacts, both beneficial and adverse, associated with the identified policy options. To do this, it is helpful to develop a story about how each policy option could change the status of the problem.

An example story for a potential regulation to ban the use of an agricultural fertilizer because of health concerns for the fertilizer applicators is provided in Exhibit 2.2. In brainstorming these impacts (see Exhibit 2.2), each change attributable to the policy option represents an impact of potential interest for the RIA.

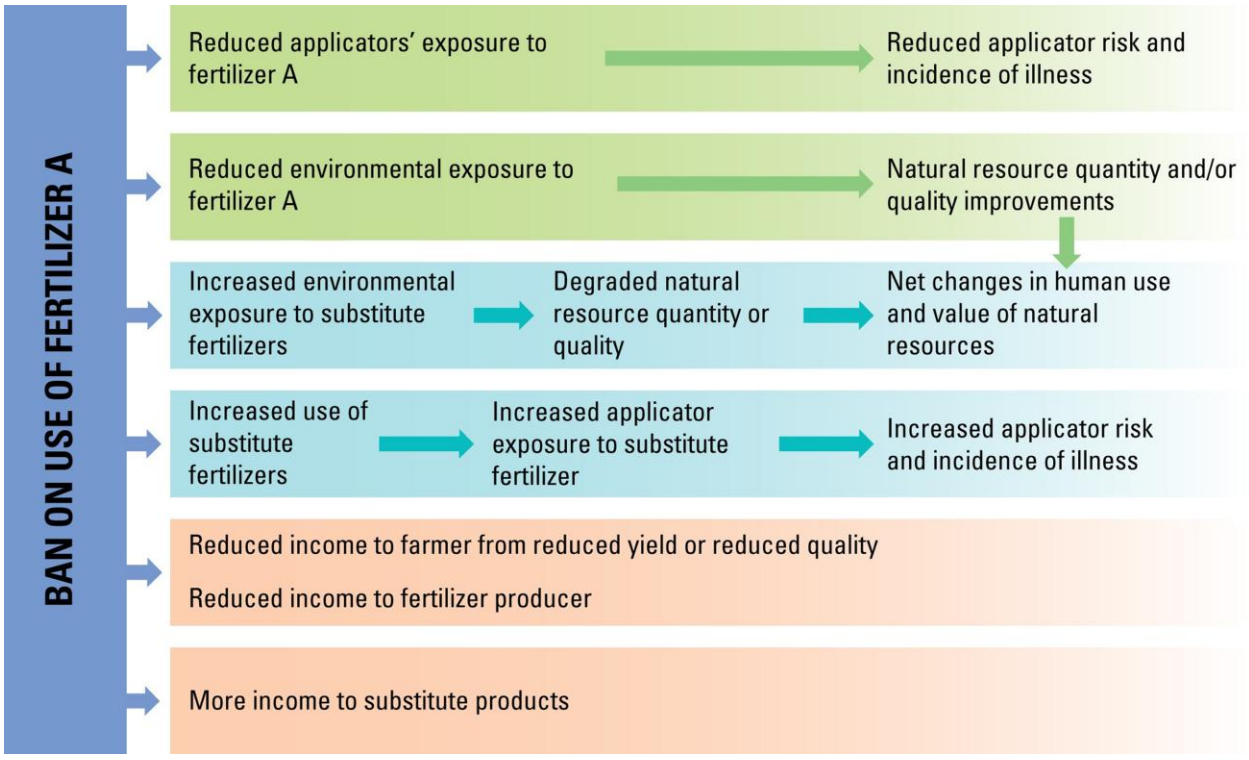

Exhibit 2.2. Limited hypothetical summary of impacts from RIA team brainstorming for the ban of an agricultural fertilizer to protect health of applicators.

As Exhibit 2.2 shows, a regulatory option to address health risks to fertilizer applicators could generate many impacts in different areas that would require evaluation by a number of experts. In Exhibit 2.2, the outcomes highlighted in green are the intended beneficial effects. In this case, there are also potential adverse health and environmental impacts, highlighted in blue. It is possible that increased human exposure and health risks associated with the use of substitute fertilizers would be an unintended consequence that would offset the desired progress on the specific problem (highlighted in green).

The initial scoping of potential impacts of a regulatory or policy action is done with the key question of the RIA in mind: Do the benefits of the action justify the costs? This is the central question of a BCA, and it requires a tally of all the benefits and all the costs, both financial and nonfinancial. For example, a reduction in illness means a reduction in medical care costs (a financial benefit) and an improvement in quality of life (a nonfinancial benefit).

Decision-makers also often want to know who gains and who loses from a regulatory or policy action. Addressing this question goes beyond a BCA to include an analysis of how the benefits and costs are distributed and how the benefits and costs show up in the economy in terms of changes in jobs and competitiveness in various sectors of the economy. This additional analysis is often called an "economic impact analysis," and it may include a quantification of impacts that are offsetting in terms of the net impacts of the policy action. For example, a regulation that requires installation of pollution-control equipment for manufacturers of widgets may mean a loss in jobs making widgets, because the pollution-control requirements mean higher widget prices and therefore demand for widgets decreases. However, the increased demand for pollution-control equipment means an increase in jobs making the pollution-control equipment, thus offsetting to some extent the job loss in the widget industry. The RIA manager determines at the outset if an economic impact analysis is needed as part of the RIA, and incorporates this into the plans for the analysis.

Advantages of group brainstorming include:

- Seeing and developing connections between impacts associated with the policy option as a group that may have been missed by an individual. For example, a resource economist may not initially see how the ban described in Exhibit 2.2 could affect water-related recreational activities until an exposure assessor describes how the ban could reduce the fertilizer loading in watersheds, which could reduce the number and severity of noxious algal blooms. At that point, the resource economist could note that the change in water quality could affect the type, number, and quality of recreational trips to affected waterbodies, changes that could potentially be quantified and monetized.

- Being able to develop causal linkages between impacts and having a sense of when the impacts might be realized.

- Having the ability to identify additional policy options by discussing links between impacts.
- Being able to foster a dialogue between team members with different expertise.

The team should then place impacts into the following categories based on how readily they can be quantified and monetized:

- ***Readily quantifiable and monetized:*** A robust body of results, literature, and models is available that can be used to quantify and monetize an identified impact.
- ***Quantifiable but not readily monetized:*** Information exists to estimate an impact quantitatively in terms of the risk level and physical or biological effects, but the available information is inadequate to support monetization without undertaking new primary valuation research.
- ***Describable only in qualitative terms:*** The impact can only be described qualitatively because of data and/or analytical constraints (e.g., lack of models).

Completing this categorization will assist the RIA team in the following ways:

- First, it will provide the team with an early sense of how close their RIA will come to addressing all impacts in a quantified and monetized BCA. Importantly, if this categorization concludes that not all impacts can be readily quantified and monetized, the RIA team can determine the potential scope of the bias in a BCA. For example, if in the team's view the impacts that are likely to remain nonmonetized are insignificant, the team can compare monetized benefits to costs, which is likely to be informative. The omissions can then be addressed as part of a qualitative discussion of results. If critical impacts cannot be readily quantified or monetized, then the team may alert decision-makers early in the process and, possibly, consider whether additional RIA resources should be committed to address the information gaps.
- Second, the categorization discussion will provide an initial sense of the uncertainty in different data sources and evaluation techniques. This is important for accurately conveying uncertainty throughout the analysis and is a critical element of how results should be conveyed to decision-makers.

2.6 Determine the Depth of the Impact Analysis

The planning effort is intended to determine the range of policy options and impacts that will be considered. However, it is also necessary to determine the depth of the impact analysis, including the extent to which selected impacts need to be quantified and monetized. This section reviews the factors the RIA manager must consider when determining the depth of the impact analysis.

When considering the depth of an impact analysis, especially regarding an environmental or human health problem, it is important that decision-makers have the benefits of the policy options (i.e., the expected health or environmental improvements) expressed in the same metric as the costs to achieve these results. This metric is typically dollars, given the relative ease of summarizing compliance costs in monetary units.

For example, regulations to reduce the ignition of residential fires from cigarettes [for additional information, see Canada Gazette (2005b)] impose costs, measured in dollars, on cigarette manufacturers. One benefit of these regulations is reduced property damage, which is readily summarized in terms of dollars. It is also useful to measure the value of reduced injury and death in monetary terms so that these benefits can be added to the property damage benefits. The total value of the benefits to the public can then be compared to the costs to manufacturers.

Not all impact analyses need to take this step. If benefits for all policy options are presented in a consistent metric, such as statistical deaths avoided, a decision-maker can make a reasonable judgment about whether benefits and costs are balanced. However, the transparency and clarity of the analysis are maximized if a consistent metric such as dollars is used for both benefits and costs.

Important issues for determining the depth needed for the impact analysis include the significance of the impacts and the level of acceptance or opposition expected.

2.6.1 Determine significance of impacts from the policy options

When determining the significance of the impacts from a policy option, first assess the effects of not addressing the problem. In other words, evaluate the anticipated future burden of the problem if no further action is taken. This burden can be evaluated against other similar problems (e.g., human health or environmental challenges) to gain a sense of the relative importance of pursuing a policy option.

Beyond considering the future burden of the problem, the significance of a policy option's impacts also need to be determined. This is largely based on an assessment of the costs of implementing the policy option and the anticipated benefits from improving the current and future status of the problem. The RIA manager and team will not have detailed quantitative information at this stage. However, significance can be evaluated based on proxy measures such as the approximate number of people or businesses that will be affected or the general type of impacts anticipated. For example, a policy option with the ultimate goal of preventing deaths would be significant because of the relative severity of the outcome (e.g., a regulatory failure would mean fewer avoided deaths). In general, as the severity of the outcome or the number of people affected increases, the impacts will be seen as more significant.

Implementation costs for a policy option may be incurred for new equipment or changes in processes. For example, there might be implementation costs associated with a ban on certain

chemicals in products because substitutes do not perform as well or cost more. In some cases, products or activities might be discontinued, resulting in a loss of opportunities or future benefits (e.g., regulation of genetically modified organisms). As with the results of inaction, costs can be assessed depending on the number of people or businesses affected or the degree of change for a specific sector.

A good first estimate of implementation costs comes from the RIA team based on initial research and discussion with stakeholders or, more likely, from the team's professional experience. Other screening techniques include an informal presurvey of industry costs; consultation with external experts; consideration of findings in other jurisdictions; and determination of the number of companies affected, the capital expenditures required, and the administrative changes required. A basic formula for this estimate is as follows: the number of affected parties × an average per-party implementation cost.

The anticipated distribution of costs may also be evaluated when significance is determined as part of the planning step. For example, implementation costs may be spread across many sectors of the economy, such as with energy costs, or they may be concentrated in certain sectors. Costs may be geographically broad or limited to certain locations. Unfortunately, in the impact analysis, it is usually impossible to determine who will ultimately pay for a regulation. This is because the economy is very complex, and costs can be spread through many channels upstream and downstream from the actions or actors targeted by the policy option. Where significant costs fall on an identified group, usually through price changes, it may be possible to specify the distribution of costs and benefits. For example, this might be the case with the regulation of arsenic in drinking water. Households will pay higher prices as a direct result of regulation. Since per household costs will be higher for those served by smaller systems, rural households are likely to face a disproportionate financial burden from the regulation. In considering the distribution of costs, it may be important to note if a high proportion of producers or consumers likely to be affected by a policy option are economically vulnerable, such as native populations.

In addition to considering the total scale of the implementation costs, it is important to consider the relative scale of the costs when determining the significance of the impacts. For example, the total cost may be small relative to the whole economy, but it may be large relative to a small sector of the economy. New costs that are the result of a policy option could imperil the economic survival of some producers. Producers that compete in international markets may be more vulnerable if competitors in other countries do not face the same costs. As a result, significance might be determined by the percentage change in, for example, important factors of production in affected sectors, rather than the total cost to the economy.

In contrast to considering preliminary cost estimates when assessing significance is evaluating the potential benefits of each policy option. In other words, what impact will the option have on the problem? Care must be taken in this preliminary benefits estimation to avoid prejudicing the process and conclusions of the final RIA.

Arsenic in drinking water case study:
How significant are the impacts of the proposed policy options?

Changing the allowed concentration of arsenic in drinking water would affect those drinking water suppliers and their customers with elevated arsenic levels. The primary method for reducing arsenic concentrations is to remove the arsenic through treatment. Available engineering estimates of the costs to remove arsenic from drinking water suggest that the annualized installation and operation costs are on the order of $50 per household for large systems and $600 per household for small systems. This difference exists because comparable capital costs are spread over many more households in the larger systems.

One way to assess the significance of the costs is to estimate the effects on consumer prices. For arsenic in drinking water, 25% of systems may report concentrations above 8 micrograms per liter levels. If these are small systems, the total costs per household would likely double or triple typical annual drinking water costs. For large systems, the increase in costs would be much smaller per household because the capital costs are spread over many more households. Normally, large price impacts on basic services such as water would be considered "significant" and worthy of more detailed analysis.

As with costs, it is important to consider the potential type, distribution, and relative impact of a policy option's benefits as well as its total impact. For example, significance could be assessed by the percentage of the problem the policy option will remedy and the level of confidence the experts have that these actions will be effective in reducing the problem. Uncertainties about changes in exposures and dose-response relationships must be considered as part of this preliminary benefits assessment in order to gain an idea of the possible range of benefits. Ask the question, would reasonable information produce estimates that range within a small factor around a central estimate (e.g., two or three times the "best" estimate), or is the reasonable range described more in terms of orders of magnitude of variation?

A useful expansion of this effort to determine significance is to complete a quick "back of the envelope" monetized assessment of the impacts. This is done by using assumed values for relationships and outcomes that team members believe are relevant based on their experience. The goal is to help the RIA manager with decisions about where to focus the team's data collection and analysis efforts. For example, drawing on the hypothetical example in Exhibit 2.2, the team may quickly determine that the health impact of interest is any potential change in mortality risks given the high monetary value typically assigned to avoiding a premature death. Similarly, the team may believe that the most important impact to the former users of fertilizer A would be the increased costs associated with using substitute fertilizers. In this case, the RIA team could then prioritize its information needs to focus on addressing these two impacts.

2.6.2 Determine the amount of acceptance of or opposition to the policy options

In determining the depth of the impact analysis needed for the RIA, it is important to assess the public's acceptance of a potential policy action. An early assessment of the level of public acceptability need not be a detailed analysis that follows any set methodology. Rather, it can be accomplished through less formal means. Possible vehicles for gathering this information include:

- Discussion with subject matter experts within the department and elsewhere in government;
- Media and Internet surveillance for references or discussions that relate to the issue or to past, similar actions;
- Public reactions or responses to similar actions in other countries; and
- Any other means that might help the analyst gain perspective on the types and extent of the concerns that could be held by stakeholders.

The RIA manager should develop a concise list of all potential stakeholder groups that would be affected by the proposed initiative. This matrix of potential stakeholders should be populated with assessments of the power, legitimacy, and intensity of action, as displayed in Exhibit 2.3. This assessment of stakeholders is not meant to suggest that the content, methods, or conclusions of an RIA be based on anything other than an objective interpretation of available science and data. However, because the RIA is being performed to support policy decision-making, it is important to understand the level of scrutiny and controversy the analysis is likely to receive when scoping and depth decisions are made.

Through this effort, team members are able to recognize that different groups or individuals may have different views about the significance of the problem and whether proposed policy options will benefit society. The RIA manager should have a sense of what the most common views are likely to be in determining the scope for the RIA.

The purpose of the RIA is to provide objective, evidence-based information to the decision-making process. Thus, political support or opposition to the policy options should not influence the analysis. However, because the analysis supports the decision-making process, the manager must be aware of the support or opposition that different policy options may receive. This will help the analyst decide on the scope and detail needed for the RIA when answering the questions likely to arise in the decision-making process.

Exhibit 2.3. Assessing stakeholders power, legitimacy, and intensity

Dimension	Assessed along the following axis					
Power	To the extent that the stakeholder group is effectively organized, endowed with financial resources and effective leadership, capable of directly interacting with the public, capable of accessing procedural tools and the media, strategically or focally important, able to build coalitions, not dependent on government, regionally potent with little opposition in other regions, and integral to the implementation of the policy, then – whether it is supportive or opposed – it will be a powerful player.					
	Supportive			Opposed		
	High	Medium	Low	High	Medium	Low
Legitimacy	To the extent that the stakeholder group is able to tap into widely shared moral or political values, make recognizable legal claims, employ effective rhetorical devices, marshal expert authority, put forward a clear and simple message, point to a functioning internal democracy, argue that the initiative will harm it (as opposed to simply not benefiting it), call upon a public- or national-interest reputation, make both majoritarian and merit-based arguments, "owns" the issue, and remains free from buy-in and untainted by extra-legal tactics, then – whether it is supportive or opposed – it will command legitimacy.					
	Supportive			Opposed		
	High	Medium	High	Medium	High	Medium
Intensity	To the extent that the stakeholder group's at-stake interests are concentrated as opposed to diffuse, urgent, or high priority; have no alternative means of realization; have created stakeholder investment in the issue; are emotionally felt by members; and lend themselves to strong expression by leaders for the purposes of heightening solidarity, then – whether it is supportive or opposed – the group will engage the issue with intensity.					
	Supportive			Opposed		
	High	Medium	High	Medium	High	Medium

For example, some groups may have strong preferences for protecting human health and the environment and a predilection to suspect that pollutants and chemicals are harmful. These views may be based more or less on the scientific evidence. In addition, some topics tend to generate a great deal of fear and suspicion, in which case the scientific evidence may also be regarded with suspicion. It is important to remember that public perceptions of risks to human health may not be realistic or may be heavily influenced by anecdotal information.

Public concerns might also exist about the equity or fairness of perceived impacts of the proposed options. These concerns might be fueled by perceptions about who bears the costs and who enjoys the benefits. These kinds of concerns could favour or fuel opposition, depending on the circumstances.

In some situations, opposition may focus on the underlying evidence that indicates there is a significant problem or the causes of the problem. For example, some who oppose intervention to reduce greenhouse gas emissions question whether such emissions are the cause of observed trends in global temperatures. When there is disagreement among the experts as to the underlying causes of a problem that an initiative seeks to address, there is likely to be opposition based on the validity of the evidence as it relates to the seriousness and causes of the problem.

2.6.3 Combining information – making an informed classification decision

The Government of Canada is committed to ensuring that any implemented policy option provides positive net benefits to Canadians and that policy options are designed to obtain the greatest net benefit possible (e.g., Government of Canada, 2007). This guidance creates a hierarchy regarding the depth of the impact analysis that is conducted for an RIA. The depth of the analysis has implications for how useful the results will be for decision-makers. This hierarchy is as follows:

- ***Minimum acceptable result:*** The minimum standard for an RIA will be to develop a table that systematically compares, using consistent qualitative descriptors, expected negative and positive impacts for the policy options under consideration. Each solution should be compared according to its impact on the problem and its costs.

- ***Somewhat useful:*** A somewhat useful RIA will quantify, and potentially monetize, some of the positive and negative impacts for the policy options under consideration. RIAs in this category provide an opportunity for some comparative analyses, such as cost-effectiveness analyses (CEA) and limited BCA, which can more readily account for the timing and extent of the impacts.

- ***Most useful:*** The most useful RIA quantifies and monetizes all (or most) identified potential benefit and cost impacts of significance. These analyses may also include an assessment of how the benefits and costs are distributed demographically and geographically. As a result, RIAs in this category can support a comprehensive BCA as well as some evaluation, although it may be limited, of potential social impacts (e.g., environmental justice) based on the anticipated distribution of impacts.

This hierarchy of usefulness emphasizes the importance and desire to complete RIAs that support a reasoned BCA conclusion. This preference for using BCA to evaluate policy options is also clearly reflected in directives and guidance for regulatory analyses produced in Canada (e.g., Government of Canada, 2007), the United States (e.g., OMB, 2003), and Europe (e.g., OECD, 2009).

In addition, guidance exists with respect to how initial implementation cost estimates can be used to determine the depth of the RIA analysis. Exhibit 2.4 provides an impact classification hierarchy based on the estimates of the present value for compliance costs. With this classification, two tests can be used to determine if an RIA should be more quantitative:

- One of the thresholds commonly used in Canada, Europe, and the United States over the last two decades for applying a quantitative economic evaluation is when the estimated costs for a proposed policy option are medium or high (i.e., when the impact is expected to exceed $10 million in present-value private-sector costs).

- The RIA should also be more quantitative when total costs are below the medium or high impact classification levels in total (i.e., less than $10 million in present value Canadian dollars), but when these costs are expected to be borne mostly by one sector.

Exhibit 2.4. Cost impact classification hierarchy

Impact classification	Cost estimate Present value (PV)[a] or annual value [dollars in millions (M)]
High	$100 M or above PV or $10 M or above annual
Medium	$10–$100 M PV or $1–$10 M annual
Low	< $10 M PV or < $1 M annual

a. PV – all costs are corrected (discounted) to present-day terms (i.e., dollars) using an accepted method and discount rate. Costs are defined as incremental from the current baseline (i.e., anything new that a company or household must do to comply).

Source: These are the categories of gross costs presented by the Treasury Board of Canada Secretariat (2009) for classification of proposals as low, medium, or high impact.

Given the clear preference for quantifying and monetizing costs and benefits in an RIA, the RIA manager must evaluate the technical complexity and resources required to complete such an assessment of the policy options under consideration. One aspect of this assessment should focus on whether there is a need for original data collection (e.g., industry cost survey, new economic valuation study) or whether available data sources will be sufficient for the analysis. In this assessment, the RIA manager should also recognize that it is very rare that all costs and benefits can be monetized. However, benefits and costs may be quantified and presented so that a decision-maker can reach an informed conclusion about whether the benefits and costs are balanced (Shapansky and De Civita, 2002).

Policy and regulatory decision-making always occurs in a context of incomplete and limited information. The RIA manager's role is to design, conduct, and present results of an impact analysis that simplifies and synthesizes a complex reality so that key decisions can be made. Thus, the

judgment of the RIA manager and analysts about how to select, approximate, and present information is critical.

The key question with respect to the RIA's depth is how best to support decision-making given limited time and resources to devote to the analysis. The more time and resources that are devoted to the analysis, the better the information is likely to be. However, it is necessary to determine the amount of information needed to support decision-making. Such a judgment relates to how high the costs are and to "how close the call is" regarding whether the benefits of the initiative are sufficient to justify the costs. When costs and benefits are believed to be close and the stakes are high, it may take a considerable amount of resources to conduct an adequate analysis. If it is easy to demonstrate that the benefits far exceed the costs, then the analysis will require fewer resources and there will be a lower priority on fully describing all potential impacts.

In determining depth, policy options with significant impacts clearly merit the devotion of more resources to the analysis. However, the RIA manager must also determine if more resources will improve the analysis. For example, there may be uncertainties that cannot be resolved by any reasonable expenditure of time and effort.

In general, when assessing the required depth of the impact analysis, the RIA manager must determine the resources needed to answer the following questions so that decision-makers can feel confident with the course of action they select:

- What is the problem being addressed, and why did it emerge?
- What will happen if the government does not act?
- What are the consequences of government action?
- Why is the proposed solution the best one, that is, why does the solution most effectively address the problem at the lowest cost to the country?
- Can the government implement the policy effectively?

The cost and stakeholder acceptance level classifications can be used to inform an initial decision on the depth of the RIA (Shapansky et al., 2003).

All possible combinations of rankings for these two elements are listed in Exhibit 2.5. In short, a high-cost impact or low level of stakeholder acceptance automatically indicates that a full quantification effort be applied in the RIA. A more detailed explanation of what is expected in the three levels – low, medium, and high – of RIA effort is provided below.

Exhibit 2.5. Combinations of cost impact and acceptance levels (H – high, M – medium, L – low) leading to analysis effort

Cost estimate	General stakeholder acceptance level	Proportionate RIA effort
H	H	H → Full quantification[a]
H	M	H → Full quantification
H	L	H → Full quantification
M	H	M → Quantification of salient costs and benefits[b]
M	M	M → Quantification of salient costs and benefits[b]
M	L	H → Full quantification
L	H	L → Qualitative consideration
L	M	M → Quantification of salient costs and benefits[b]
L	L	H → Full quantification

a. Full quantitative RIA including distributional analysis.
b. Quantification of costs and benefits where readily available; a qualitative description of the remaining salient issues.

Major/high-cost initiative – full quantification of direct impacts

- A major initiative, as classified by the above criteria, warrants a major effort in determining the impacts of the solutions under consideration. The impacts from a major initiative are likely far-reaching, and the economic (and concomitant political) ramifications should be anticipated as best as possible.

Desired results for each solution considered include:

- Full quantification of direct costs incurred by industry, consumers, and government to implement the solution;
- Discussion of dynamic costs such as effects on competition and innovation;
- Full quantification of benefits to health, safety, consumer welfare, and the environment for Canadians; and
- Complete distributional analysis (including equity and social implications) and wider economic consequences.

These efforts are commensurate with the anticipated impact. The largest impacts are assessed and quantified; the less significant impacts may be left unexamined as they are unlikely to affect the decision. The more that the decision appears to be a close call, the more closely the less significant effects will need to be examined. Note that data must be available for statistical analysis and to establish confidence in the estimates. Where data are unavailable, the data gaps and assumptions need to be highlighted. It may be possible to describe the expected direction and general magnitude of change for those impacts that cannot be quantified.[1]

Intermediate/medium-cost initiative – quantify salient costs and benefits

- An intermediate initiative, as classified by the above criteria, warrants a more moderate effort in determining the impacts of the solutions under consideration. The impacts from an intermediate initiative are not likely far-reaching.

Desired results for each solution considered include:

- Quantification of the major direct costs incurred by industry and government to implement a solution;
- Discussion of dynamic costs such as effects on competition and innovation;
- Quantitative description of the benefits using some kind of metric (e.g., deaths avoided), with at least a qualitative description of impacts such as a major or minor reduction; and
- Distributional analysis indicating which stakeholder and public groups will be affected positively or negatively by these changes.

As above, these efforts are commensurate with the anticipated impact.

Minor/low-cost initiative – qualitative BCA

- A minor initiative, as classified by the above criteria, is limited to a qualitative effort in determining the impacts of the solutions under consideration. The impacts and subsequent consequences from a minor initiative are limited.

1. This paragraph applies to all the levels of the RIA.

Desired results for each solution considered include:

- A qualitative description of the direct and indirect costs incurred by industry and government to implement a solution;
- A qualitative account of benefits to health, safety, and the environment for Canadians; and
- A qualitative consideration of the most important distributional implications, if any, for specific groups of interest.

2.7 RIA Timing Considerations

The RIA manager needs to determine the timeframe for the analysis in the context of the decision-making process. This will include the time required for the initial analysis, comment periods, and consultations on preliminary and draft methods and results of the RIA.

Establishing the timeframe for the analysis is important, as it can affect the feasible scope and depth of the analysis or affect the required resources to ensure that a desired scope and depth of the analysis are achieved. Specifically, shorter timeframes are likely to require a larger team, all else equal, because team members will not have the time to move from one issue to another while conducting the impact analysis.

3. Executing Impact Analysis for Selected Policy Options

An RIA is best viewed as a tool to help decision-makers compare different regulatory or policy options for a specific problem. Conducting an RIA involves selecting and organizing diverse information, analyzing data, and clearly and informatively communicating the results to those making regulatory or policy decisions (and those who wish to review the basis of the Government's decisions).

The Government of Canada's stated commitment is to ensure "its regulatory activities result in the greatest overall benefit to current and future generations of Canadians" (Government of Canada, 2007, p. 1). Therefore, when policy options are considered for a problem, the focus of the RIA is to determine if this commitment will be met.

This chapter describes the process of executing a successful impact analysis. The first section includes a discussion of considerations that may need to be made when developing an overarching plan for the analysis. The remainder of the chapter describes how an RIA team conducts the analysis. This includes quantifying and comparing the expected beneficial and adverse impacts of the policy options under consideration, addressing uncertainty, and conducting distributional analyses of the impacts.

This chapter is not intended to be a detailed guide on the technical aspects of conducting an impact analysis. A number of excellent technical guides are available can be used for more detailed guidance when conducting a BCA as part of a regulatory analysis (e.g., OMB, 2003; Australian Government, 2006; European Commission, 2009; OECD, 2009; USEPA, 2010).[1] As noted previously, this handbook is intended to educate an RIA manager about the process of conducting an RIA in the regulatory decision-making context; it does not provide all the technical guidance needed for specific analyses.

This chapter focuses on a quantitative impact analysis that is appropriate for the assessment of policy options expected to have a significant impact. Assessments for low-impact policy options follow a similar reasoning in that a rationale is developed to explain why the effort is worth undertaking, but they do not require a quantitative analysis. An example of a qualitative assessment is provided by the proposed amendments for addressing potentially hazardous substances in glazed ceramics and glassware (Canada Gazette, 2005a).

1. The Treasury Board of Canada Secretariat (2007b) interim guide can also be consulted as a resource. This guide is currently being revised.

3.1 Develop a Detailed Plan for the Analysis

After the problem and baseline have been described and the scope, depth, and timing of the analysis determined (see Chapter 2), the next step is to develop a detailed plan for the analysis. This plan should identify major components of the analysis and how they will fit together. The plan should include what will be quantified, what will be monetized, and what will be left in qualitative terms.

This initial planning step may include additional brainstorming sessions with the RIA team (see Chapter 2, Section 2.5, regarding brainstorming and the scoping effort) to determine specific approaches for quantifying the most important benefits and costs of the policy options under consideration. As data are collected, adjustments will be made to the initial analysis plan in order to accommodate data limitations and new information. However, it is important to start with a plan for the whole process so that time and resources are appropriately allocated.

3.1.1 Components of the analysis

Exhibit 3.1 shows a flowchart of a comprehensive BCA for an RIA involving safety, health, and environmental risks. Benefits and costs flow from the same starting point. For example, the policy option may require a change in behaviour (e.g., increased use of seatbelts), installation of specific pollution control equipment, or a change in production processes or ingredients to reduce public health hazards.

One challenge of conducting an RIA is to ensure that all the pieces fit together. It is clear from Exhibit 3.1 that contributions from many different fields of expertise are needed. At each step, the expert must know what to expect from the previous expert in terms of what will be quantified and in what units it will be measured. Common approaches to addressing uncertainty and data gaps may also be appropriate.

Analyses with some complexity usually require several iterations and consultations among RIA team members. As each component of the analysis progresses, there are likely to be changes necessitated by data and analysis limitations and new findings that emerge. Consequently, coordination and communication among team members are essential.

3.1.2 Areas of expertise for an RIA team

For most significant RIA efforts, a number of people will be involved. The analyst managing the RIA will oversee the technical analysis and also coordinate the interactions of individuals and groups who will have input to or who take an interest in the RIA and its findings.

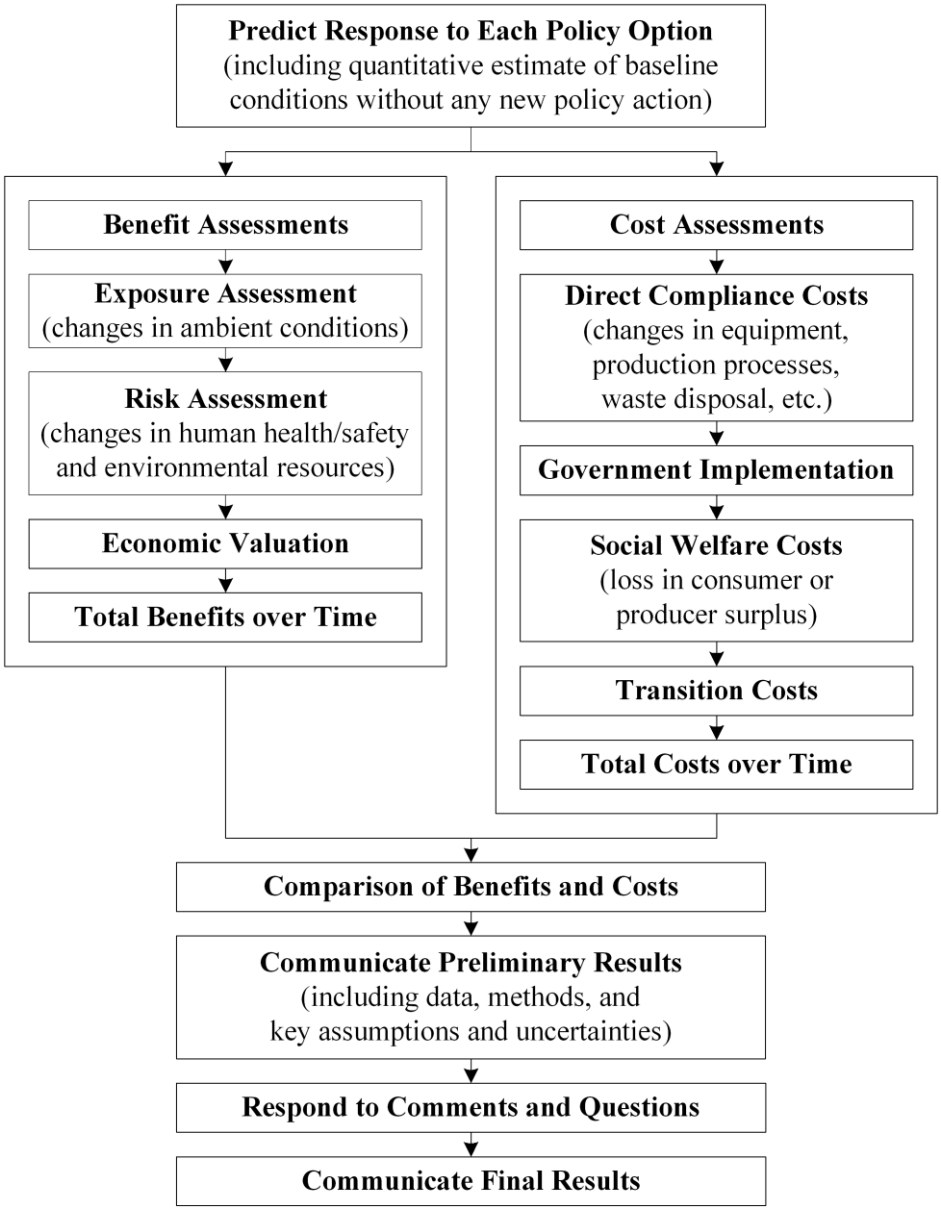

Exhibit 3.1. Flow chart of a BCA.

An RIA team must be able to develop, adapt, and incorporate information in a number of subject areas in order to identify, quantify, and monetize major negative and positive impacts needed for a focused analysis. The list below identifies the basic skill sets an RIA team should have in order to evaluate policy options designed to address a human health or environmental problem (note that specific titles or academic degrees may vary depending on the individual RIA). This list also includes descriptions of the tasks individuals with these skills will need to complete and how the products of their work will relate to other components of the analysis.

- ***Industrial impact assessment:*** Most policy options designed to address a human health, public safety, or environmental problem require a change in industrial processes or inputs. Determining the impact of this change typically requires individuals with experience and expertise with the affected industry or a related field. The team members with these skills will identify current practices in the field that could be affected by the policy options; develop a description of how each policy option will affect industrial operations (e.g., processes, materials used, partnerships); and identify the major costs and benefits of each option addressed in the RIA. As the RIA is developed and data are collected, these individuals will also develop estimates of the net change in costs for the affected industrial parties. This may require some engineering expertise, as well as industrial economics, depending on the nature of the problem being addressed. To complete this effort, these individuals will identify and process the data required for the cost assessment. This includes determining if the necessary data are already available and, if not, developing and implementing an additional data collection effort (e.g., industry survey, targeted interviews) within the constraint of available resources. The industrial impact assessment also includes an assessment of the effect of each policy option in terms of reduced pollution emissions or other sources of risk to health, safety, or the environment.

- ***Pollution dispersion/transport:*** Pollutants are often dispersed, transported, and chemically or biologically transformed in the environment before they result in a change in exposure for humans or natural resources. Some expertise in these dispersion and transportation processes may be needed to quantify the changes in relevant concentrations in all pertinent locations. In addition, expertise in a wide range of physical sciences may be needed, including atmospheric chemistry, groundwater geology, and watershed or ecosystem sciences. For example, a policy option might reduce emissions of sulphur dioxide, which is transported and transformed in the atmosphere into fine particulate matter, which poses a significant human health risk. An atmospheric chemist, or related expert, will determine how sulphur dioxide emissions reductions attributable to a policy option would translate into changes in ambient particulate matter concentrations at all locations. This determination may also include an assessment of how these concentrations would vary for different weather conditions or seasonal variations.

- ***Exposure assessment:*** The policy options to address most pollution-related environmental and human health problems involve some combination of changes in the access to, production of, use of, or release of different polluting substances (i.e., stressors). In most cases, these changes can be expected to reduce exposure to health-impacting or welfare-impacting stressors. RIA team members with expertise in exposure assessment will determine how changes in ambient conditions as a result of policy options will affect any exposures to the stressors that are relevant for the risk assessment. Critically, the exposure assessor will consider both the direct and indirect changes that could result from a regulatory action's impact on behaviour (e.g., possibly offsetting cumulative exposures if improved environmental conditions result in behaviour changes, such as more time spent outdoors). The exposure assessors will coordinate closely with the risk assessors to ensure that exposure measurements that can most easily be incorporated into the risk assessment (e.g., maximum daily values, seasonal totals, cumulative lifetime exposures) are provided.

- ***Health, safety, and environmental risk assessment:*** The risk assessment experts on the team will identify and quantify specific health and/or environmental impacts that could result from changes in exposure attributable to the policy options. The risk assessor will integrate estimates of changes in exposure with available concentration or dose-response functions to develop the desired quantitative estimates of changes in outcome incidence (e.g., hospitalizations, premature mortality, fish populations). The risk assessor will work closely with the resource/outcome valuation experts to identify outcomes that could be quantified based on exposure changes that are most relevant because they can be readily monetized. Their work, in turn, will influence discussions between the risk and exposure assessment experts. The risk assessment is used to evaluate the risk reductions from each policy option.

- ***Economic valuation of health, safety, and environmental benefits:*** If successful, policy options will result in some change in risks to human health and safety or to environmental resources (e.g., reduced numbers of premature deaths or emergency room visits, improved water quality). The economic value that results in human health and safety and/or the quantity or quality of environmental resources must be determined to complete a fully monetized analysis. Any additional intended and unintended impacts attributed by the RIA team to the policy options may need to be valued. The economic valuation specialist, typically an economist who specializes in the valuation of nonmarket resources, will develop the monetary estimates associated with these impacts. This individual must be familiar with acceptable valuation techniques and valuation databases for different types of impacts/resources in order to assess whether existing valuation estimates may be used (e.g., valuation by "benefits transfer"). The individual will develop, implement, and evaluate primary valuation studies, within the constraint of available resources, should specific impact values be required. As others have noted (e.g., Hoffmann and Krupnick, 2009), valuation experts work closely with risk assessment experts to ensure that, where possible, physical outcomes are quantified in a manner that can be readily monetized.

All of these skills are required to assess the impacts of policy options to address a major human health or environmental problem, although the specific expertise needed varies depending on the nature of the problem and the policy options under consideration. Ultimately, RIA team members must be flexible and ready to adapt to the specific needs for a given RIA situation. The importance of these qualities is suggested in the following discussion of regulatory analyses:

> You will find that you cannot conduct a good regulatory analysis according to a formula. Conducting high-quality analysis requires competent professional judgment. Different regulations may call for different emphases in the analysis, depending on the nature and complexity of the regulatory issues and the sensitivity of the benefit and cost estimates to the key assumptions (OMB, 2003, p. 3).

As previously mentioned, the impact analysis process is an iterative one. The judgments made at an early stage must be validated and refined as the information collection proceeds. To be successful, the RIA team completes its work in a collaborative manner with an emphasis on frequent and open discussion and a willingness to adjust initial plans as obstacles arise or new insights or data become evident. This type of communication is critical because information from multiple technical areas must be integrated and analyses across multiple disciplines must be coordinated so that each step in the analysis produces accurate and informative results that can be incorporated into subsequent steps in the analysis.

Exhibit 3.2 describes the characteristics of core RIA team members and relates them to the individuals and groups they rely on for information as they complete their analysis.

3.2 Establish the Baseline for the Analysis

The central purpose of the RIA is to evaluate the *impacts* from policy options that are being considered to address a problem. By definition, these impacts represent changes in future conditions that would not have occurred absent the implementation of the policy option. The baseline conditions for the RIA represent the anticipated consequences under a scenario where there is no new intervention. In other words, the baseline is a "no further action" scenario, commonly called the "status quo" scenario (or the counterfactual).

The baseline is assessed to some extent in the RIA planning process. At the early planning stages, it is necessary to develop some information about the magnitude of the problem of interest and how it is likely to change over time if no action is taken. When the full analysis is conducted, it is necessary to fully specify the baseline in quantitative terms to the extent that this is required by the planned scope and depth of the RIA.

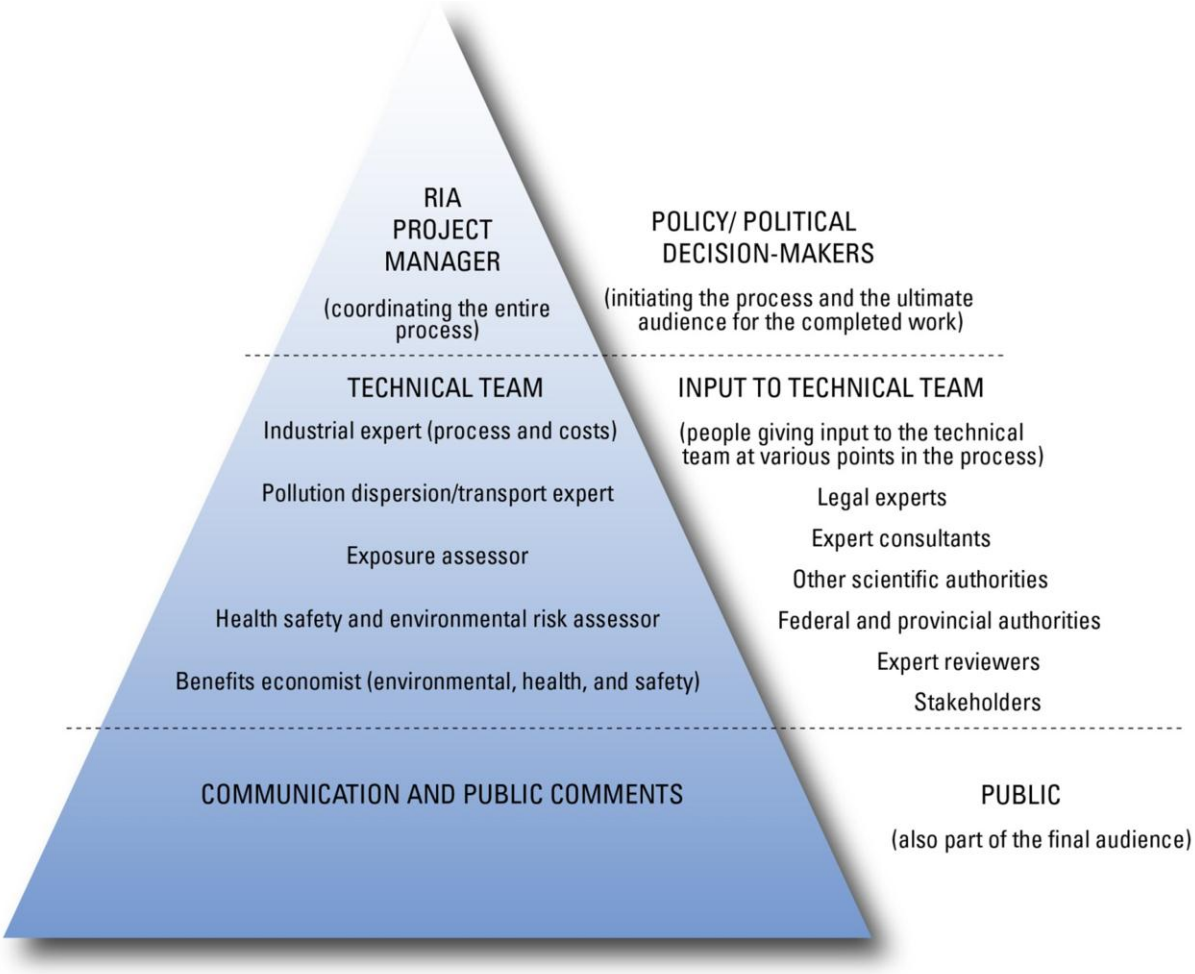

Exhibit 3.2. Participants in the RIA process.

The concept of a "no further action" scenario relative to the impact of a potential policy option is illustrated in Exhibit 3.3. The exhibit illustrates a situation where a policy option is developed to address a contamination problem that is expected to worsen over time if no further action is taken. In this illustration, the difference in the future begins to emerge sometime after the policy option is implemented, perhaps reflecting a phased implementation or an option that becomes effective only as existing stocks of a good are replaced. The impact of the policy option in addressing the problem is defined relative to the baseline. This spans the period of time when the baseline path differs from the policy option path. The distance between the paths over the whole time period measures the impact of the option.

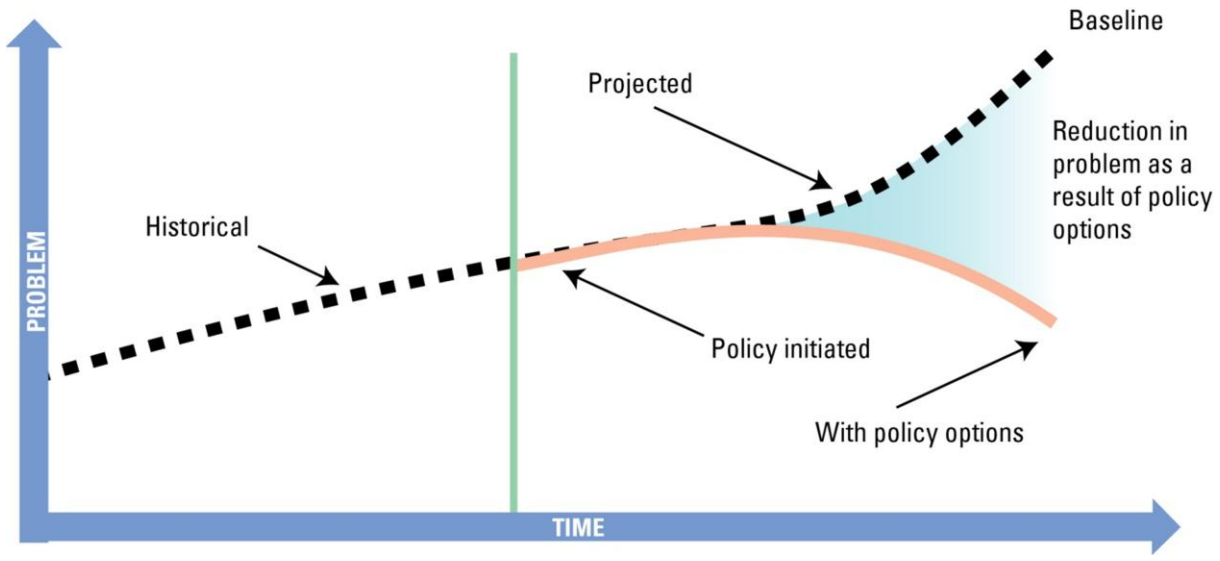

Exhibit 3.3. Illustration of potential difference in future states comparing baseline and "with policy option" scenarios (modified from presentation by the Treasury Board of Canada Secretariat, 2007b).

One common way to draw the baseline is to assume that the future resembles the past. In other words, it is assumed that a problem's status will not change over time. But this is often inaccurate. A critical feature to note in Exhibit 3.3 is that the "baseline" scenario is not held constant over time (i.e., the baseline path for the problem is not flat). The trend in the baseline path reflects expectations that the status of the problem in question is expected to change over time if no policy option is implemented. This is an explicit recognition that the problems being addressed are typically influenced by multiple factors that could, on balance, result in the problem staying the same, getting worse, or getting better, even if no new options are undertaken to address the problem.

For example, consider the RIA for the regulation of sulphur in gasoline [for additional details, see Canada Gazette (1999)] with estimated baseline emissions for the period 2000 to 2020. The projections without any new intervention showed an increase in emissions over this time period due to population and economic growth. This meant that without any regulation, the air quality impacts would have worsened as a result of the increased emissions. In addition, population growth meant that more people would have been exposed to the worsening air quality. As a result, the incidence of adverse health effects in the population was expected to increase as a result of both population growth and increased emissions. Both effects were accounted for in the estimation of the baseline (i.e., without regulation) scenario.

The entire RIA team should be involved in establishing the baseline projections. Because each team member evaluates future changes in specific areas, it is important to have their input at the outset to ensure that reasonable assumptions are made with respect to their area of expertise. This group development of the baseline will help ensure that all influences relevant to the problem under consideration are identified and addressed. The baseline definition should produce a timeline that describes the future state of the world at different points in time with no further action. Factors that are often important in quantifying a baseline include expected economic and population growth and any policies already in place that may continue to have an effect on a problem in the future. The importance of establishing the baseline conditions for determining the impacts from a policy is both visibly clear from Exhibit 3.3 and has been emphasized in a number of reviews of regulatory analysis documents and guides (e.g., OMB, 2003; Treasury Board of Canada Secretariat, 2007a, 2007b; OECD, 2009).

In establishing this baseline, the team should expect that its initial effort will require revision over time, including the development of additional detail as more information is obtained. However, the initial team effort to define the baseline will produce a mutually agreed upon set of conditions from which the RIA team members can begin to work and will have initiated the open dialogue that is critical to the team's success. It is also important that assumptions made in estimating the baseline be used consistently in the intervention scenarios. For example, the same assumptions regarding future population growth should be used in all scenarios, unless a specific policy options is expected to have a direct effect on population growth.

Arsenic in drinking water case study: Response to policy options

Drinking water guidelines or standards are usually defined as MACs. These are concentrations that water providers (e.g., municipal water utilities) are not expected to exceed in the drinking water delivered to the consumer's tap. A required standard makes defining the response to the policy option relatively straightforward in most (but not all) circumstances, because in most cases, meeting the standard requires the addition of suitable forms of water treatment. However, utilities might also comply by switching the water source (e.g., closing an existing well and using a new well that yields higher-quality water) or by exiting the market (i.e., closing down the supply).

In developing an RIA, it is important to know what type(s) of treatment process water providers are likely to use to meet the standard. The compliance option decisions by regulated entities will have impacts on both the cost side and the benefit side of the ledger. For example, in most cases, in order to meet the drinking water standard, new water treatment processes will be added by the utility. These additional treatment processes may reduce the concentration of several water contaminants in addition to the compound being regulated. In such a situation, water utility customers may receive additional health risk reductions beyond those arising from reducing exposures to the contaminant targeted by the standard. These water treatment benefits from reducing additional health risks should also be counted as a benefit of this regulation if the costs are included. Likewise, if a standard or guideline may elevate other risks (e.g., when treatment process residuals concentrate compounds to high levels and must be managed as a hazardous waste), then these additional potential risks (and/or ancillary compliance costs) also need to be taken into account.

If there is great uncertainty about the future, as there often is for policy issues concerning a fairly long time horizon such as global warming, it is acceptable to have two or three baselines, each reflecting different underlying assumptions. In this case, each possible policy option will be compared to each baseline. The underlying assumptions must be clearly identified so that the decision-maker can interpret the different results and weight them according to his or her own judgments regarding the realism of the alternative assumptions.

3.3 Predict Response to Policy Options

The quantification of the costs and benefits of a policy option starts with an evaluation (quantification) of how people might respond to the policy option's impacts. In some cases, the change itself is defined by the policy option, as with command-and-control regulations that are very explicit about the pollution-control equipment or emissions limits that are required of all producers. In other cases, such as with market incentives and consumer information, some analytical work must be done to predict how households or businesses will respond and what effect they will have on pollution concentrations or exposures.

3.4 Assess Expected Benefits

For a policy option to receive serious consideration, the RIA should demonstrate that it would provide a net benefit to Canadians. Hence, the RIA team's efforts focus on quantifying expected benefits in monetary terms as much as possible. This usually means quantifying the number of cases of illness or mortality that will be prevented or quantifying some other measure of physical/biological changes such as a reduction in populations of fish species targeted by anglers. The key is that a metric that is as close as possible to the final impacts of interest be chosen. For example, it is more relevant to determine the number of asthma-related hospitalizations prevented than to simply estimate the change in air pollution concentrations in an urban area. The first is an impact of interest; the second is a risk factor for that impact. The appropriate economic valuation of these impacts is then determined.

In the benefit-cost framework, benefits are best viewed and defined from a social welfare perspective as impacts that increase the overall wellbeing of society (i.e., they increase individual utility and social welfare). Benefits valued in markets are only one part of the overall benefits because benefits that lack markets also often have economic value. Generally, benefits are associated with an increase in the quality and quantity of desired outcomes or with a reduction in the quantity and severity of adverse outcomes. Exhibit 3.4 shows a typology of benefit categories with examples focused on environmental and pollution control initiatives.

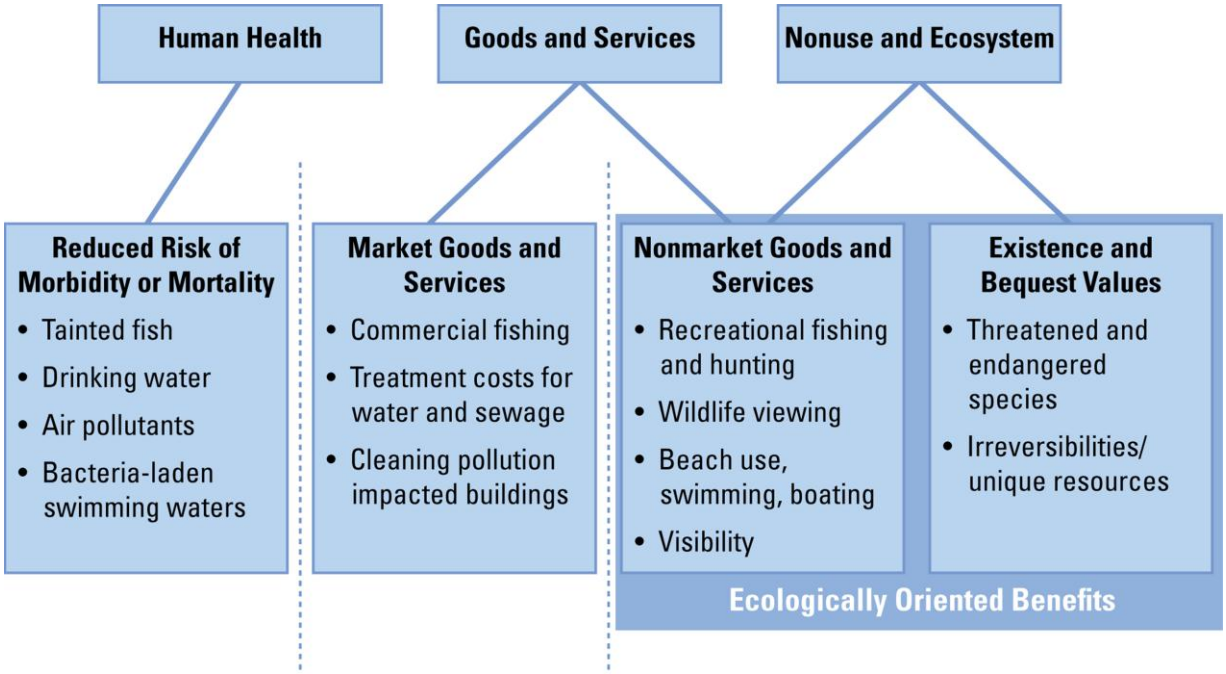

Exhibit 3.4. A typology of benefit categories.

Policy options that generate increases or protections in any of these benefit categories affect human welfare and have economic value. In addition to caring about human health and market goods and services, people care about nonmarket goods and services because these things affect their quality and enjoyment of life. They also care about the natural environment and ecosystems because they value their preservation even if they do not directly use them.

The goal of the benefits assessment task is to produce a timeline with a description of the benefits from each policy option along with a quantitative metric of each benefit and its associated monetary value. In addition, it is useful to include information on the populations that benefit, defined by age, geographic location, and socioeconomic status, to the extent that this can be reasonably determined.

Development of the quantitative and monetized benefit estimates, especially for policy options that address human health and environmental problems, typically poses challenges because of a lack of supporting data and method limitations, including:

- ***Limited quantitative models:*** Many potential impacts lack models that can be used to quantify specific links in a chain of benefits. In some cases, the models are not easily linked to complete a cycle that moves effectively from estimating changes in emissions to

calculating changes in exposure to producing quantitative estimates of change in human morbidity and mortality.

- ***Limited economic valuation results:*** A relatively limited number of nonmarket impacts have been valued in the natural resource and human health economics literature compared to the scope of impacts that can result from different policy options. Methodological and data limitations may further restrict the pool of results that are suitable for use in an RIA.

Although this handbook presumes users are familiar with many of the technical issues associated with benefits assessment, several topic areas and specific references are highlighted in the following sections for their relevance and importance to benefits assessment.

3.4.1 Exposure and risk assessments

Exposure and risk assessments are conducted to quantify the change in the stressor (e.g., pollutant) that people (or environmental resources) are exposed to as a result of the policy option and to quantify the change in health risk that accompanies this change in exposure. The purpose of the analysis is to estimate the benefits to everyone and every resource impacted by a change in exposure. Consequently, it is important to estimate risk changes not only for the most sensitive individuals but also for the entire population affected.

For example, people with asthma are at risk of a higher rate of asthma attacks and hospital visits when exposed to air pollutants, and these may be very serious health outcomes. People with asthma are a relatively small portion of the total population. However, effects of respiratory symptoms and illnesses in the general population should also be included in the assessment. Even if the impacts on the general population are less serious on average, they are experienced by a much larger at-risk population and therefore will likely represent a significant component of health effect impacts of the policy option.

Exposure and risk assessments must be coordinated with the economic valuation so that the risk changes are quantified in metrics that are of greatest use for economic valuation. When performing an economic valuation, the expected change in the number of cases of injury, illness, or death is needed, not just a determination of the level of exposure that could be considered safe. Exhibit 3.5 shows the linkages among the exposure assessment, risk assessment, and monetization that must be coordinated as part of an assessment of benefits.

A common approach in risk assessment is to adopt a "precautionary" approach by using consistently conservative assumptions (i.e., margins of safety) to determine the level of exposure that can be assumed to be safe. This worst-case scenario answers a legitimate risk management question, but it is not the question that is most relevant in the context of an RIA. Policymakers do not want to be presented with only the worst-case scenario, particularly if it is highly unlikely to occur. They also need to know the most likely scenario. The primary goal in the RIA is to develop a best estimate of

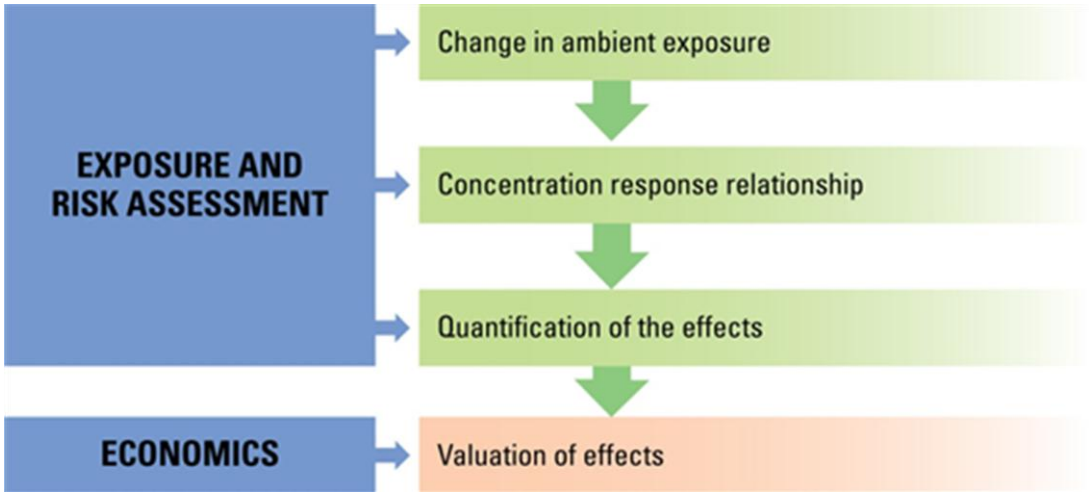

Exhibit 3.5. Integrating the disciplines to assess benefits in an RIA.

the expected change in risk, not an upper or lower bound. Because there may be significant uncertainties about these estimates, these uncertainties must be stated. However, the best approach for addressing uncertainty in an RIA is to provide a central or mean estimate of the expected change in risk and include a range, distribution, or alternative estimates if there are significant uncertainties that can be quantified. This is more appropriate than focusing on a worst-case scenario because of uncertainty. The precautionary approach is best viewed as a reflection of specific policy considerations rather than strictly analytical methods (Jacobs, 2006). This does not mean that benefits estimates developed using the precautionary approach are invalid or without informational value. It does mean that these results are more appropriately viewed as a special sensitivity analysis rather than a reflection of most-likely outcomes.

Arsenic in drinking water case study: Exposure and risk assessment

Exposure and risk assessments are rarely straightforward, as there typically are many factors to consider. For example, arsenic ingestion risks are believed to arise based on accumulated lifetime exposures. Exposure assessments may be based on a series of standard risk assessment assumptions (e.g., assuming that a typical person ingests 2 litres per day from the same source for 70 years). These standard assumptions may greatly overstate the lifetime exposure for most people. Actual lifetime accumulated exposure depends on how much water a person typically ingests each day from the impacted water supply. Some people drink 2 litres per day, but data indicate that an average person drinks 1.1 litres per day, which reduces the daily exposure by nearly half relative to a 2-litre assumption.

In addition, few people drink tap water from the same water supply for the entire day or over their entire lives. People have daily activity patterns that often include spending several hours in locations supplied with water from a source that is different from the one they access at home. Also, people periodically change the location of their residence (often several times) over the course of their lifetimes. Thus, it is useful to develop a more realistic distribution of the typical lifetime accumulated exposure rather than rely on simplifying assumptions that may be overly conservative (i.e., the standard assumptions may overstate typical lifetime exposure levels to a considerable degree).

Dose-response functions create similar challenges. These relationships typically require extrapolation from high exposure levels (such as imposed on laboratory animals) to much lower environmental exposure levels in humans. The approaches applied to make these extrapolations (e.g., whether to apply a linear no-threshold dose-response function) can have large impacts on the calculated risk estimate at relevant environmental levels of exposure. For example, a sublinear dose-response function applied to arsenic data from epidemiological evidence from high doses in Taiwan may yield risk level estimates for Canada-relevant arsenic levels that are only 10% to 20% of the risk levels derived from a linear dose-response extrapolation.

Therefore, it is important to consider a range of plausible exposure and dose-response inputs when developing risk estimates for the RIA context. Standard risk assessment protocols and assumptions may embed a considerable degree of conservatism in the risk estimates and, thus, overstate the most likely level of baseline risk and the likely level of risk reduction to be attained by a given policy instrument. To support decision-making in the risk management context, an RIA should also provide estimates based on alternative exposure and dose-response assumptions if they are at least as plausible as the risk assessment default values.

3.4.2 Economic valuation of nonmarketed benefits

Valuation methods for benefits are used to measure how those affected by the policy value the market and nonmarket benefits that they incur. If an impact is realized in an established consumer market (i.e., marketed), the analysis simply uses the market price to value it. Determining the monetary value of nonmarket benefits is more challenging. It is the values of the benefiting public that are sought for use in this analysis, not the judgments of the analyst or the policymaker. The monetary measure used by economists to reflect this value is the maximum payment the individual would be willing to make in order to obtain that benefit if such a transaction were feasible. This is what is meant by *willingness to pay* (WTP). For goods bought and sold in the market, a reasonable

lower bound for this value can be estimated based on the market price. However, for goods such as health and safety that are not directly purchased, the WTP values must be estimated or inferred indirectly. The WTP measure of value is a well-established concept that is consistent with the goals of BCA in seeking an efficient allocation of resources to maximize society's wellbeing.

WTP values for reductions in health and safety risks represent the values to the individuals who experience the reduction in risk in terms of what other goods and services they are willing to give up in exchange for the risk reduction. WTP values can be expected to reflect all the reasons why people may value lower risk, including the value of lower risk of out-of-pocket costs that might be associated with illness or death (including medical treatment and lost income) plus the value of lower risk of the lost enjoyment of life (in the broadest sense).

WTP is expected to reflect all the reasons why a person puts values on a reduction in their own risk of illness, injury, or death. Consequently, WTP is expected to exceed the value of the financial impact to the individual associated with a change in risk. A commonly used measure of monetary value for human health and safety, cost of illness, does not reflect the full effect of the change in health risk on a person's wellbeing. *Cost-of-illness* estimates measure medical expenses and lost income[2] due to death or illness, including the value of lost earnings and the value of lost time. This is sometimes called the human capital approach because it measures the value of a person's productivity rather than the person's full value and enjoyment of being alive and healthy. It is a valid measure of the types of financial effects of public health and safety policy options, but it places no value on the time or the lives of those who are not in the labour market or on the value of avoided pain and discomfort. From the perspective of trying to maximize society's overall wellbeing, counting only the cost-of-illness benefits in a benefit assessment of programs to protect public health and safety would lead to an under-investment of society's resources in public health and safety.[3]

2. Lost income in this context is a measure of the value of illness, injury, or death, which is a direct benefit of policy options that reduce illness, injury, or death. This is not an indirect effect on income that should be excluded in BCA (see Section 3.5).

3. An important caveat is that individual WTP values are not expected to reflect the value of reducing medical costs that are incurred by others. Thus, expected reductions in public health care costs, for example, should be added to individual WTP values to obtain the total social benefit of a given reduction in health risk.

Compounding effects of multiple precautionary assumptions

In the case of assessing the cancer risk of methyl tertiary butyl ether (MTBE; a gasoline additive that has contaminated groundwater in some locations), use of a linear dose-response and a high-end exposure estimate result in a significant overstatement of the expected number of cancer cases.

(a) Use of linear dose-response function (relative to suitable nonlinear alternative)	
MTBE illustration at mean	13x
(b) Use of 95th upper confidence limit (relative to maximum likelihood)	2x to 3x
Combined illustrative impact if both (a) and (b) are applied	26x to 39x
Impact when combined with exposure assumptions	280x to 860x

Note that results are case specific, depending, for example, on the degree and type of nonlinearity over the relevant exposure range and the difference between high-dose data points and low doses of regulatory relevance.

In this case, there is some evidence that the cancer risk is not linear and is smaller at lower exposures. Using a linear dose-response approach results in a risk that is roughly 13 times greater than with the nonlinear approach. In addition, using the common practice of taking the 95th percentile of the dose response, rather than the 50th percentile, increases the risk estimate another two to three times. The combined effect of these choices is to increase the cancer risk estimates by 26 to 39 times.

If this is further combined with a high-end estimate of exposure (e.g., the amount of water an average person consumes), the cancer risk estimate is roughly 280 to 860 times greater than when the nonlinear dose-response approach, the maximum likelihood value from the dose-response function, and a mid-range value for an exposure estimate are used.

Valuation of human health impacts

The reduction of human health risks is a goal of many proposed policy options. The changes in these risks represent important monetized benefits for these options, especially when they may affect the risk of premature mortality (e.g., see Chestnut and Mills, 2005).

A number of issues must be addressed when identifying, using, or developing valuations for potential human health impacts. Previous RIAs for similar risks or for environmental problems related to pollutants associated with morbidity and mortality risks (e.g., particulate matter and ozone, waterborne contaminants) can serve as relevant templates when discussing valuation and initial monetary values. In addition, guidelines for preparing RIA-type economic analyses (e.g., USEPA, 2010) have addressed many of the issues surrounding human health valuation in considerable detail. The Government of Canada's Policy Research Initiative (PRI) has also developed several publications that address issues associated with the measurement and valuation of changes in mortality risks (Chestnut and De Civita, 2008; Graham and Hu, 2008).

Changes in mortality risk are usually valued using what economists refer to as the value of a statistical life (VSL). These are estimates developed from studies of how people value small changes in their own mortality risk based on the tradeoffs they make between their own mortality risk and their own income. As such, these estimates reflect more than the financial impacts of risk and in fact reflect all the reasons why people care about their own health and safety. It is important to note that although these estimates are summed across a population and reported in terms of values per "statistical" life, they are based on choices regarding small changes in risk, which is what is relevant in most RIA contexts. In these contexts, the individuals at risk are not personally identified and what is being valued is a small change in risk for many people.

For example, some studies have found that annual wages are $600 higher than average for jobs with an annual risk of on-the-job fatality that is 1 in 10,000 higher than average (Viscusi and Aldy, 2003). This means that there is one death for every 10,000 workers and this group of 10,000 as a whole has been compensated $6,000,000 for each worker taking this incremental increase in risk. The VSL in this case is thus $6,000,000.

One limitation of the VSL estimates available in the literature is that most of them are based on risks of accidental death in the workplace or in the transportation sector. There may be differences in how people value reducing mortality risks for cancer or other chronic illness that may be associated with nonwork, environmental exposures. The age when the risk change occurs and the type of illness involved might also change the valuation. However, the literature does not answer these questions regarding how VSL may vary with any confidence. Chestnut (2009) reviewed this literature and made suggestions about which sensitivity analyses may be appropriate when applying available VSL estimates in contexts that differ from their original derivation.

In short, RIA analysts should be familiar and comfortable with the issues addressed in these publications when completing an RIA that addresses potential changes in human health outcomes. This is an area of considerable ongoing research in both the human health and welfare economics fields, with strongly held views and important precedents for the use of values that the analyst should be aware of.

3.4.3 Valuation of environmental outcomes and natural resources

As with human health outcomes, there is a wide range of issues associated with development and use of economic valuation estimates for different environmental outcomes and natural resources.

Case-specific valuation results will always be preferred, such as developing these values through a tailored survey effort. However, this work is rarely undertaken because of the costs and the potential need to receive extensive Government clearance for the effort.

Arsenic in drinking water case study: Economic valuation of reductions in risks to human health

Valuation of risk reductions for human health – such as when a program is expected to reduce the risk of premature mortality – raises several important issues. A strong body of empirical evidence from peer-reviewed economic studies provides credible estimates of how much people are willing to pay to reduce low-level mortality risks. These studies provide monetary estimates for what economists refer to as the "value of a statistical life." These VSL estimates are considered credible and point to a central value of about $6.5 million per premature fatality avoided (2007 Canadian dollars).

In applying these VSL estimates, it is generally important to consider how the context used in the underlying studies generating the VSL values may differ from the policy context to which the VSL number may be transferred. VSL estimates in the literature often are derived from studies examining mortality risks from events that may occur suddenly to people in the prime of life (e.g., motor vehicle accidents, occupational hazards). In contrast, the cancer risk associated with changes in arsenic exposure generally involves cancers that occur later in life, and there may be a considerable time lag from when exposures change to when a reduction in cancer risk is realized (i.e., cessation lag). This implies that adjustments to available VSL estimates may be appropriate to account for the time lag (e.g., latency, cessation lag) between when a policy is implemented and when costs are incurred, and the later period when health risk reductions may eventually become evident. In this context of delayed benefits, discounting VSLs to account for the anticipated latency period is warranted.

The appropriate discount rate to use in this case is the person's rate of time preference regarding future health risks; however, there is considerable uncertainty about what this rate is. It is not necessarily the same as the rate a person would discount future income. Boardman et al. (2009) discuss the conceptual issues related to discounting in policy analysis and give some summaries of various types of discount rates observed in the empirical literature.

Another adjustment may be considered if the premature mortality risks are viewed differently. This may arise, for example, where there is evidence of a high "dread" factor associated with some cancer risks compared to other fatality risks. Thus, some may consider whether a "premium" is warranted to add to the VSL estimates to reflect the added dread associated with cancer risks (i.e., when contrasted to the risks underlying the VSL estimates).

Because the literature is inconclusive as to the magnitude of the specific adjustments that are appropriate in these situations, analysts should consider alternative assumptions and sensitivity analyses (see Chestnut, 2009).

As a result, benefits transfer, the process of adopting and adjusting results from one valuation study for use in another study, is widely used by RIA teams to develop values for changes in quantity or quality of environmental outcomes and natural resources. Discussions of the relative strengths and weaknesses of benefits transfer and criteria for considering the appropriateness of a benefits transfer have been presented in a number of regulatory guidance documents (e.g., USEPA, 2010) and summarized in a number of research articles (e.g., Boyle et al., 2009, 2010). The RIA analyst should review the relevant guidance before completing a benefits transfer.

Also of considerable importance, efforts have been made to develop searchable databases of resource valuation studies. Among these databases is the Environmental Valuation Reference Inventory (EVRI), which is maintained by Environment Canada and the USEPA (EVRI, 2010). EVRI and other similar valuation databases provide users with access to searchable fields that link to specific studies. In the more complete databases, such as EVRI, these links can be used to retrieve the studies' valuation estimates along with relevant information such as the valuation scenario and methods that are critical elements of evaluating a result's suitability for use in benefits transfer.

A critical element throughout the benefits assessment is the tracking, evaluation, and incorporation of uncertainty in benefits estimates. These issues are highlighted by those policy options with benefits that have the potential to be quantified and monetized. The production of quantified and monetized impact estimates often requires linking separate models, each with its own uncertainties. The assessment may also use expert judgment about the level of precision in critical assumptions used in the analysis as part of the uncertainty evaluation. The RIA manager needs to work with the RIA team to develop standard approaches for addressing and assessing uncertainty in each step of the analysis so that the cumulative uncertainty across all the steps can be reasonably evaluated. Options for assessments of uncertainty are discussed in greater detail in Chapter 4.

3.5 Assess Expected Costs

Costs are defined from an economic perspective as impacts that reflect a potential loss of opportunity relative to the baseline scenario through a commitment of some combination of time, personnel, and resources. In this context, the generation of adverse outcomes reflects a cost that must be accounted for. For example, using the example of the ban on fertilizer A in Chapter 2 (Exhibit 2.2), any adverse impacts associated with the increased use of substitute products would represent some of the potential costs of this response.

Morgenstern and De Civita (2008) provide a useful and relevant discussion of specific issues that can arise and must be accounted for when developing estimates of the costs for potential policy options. Specifically, they provide the following categorization of possible regulatory option costs that can help guide the RIA team's consideration and examination of potential costs:

- ***Real-resource compliance costs:*** These are typically associated with:
  - Purchasing, installing, and operating new control equipment
  - Changing the production process by using different inputs or different mixtures of inputs
  - Capturing the waste products and selling or reusing them.
- ***Government implementation costs:*** These include costs to government entities for monitoring, administration, and enforcement required under new policy options.
- ***Social welfare losses:*** These are associated with changes in consumer and producer surpluses involving changes in the price (or decrease in the output) of goods and services that occur as a result of a policy option.
- ***Transitional costs:*** The resources, including labour, that are displaced because of option-induced reductions in production are usually reallocated to other productive uses and therefore do not reflect a direct cost of the policy option. However, there are often private real-resource costs of reallocating those resources, which are called transitional costs. These transitional costs should be counted as costs of the policy option.

As with other elements of the RIA, it is important to remember that the costs of the policy options that are being estimated in the RIA framework are also evaluated and accounted for as marginal changes from the baseline scenario. For example, if a facility buys one pollution control device in the baseline scenario and two in response to a policy option, then only the cost of the second unit should be included in the cost assessment.

A second important consideration when developing cost estimates is to ensure that in reviewing impacts, costs are not mistakenly double-counted. For example, higher production costs as a result of new pollution controls will mean losses in producer and consumer surplus, which are direct costs of requiring the new pollution controls and are counted as costs of the regulation. The ripple effects of the higher costs of production, such as a loss in jobs in that industry, are not counted as costs because these reflect a distribution of the initial costs through the economy and not additional separate costs. There may, however, be transitional costs as a result of the shift in employment from one industry to another. Changes in jobs are generally included in an economic impact analysis that may be used to assess the distributional impacts of the policy options (see Section 3.7).

The goal of the cost assessment task is to develop a timeline that describes who is incurring costs at any point in time, a qualitative description of those costs, and a quantitative estimate of the nominal monetary value of the costs. Although these monetary values will ultimately be expressed in PV terms (see discussion of combining benefits and costs below), the summary of these costs in nominal values over a specified time period preserves an important degree of analytical and presentation flexibility.

In developing these cost estimates, the RIA team will need to observe, track, and account for uncertainty (e.g., ranges of cost, confidence intervals) in their results, when possible, so that this information can be combined with similar information from the benefits assessment. As with the benefits assessment task, options for addressing the uncertainty in these estimates is discussed in greater detail in Chapter 4.

Arsenic in drinking water case study: Costs

One common aspect of water treatment is that the costs generally exhibit what economists refer to as "economies of scale." This means that the cost per gallon of treated drinking water will be much higher in small communities than in larger ones (all else equal). For most arsenic removal processes, this may mean, for example, that in a town supplying water to fewer than 100 households, the total annualized costs of arsenic removal may amount to $600 per year for each household. In contrast, costs in larger communities (e.g., serving 50,000 to 100,000 people) are more likely to be on the order of $50 per year per household.

In terms of complying with drinking water standards, the municipal water utilities that initially incur compliance costs will typically recover these expenses by raising water rates to the households they serve. Thus, the people who receive the safer drinking water also will typically bear the costs of compliance with the regulations.

The differentials in how much cost is borne by different households (e.g., urban versus rural communities) raise several important equity considerations. For example, is it fair to have families in small rural communities pay more than 10 times as much as their urban counterparts, when both types of households receive the same health risk reductions from the standard? Or, should smaller communities be exempt from the standards because they face relatively high costs, which raises questions about environmental justice with regard to providing different levels of health protection to different people? Or, should some additional policy instrument be considered in conjunction with the water quality standard in order to specifically address the cost inequities (e.g., a cost-sharing subsidy plan to assist smaller communities with compliance costs)? When developing an RIA, analysts must be alert to how these issues might emerge and consider policy instruments that may help address these issues.

Decision-makers are often interested in who will bear the costs as well as what the total costs will be. These are often difficult questions to answer. The costs of policy options such as environmental regulations may be borne at very different levels by different individuals or groups across society. For example, the costs of an air pollution emissions standard for an industrial sector will initially be borne by the company that owns and operates the regulated facility. However, those costs will be passed forward and dispersed across many different types of individuals, including customers and consumers who will face higher prices when they purchase the company's products. These compliance costs may also be passed "backward" to be applied to the factors of production in the form of employee salaries that may not increase as much as they would otherwise and/or to stockholders who may receive reduced dividends or capital appreciation. Such "transfers" of costs are relevant to the ultimate distribution of costs, but they do not change the total costs and therefore should not be added to the direct costs that the regulated industries incur.

3.6 Compare Benefits and Costs

With qualitative and, ideally, quantitative and monetized summaries of the potential benefits and costs for the different policy options, the RIA team will integrate these results and provide conclusions with respect to the potential *net* impacts.

The first and most obvious step in this process is to simply produce an integrated timeline with a quantitative estimate and qualitative description of the expected benefits and costs. In some situations, this alone may be enough to draw conclusions about whether the potential policy options, collectively, appear to be in the best interest of Canadians and, possibly, which option would be most preferred. However, it is more likely that the assessment will require the integration of the costs and benefits while taking explicit account of the impact of social time preferences through the discounting of impacts.

The motivation for discounting and the strength of the supporting evidence are widely recognized (e.g., OMB, 2003; Jacobs, 2006; OECD, 2009; USEPA, 2010). It is widely accepted that benefits and costs that occur in the future have less value than if those same benefits and costs were to occur today. For example, if a cost of $1,000 does not have to be incurred until next year, those funds are available for other uses in the meantime. If the rate of return is 5%, then only $952 is needed today to have $1,000 a year from now to pay the cost. People all over the world have a time preference for earlier benefits rather than later benefits.

Discounting procedures in a BCA become more challenging when determining which discount rates should be used in central and sensitivity analyses. This issue encompasses discussions of whether different rates should be used depending on the nature of the impacts. A comprehensive review of these issues regarding current guidelines from the Treasury Board of Canada Secretariat and a set of recommendations for application in RIAs is presented in Boardman et al. (2009).

This handbook emphasizes development and use of monetized summaries of benefits and costs in nominal annual values until the final step when benefits and costs are compared. This approach is an attempt to simplify and add transparency to the analysis during the conversion of benefits and costs to net PVs through discounting. It is also usually beneficial to show a timeline of benefits and costs that are not discounted in addition to the PV results in order to help decision-makers understand the expected timing of the benefits and costs.

With the discounting completed, the net results can be expressed in a number of ways for decision-makers. The comparison usually involves a mix of quantitative and qualitative information. In comparing the discounted benefits to costs, it is the general assumption in RIAs that more of the cost impacts will be adequately quantified and monetized compared to the benefits. This result means that there are a number of general comparative frameworks that can be used to evaluate the net results, including the following:

- ***Benefit-cost analysis:*** As already noted, BCA is the preferred option for evaluating the net impacts of potential policy options. BCA is also the framework that seems to be most consistent with evaluating the Government's commitment to pursuing policy options that provide the greatest overall benefit to Canadians (Government of Canada, 2007). However, BCA results must be carefully interpreted with respect to the quality of the input data and the scope of the benefits and costs that have been monetized compared to those that can only be described qualitatively. Jacobs (2006) recommends the use of soft BCA, which combines a mix of metrics and qualitative information presented systematically across options.

- ***Cost-effectiveness analysis:*** Where there is a decision to intervene at any cost or where there is a dominant benefit that can be quantified in a standard metric, but not dollars, for each policy option, the cost for providing a unit of benefits can be calculated (i.e., divide net PV cost by total discounted benefits). The resulting measure can be used to compare the cost per unit of benefit for different policy options. However, there is no guarantee that a policy option selected on the basis of lowest cost per unit of benefit provided will furnish benefits that outweigh costs or that the correct *scale* of implementation will be selected. At a minimum, however, the RIA should demonstrate that the lowest-cost option is chosen for any given level of benefits (OECD, 2009).

- ***Break-even analysis:*** An analytical option that addresses gaps in the monetization of benefits is the break-even analysis (e.g., OMB, 2003; OECD, 2009, USEPA, 2010). This approach asks what level of monetization would be required for nonmonetized benefits to have monetized benefits exactly offset net PV costs. The results of this analysis are then subject to a general plausibility test regarding what the value of the nonmonetized benefit would have to be for total benefits to equal or exceed the total costs. This could be based on known values of related or similar outcomes, or other common-sense approaches, to assess the plausibility that the benefits could be worth this amount.

The goal of this task is to determine whether there are policy options where the PV of benefits exceeds the PV of costs and, if so, for which option this difference is greatest. Because this task integrates results from several other tasks, one of the main goals is to address the quantitative treatment of time. The other goal, development of approaches for addressing cumulative uncertainty, is significant enough that it is the focus of Chapter 4. The question of who gains and who loses, and how the impacts ripple through the economy in terms of jobs and competitiveness, are addressed in an economic impact analysis.[4]

4. Guidelines and recommendations for conducting economic impact analyses are included in USEPA's existing guidelines for preparing economic analyses (USEPA, 2010; see Chapter 9).

Break-even analysis

When the potential benefits of a proposed initiative are unavailable, but reliable compliance cost data exist, an alternative approach may be to conduct a break-even analysis.[a] The idea behind this approach is to provide decision-makers with *some* information to help them determine a course of action, even when *all* the information cannot be obtained. Although this will not provide a clear indication of the efficiency of the proposed initiative, it represents an additional context that may assist decision-makers in determining next steps.

For example, take the case of regulating the amount of lead in candlewicks.[b] This was a regulatory initiative proposed by Health Canada in 2003 as part of the departmental Lead Risk Reduction Strategy, an initiative conceived to impose regulatory limits on the lead content of consumer products to which children could be exposed. Specifically, this proposed regulatory framework dealt with banning candles with lead-core wicks and lead-core candlewicks in Canada, making it illegal to advertise, sell, or import them in the country. These products were defined as candles and wicks containing a metallic core having more than 0.06% lead by weight in the metal.

For children, the health effect of most concern from lead, and one that is most often valued in the economic literature, is a decrease in intelligence, measured by a 1-point decrement in intelligence quotient (IQ) resulting from the lead exposure. However, due to the limited amount of data and information available, the expected number of potentially avoided cases could not be estimated. Reliable cost data did exist; however, it was estimated that the compliance and regulatory costs over the lifetime of this regulation have a PV of $90,000. Since a typical BCA could not be conducted due to a lack of benefits data, a decision was made to conduct a break-even analysis.

The value of avoiding one case of decreased IQ and associated treatment was determined to be on the order of $6,000 to $10,000.[c] The cost data were then divided by the value of avoiding one adverse health effect to identify the number of avoided cases that would be required to offset the cost. It was determined that this proposed regulation would be efficient as long as, over its lifetime, 9 to 15 cases of lead poisoning are avoided a year ($90,000/$10,000, $90,000/$6,000). This information, provided to decision-makers, would then contribute to a complete picture of the outcomes of the proposed regulatory initiative.

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a. As described by Krutilla and Fisher (1975).
b. See Canada Gazette (2003).
c. All dollar values are in 2000 Canadian dollars.

3.7 Assess Distributional and Equity Issues

Although Government directives highlight the need to evaluate the overall impact of proposed policy options on Canadians (Government of Canada, 2007), decision-makers are also likely to be interested in a range of equity issues associated with how identified benefits and costs are likely to be distributed throughout the Canadian society.

Such assessments draw on the information developed in the benefits and cost assessment tasks that identified which economic sectors or population groups are likely to realize these benefits and costs. In practice, however, distributional analysis is extremely difficult to do, especially for cost impacts. This is because costs are diffused throughout society, rippling through the economy upstream and downstream from the original direct compliance cost. The distribution of benefits is usually easier to assess because benefits apply to more easily identifiable groups.

Arsenic in drinking water case study: Comparison of benefits and costs

When comparing benefits to costs, numerous issues may arise. Ideally, the RIA will clearly portray how benefits compare to costs and reveal the net benefits (i.e., benefits minus costs) for each relevant policy option. It also is useful to consider the "incremental" net benefits of moving from each policy option to the next most stringent alternative. This incremental analysis should examine how the added benefits compare to the added costs when moving from the baseline to the least stringent option, and then again when considering moving from the least stringent option to the alternative that is next most stringent, continuing on to the most stringent alternative.

In developing an RIA and considering what results to portray to decision-makers, it is important to observe how key factors may influence the net benefit (or incremental net benefit) outcomes. For example, using a linear dose-response function in an RIA for arsenic in drinking water will generate benefit estimates that may be 5 to 10 times greater than if a sublinear dose-response function were applied. This, in turn, might well indicate that a more stringent standard is warranted (on a net benefit basis) using the linear model as the basis for the RIA benefits, but a less stringent standard may seem the better choice to maximize net benefits when the sublinear alternative is applied.

If the scientific evidence suggests that both dose-response functions are equally plausible, then both sets of outcomes should be portrayed in the RIA. If one model is more scientifically plausible, then it should serve as the basis for the primary RIA results (with the alternative model possibly used and discussed as part of the sensitivity analysis).

Likewise, it may be useful to disaggregate a national analysis. In the arsenic illustration, for example, the benefit-cost tradeoffs in small communities are very different than those in large communities because the cost of compliance per household is considerably higher in smaller communities. In this situation, it will be useful for the decision-makers to see the benefit-cost results for small systems, along with the results for larger communities or the nation as a whole.

The details of these analyses are likely to be determined based on case-specific information. However, guidelines for these analyses, such as US Executive Order 12898 which addresses environmental justice assessment criteria for US regulations (Executive Order 12898, 1994), typically focus on whether benefits and costs are being disproportionately realized by specific segments of the population. The PRI has developed some information with respect to the evaluation of distributional effects of potential regulatory options (Hoffmann, 2009).

Arsenic in drinking water case study: Distributional and equity issues

As noted in a previous text box, a common aspect of drinking water treatment is that the costs generally exhibit what is referred to as "economies of scale." This means that the cost per gallon of treated drinking water will be much higher in small communities than in larger ones (all else equal). For most arsenic removal processes, this may mean that in a small town where water is supplied to fewer than 100 households, the total annualized costs of arsenic removal may amount to $600 per year for each household. In contrast, costs in larger communities (e.g., serving 50,000 to 100,000 people) are more likely to be on the order of $50 per year for each household.

These differentials in how much cost is borne by different households (e.g., in urban versus rural communities) raise several important equity considerations. For example, is it fair to have families in small rural communities pay more than 10 times as much as their urban counterparts, when both types of households receive the same health risk reductions from the standard? Or, should smaller communities be exempt from the standards because they face relatively high costs? This then raises questions about environmental justice with regard to providing different levels of health protection to different people.

When developing an RIA, managers and analysts must be alert to how these types of ancillary policy issues might emerge and must consider policy instruments that may be suggested as ways to help address these issues. In the arsenic compliance cost situation, the RIA manager should identify the issue for decision-makers and consider suggesting an additional policy instrument in conjunction with the water regulation in order to specifically address the cost inequities. For example, a cost-sharing subsidy plan to assist smaller communities with compliance costs may be an important policy option to be considered in conjunction with the setting of the drinking water standard.

4. Quality Assurance and Uncertainty Assessment

An RIA is a tool that is intended to inform and support decision-makers as they weigh their options and make policy and regulatory decisions. RIAs also inform stakeholders and the general public about the quantitative empirical basis and qualitative factors the Government uses to weigh the policy options and make its decisions. To be effective in these important functions, an RIA must clearly, transparently, and accurately convey critical information with respect to the nature, timing, scope, and magnitude of potential beneficial and adverse impacts associated with each policy option being considered to address the identified problem.

To produce an RIA with these essential characteristics, the RIA system develops and implements robust processes to ensure that the quality and scope of the analyses meet the needs of the decision-makers. Quality control cannot be wholly done by individual RIA analysts, but should be embedded into the standard RIA process.

No matter how carefully an RIA is conducted, uncertainty in the conclusions is inevitable, because forecasts of what to expect in the future are never fully certain. The assessment of uncertainty is best incorporated at every step of the analysis, and key sources of uncertainty identified and communicated to decision-makers. This should be balanced with what the analysts are most confident about. The presentation of uncertainty can be done so that the conclusions of the RIA are not unnecessarily undercut, but are put in a realistic context.

There are many things the RIA team can do to control the quality of the RIA. This includes ensuring that the analyses and portrayal of results accurately reflect the variability in the expected response to the policy options, and the uncertainty in the underlying data and technical analyses and its conclusions. The RIA process is unlike academic research or a focused examination of a specific element of input to the analysis, which may have its own specialized field of study (e.g., toxicology). In the RIA process, the RIA manager must address quality assurance and uncertainty across many different fields of expertise at a level that is relevant for the policy question under consideration. The manager must also consider how uncertainty is addressed at each stage of the analysis and how uncertainty may be compounded when multiple sets of independently produced results are integrated to produce final results. This requires the RIA manager to balance statements about (1) what the RIA team has learned from the body of relevant information and their associated conclusions about net impacts with (2) the need to recognize the sensitivity of the results and conclusions to critical assumptions and the manner in which uncertainty and data limitations have been handled.

To achieve this balance, the RIA manager implements quality assurance processes and has a clear plan for addressing and reflecting uncertainty and variability throughout the analysis and, especially, within the final results. The importance of these efforts is revealed by how guidelines for preparing regulatory analyses and discussions of how to evaluate regulatory options typically address the uncertainty issue as a distinct topic (e.g., OMB, 2003; Government of Canada, 2007; Morgenstern and De Civita, 2008; USEPA, 2010).

This chapter provides a review of some of the methods and tools the RIA manager should consider when addressing quality assurance, transparency, and uncertainty in an RIA.

4.1 Quality Assurance Recommendations

To establish confidence in the regulatory process, the RIA results must incorporate the best available information and be accurate, transparent, and reproducible with the information provided.

Quality assurance in an analysis is often viewed as a process implemented to evaluate final results. However, in the RIA context, quality assurance is more appropriately viewed as an ongoing task that is performed throughout the RIA process. Quality assurance begins at the first step in the RIA development and continues through the checking of results. Quality assurance is only completed after any questions decision-makers may have regarding data, methods, or conclusions are addressed. A key to a quality assurance program's success is to have the RIA manager and team approach the task with an openness and willingness to seek, receive, and incorporate constructive feedback and criticism offered to improve the analysis.

In addition to establishing the proper attitude toward this task, the RIA manager takes a number of steps to ensure the high quality of RIA results. These steps can generally be thought of as efforts undertaken to address the following three questions:

1. ***What?*** The RIA manager ensures that all sources of information used in the RIA are accurately and adequately described. Complete transparency is the guiding principle. This means describing source data at a level of detail that enables another analyst to locate and reasonably retrieve the same information being incorporated in the analyses. For example, this would mean describing which of several possible concentration-response functions was selected for the risk analysis and citing its specific source in the literature. If this task is well addressed, another analyst would be able to replicate the analysis. An important component of these efforts includes documenting the uncertainty associated with the underlying data and information used in the RIA.

2. ***Why?*** Development of an RIA requires making choices with respect to assumptions for an input or selection of a main result from a group of potentially valid options. When such choices are made, the reasoning behind the selection must be presented in order to avoid the impression of arbitrary selections. For example, if one concentration-response function is

used in an RIA when the literature reveals that other forms are also possible, then the RIA should include a clear explanation for why one form is selected and applied rather than the others (and, typically, some level of sensitivity analysis would be suitable to indicate the degree to which this choice impacts the final results). All assumptions should be transparent so that their reasonability can be scrutinized.

3. ***How?*** Development of quantitative and monetized impact estimates requires linking and processing information from a number of disciplines. Typically, this integration includes melding efforts by ecologists and/or human health risk assessors (to identify and quantify risk levels) with methods and perspectives applied by economists (to develop monetary estimates of the values for these impacts). The integration steps taken to develop these estimates must be presented and described with sufficient clarity and transparency so those who are interested in checking and reproducing the results have a reasonable opportunity to do so.

The quality of the RIA's results, and the adequacy of the presentation of the information and processes used to develop those results, is best evaluated by having a separate group of individuals attempt to replicate the original results using the RIA as their guide to data selection and analytical methods. This effort can be undertaken at different levels of intensity. A completely independent development of the results from the initial data is likely to be beyond the scope for most RIAs. However, double-checking the data entry and programming and analysis results is critical to ensuring that the RIA provides accurate information.

A relatively minimal effort would involve using the information and methods as they are presented and described in the RIA to see if the same intermediate and final results can be produced. In contrast, a more comprehensive effort would effectively evaluate the work undertaken in each step of the RIA to assess the reasonableness of the data and methods and to see if there were any critical omissions or biases in the results. Depending on the significance of the RIA effort level and the available resources, this comprehensive review could be delegated to different teams, with each assigned a narrow scope of work consistent with the relevant specific step in the RIA process.

4.2 Expert, Peer, and Public Reviews

An analysis is not complete until it has undergone some measure of scrutiny. Oversight by an impartial third party can help ensure the development of more accurate research, technically correct methodology, and, ultimately, a more representative policy. Three suggested vehicles for accomplishing this are expert, peer, and public reviews, distinct concepts that are addressed in the following sections, including when and where each should be used and what outputs should be expected.

4.2.1 Expert review

Engaging a recognized subject-matter expert to review specific or general components of the analysis is a highly valuable approach to assessing its quality or defensibility. "Expert" may seem to be a subjective term, so it is important to provide a definition of what connotes an expert before attempting to identify potential individuals. A typical characterization of an expert could be:

- Graduate degree (PhD) in relevant field;
- Experience in teaching at the university level;
- Extensive publishing in recognized journals;
- Extensive experience in applying expertise to government policy; and
- Internationally recognized expert in the field.

The identified expert should be an individual external to the RIA team who can provide objective feedback and suggestions for how work could progress to develop a more robust analysis. The expert should be engaged at an early stage in the process; this would allow the individual an opportunity to become familiar with issues and be aware of potential issues upon which to focus. The expert may have important suggestions about data sources and analysis methods for the RIA team. An early draft analysis should be provided for expert review to allow for modifications before a final report is prepared.

After independent experts with no conflicts of interest have been identified, a statement of work (SOW) that clearly outlines the questions to be answered is prepared. The expert review is not to simply seek the individual's general opinion, but to address specific aspects of the study. This is an opportunity to work with a highly respected professional in the field and a good opportunity to develop a project.

As an example of an SOW, Exhibit 4.1 provides an excerpt from an SOW for an expert review conducted for a Government of Canada project that considered air pollution and mortality risk. In this case, the expert review is of a new study being considered for use as a primary source of estimates of economic value for mortality risk reductions. The product of such a review would typically be a note or memorandum that would provide responses to these questions.

4.2.2 Peer review

Distinct from an expert review, a peer review is a less formal review of a study or process. As the name suggests, the peer reviewer is often at the same level as the initiating analyst. This reviewer is often in another department or possibly within the same department but with a different responsibility or focus. This is to provide a broader perspective than might be found within one branch or department and helps ensure attention to a full range of potential effects. A peer review typically has less structure than an expert review, does not involve a distinct list of questions to be

Exhibit 4.1. Example of questions for an expert review SOW.

The expert review (memorandum) will address the following questions:

1. Is the approach employed in this study consistent with principles of economics?
2. Do the study techniques accurately reflect the current literature and state of the art?
3. What other pertinent peer-reviewed literature should be considered?
4. Do the study results represent a significant advance over existing mortality risk valuation?
5. Does the study generate valid valuation estimates that could be readily applied in assessments of the benefits of reduced air pollution?
6. What are the strengths and limitations of the study design for addressing the basic questions related to the use of accident-based VSL estimates for assessing benefits of pollution control?
7. Does the study report present a neutral perspective on the strengths, limitations, biases, and omissions of the survey results? Have the authors appropriately interpreted their findings?
8. In what form would the study results be most appropriately applied in the context of assessing the benefits of reduced air pollution? Please comment on the following options:
    a. Base range of VSL to be used for public policy based entirely on the results of this study
    b. Combine this study's results with existing mortality risk valuation literature.

addressed, seeks a professional opinion of what has been done, and identifies any omissions and recommendations for revisions. The output from a peer review would also be less formal, perhaps in the form of an e-mail from one colleague to another.

While the expert review serves to examine the technical aspects of a study, testing for empirical accuracy and consistency with recognized literature, a peer review considers the clarity of the document and how well it can be utilized for policy purposes.

4.2.3 Public review

An additional effective means of ensuring the quality of RIAs is to provide opportunities for public review and comment on draft versions or preliminary results of the RIA. This additional scrutiny provides an opportunity for additional independent checking of assumptions and the processing of results. In addition, this public review may yield suggestions for additional sources of information or analyses that would highlight important issues associated with the problem or the anticipated impacts from the policy options under consideration.

4.3 Uncertainty Assessment

The term *uncertainty* refers to the degree of confidence in the precision of the data and the results. There will always be uncertainty in the data and underlying studies used in an RIA. Some uncertainty is acceptable if the data are seen as reasonable and have been validated through consultation, peer review, or other methods. Decisions must be made, so it is important to present the significance of the uncertainty that exists in the results and conclusions of an RIA. It is important that decision-makers understand the degree of confidence the analyst has in the RIA results. However, uncertainty should not be emphasized to the point that it undercuts the communication of what is reasonably well known and understood, thus recognizing that public policy is never made on the basis of complete certainty about the future.

4.3.1 Distinguishing variability and uncertainty

It is important to recognize and evaluate variability and uncertainty within an RIA. Each has somewhat different implications for how the empirical analysis may be developed and how the results are portrayed. Hence, it is important to distinguish between the terms *variability* and *uncertainty*. Below, some of the important distinctions and implications are described.

Variability refers to predictable variations in effects or responses that occur for known reasons. For example, there is variability in the amount of water that different individuals drink in a day. This type of variability can be measured and incorporated into a quantitative analysis. *Uncertainty*, on the other hand, refers to what is not known. A brief discussion is provided below to help identify differences between variability and uncertainty that may be important within an RIA context.

Examples of variability include differences in activity patterns across individuals within the impacted population (e.g., amount of time spent outdoors rather than indoors or the amount of tap water ingested daily), as well as variations in the natural characteristics of affected populations (e.g., body weight). These are naturally occurring differences that can be observed or estimated within the applicable populations. Weather patterns (such as the range of wind speed and direction that exist over a year and that impact air pollutant transport) are another example of natural variability.

In the example of variability in activity patterns, the impacted RIA parameter of relevance may be the level of exposure. This is because someone who consumes relatively large amounts of tap water, for example, will receive a relatively high dose for a given concentration level of a compound in the drinking water. In the case of body weight, the RIA parameter of relevance may be the level of toxicity. This is because the risk associated with a given level of chemical exposure (i.e., dose) may be characterized according to units of exposure per kilogram body weight.

In addressing variability within an RIA, there are two basic approaches. One approach is to apply the known (or estimated) distribution of relevant characteristics within the analysis. This typically entails using a distribution that reflects the array of relevant exposure and other characteristics of relevance. This approach lends itself to quantitative methods, such as Monte Carlo analysis.

An alternative approach is to apply standard or mean values for the variable parameters, such as assuming all impacted persons weigh 70 kilograms and ingest 2 litres of tap water daily. This approach is much simpler and can serve as a reasonable approach to a quantitative risk assessment within an RIA insofar as the standard assumptions reflect typical (i.e., central tendency) values rather than values reflecting the tails of the distribution. For example, if 2 litres per day is the 95th percentile value for daily tap water ingestion, use of this value would overstate the baseline risk and the level of risk reduction attained by policy options. The use of an average or median value is much more suitable for an RIA application, because the aim is to provide realistic empirical estimates of the expected response and result of the regulatory or policy options under consideration.

Uncertainty, in contrast to variability, reflects a limited state of knowledge. For example, the state of the science may not be robust enough to clearly indicate whether a linear or sublinear dose-response function better characterizes the link between exposure levels and the risks imposed by a given chemical. In the case of such uncertainty, the RIA manager may need to select one form over others as the primary basis for the empirical risk analysis. In these instances, there should be a sound rationale provided for why one form is selected when others are also reasonably plausible. Better yet, sensitivity analyses generally should be applied to reveal the implications of one choice over another with regard to parameters and functions that are highly uncertain.

4.3.2 Basic elements of uncertainty assessment

The basic elements of an uncertainty assessment are straightforward. They include identifying the limits of the data sources and methods used in the RIA as well as assumptions that were incorporated because of a lack of data, a lack of scientific knowledge (e.g., about which form of concentration-response function is most applicable), or the lack of sufficient time or resources to conduct the research needed to develop the information. The multiple baselines recommended above when the future is highly uncertain are a good example of graphic presentation of uncertainty.

The more important element of an uncertainty assessment, which is often overlooked or may be lost in a complex quantitative approach, is whether the RIA results provide enough information to reasonably recommend a specific option to address the problem at hand. Reasonability, not precision, is the guiding RIA principle with respect to addressing uncertainty. This decision-oriented view is important because it focuses on the RIA as a decision support tool and recognizes that there is always uncertainty in the RIA and decision-making process. This view also alludes to one of the important corollaries in any uncertainty assessment, namely, ensuring you understand how large the

consequences could be if the "wrong" (i.e., suboptimal) decision is made based on the results of the RIA.

An important aspect of the decision-oriented view is the recognition that there is a chance of making the wrong decision whether the decision is to take action or not take action. Take, for example, a case where cost estimates are high to reduce exposure to a chemical in drinking water and health benefits are uncertain because the health risk at low levels of exposure is uncertain. If the decision is made to take no action due to the uncertain benefits, there is a chance that the health risk is actually high and the public suffers the consequences of continued exposure to this chemical. On the other hand, if the decision is made to require removal of this chemical and it turns out that the health risk is actually quite low, then the costs (ultimately borne by the public) are imposed and no significant health benefit is gained. Couching the uncertainty in these terms can help decision-makers understand the implications in either case if the decision turns out to have been "wrong."

In developing an uncertainty assessment, it is also important to recognize that it may be necessary to evaluate parts of the RIA uncertainty qualitatively while other parts may lend themselves to a more quantitative assessment.

4.3.3 Qualitative uncertainty assessments

Qualitative uncertainty assessments are limited to a discussion of how potential impacts could be affected by varying key assumptions or estimates. Typically, this uncertainty assessment focuses on the impacts associated with qualitative data (i.e., inputs developed more from professional judgment and experience than quantitative assessments). These discussions should focus on evaluating the direction of the potential bias in current results should these assumptions be changed.

Such qualitative uncertainty assessments provide two main benefits. First, the assessment ensures that the consequences of uncertainty are evaluated for all elements of the RIA and not limited solely to quantitative inputs. Second, these assessments are likely to draw attention to critical information with respect to shaping the RIA's conclusions. By identifying these inputs, additional attention can be devoted to considering the potential implications if alternative assumptions or inputs are incorporated.

4.3.4 Quantitative uncertainty assessments

Quantitative uncertainty assessments focus on evaluating the impact of uncertainty in the RIA's data inputs and how this is compounded or mitigated by the methods used in the RIA.

A number of different methods can be used to complete quantitative uncertainty assessments. For example, Monte Carlo analyses can be used to simultaneously account for the impact of uncertainty across a number of inputs. In contrast, more focused sensitivity analyses can be used to examine the impact on the results of uncertainty in a single or limited set of key inputs. Expert elicitation (e.g., Delphi methods) approaches can also be used to guide the uncertainty assessment in a quantitative approach by providing distributions for input values based on professional judgment. These quantitative options are described in various guidance documents (e.g., OMB, 2003; USEPA, 2010). However, the selection of a particular method will likely require consideration of the nature of the available information and resources along with a ranking of the specific areas of interest to be addressed.

The strengths of quantitative uncertainty assessments come from their ability to specifically answer questions that are likely of interest to the decision-makers (and the stakeholders) such as:

- What is the range of possible benefits?
- How likely is it that an extreme value, or any given range of values, could result given the available information?
- How sensitive are the "best" results to the values selected or assumed for "critical" inputs?

As with the qualitative uncertainty assessments, implementing these quantitative approaches also should improve the confidence in the decision-making process by conveying a sense that the RIA team is not trying to ignore or downplay information that could affect the nature or interpretation of the results. Transparency builds credibility because key assumptions are explained and highlighted rather than hidden.

Perhaps the most important potential weakness of quantitative uncertainty assessment techniques is their emphasis on numerical inputs and results. These techniques address only the variance, either as reported or calculated from studies and datasets or assumed by analysts, in the data and results. In some cases, this may not be the only or even the most important component of the uncertainty in the data. Specifically, most quantitative techniques effectively provide equal status to all data in terms of the quality of the results by assuming that the numbers available are valid for use. This approach therefore cannot take into account issues such as model specification error or the validity of a technique used to develop an estimate. For example, fixed effects models can be used to synthesize concentration-response results from a number of studies, but there is not any way to initially differentiate the quality of the studies if they meet some minimal acceptance criteria. After that point, the weighting of study results is driven by the statistical variance in the available estimates.

Another important weakness of quantitative uncertainty assessments is the likelihood that applying the techniques with multiple uncertain inputs will effectively explode the range of results. This result should be anticipated because in most RIAs there will be at least one step where intermediate results

are multiplied to produce either a final result or new input for another analytical step. The issue is not that it is an inappropriate treatment of the uncertainty; rather, it is that the results can be difficult to express to decision-makers and other nontechnical audiences. For example, although a Monte Carlo analysis may produce a wide range of possible results, the distribution of results will help draw attention to a range of more plausible outcomes. The range of possible outcomes may be wide, but the probabilities of the extremes occurring in either direction are usually quite low. Decision-makers need to understand both the ranges and the likelihoods of possible outcomes. This is ultimately part of the art of developing an informative RIA and communicating the results in a meaningful manner. The struggle is typically worth the price in terms of the additional transparency and assistance to decision-makers.

5. Communicating Results and Conclusions

Communication of the RIA results is important in providing an analysis that is useful for decision-makers and other interested parties who will use the RIA to make choices about the future of Canada. Even a good technical analysis is of little use if it is not communicated effectively to a nontechnical audience. At the same time, the technical detail on data sources and analysis methods must be thoroughly documented to ensure that the RIA is transparent. These dual goals are usually accomplished by preparing a nontechnical but thorough summary and a technical report that provides all the details.

5.1 The RIA Technical Report

The RIA technical report documents all the data sources, analysis methods, underlying scientific study results, key assumptions, and any sensitivity or uncertainty analyses that have potentially important implications for the conclusions of the RIA. The guiding principles of transparency and replicability apply here in that there should be sufficient information provided that another analyst, with the appropriate technical background, could replicate the analysis.

Even though the technical report is intended for a technical audience, the readers are likely to have varied backgrounds and training. Consequently, it is best to avoid unnecessary technical jargon and to define terms and acronyms that may be common in one field but not necessarily understood in other fields. The RIA is a multidisciplinary effort that will be read by a multidisciplinary audience. This does not mean that the fundamentals of each technical field must be explained, but it is appropriate to include references for basic techniques and approaches used in the analysis.

Exhibit 5.1 shows a typical table of contents for an RIA technical report. Of course, each table of contents will vary depending on the nature of the problem, but most RIA reports will include the major sections shown in this exhibit. A more detailed example of the potential structure and contents for an RIA technical report is provided in Attachment 1.

The Executive Summary provides a nontechnical overview of the problem, the policy options considered, the impact analysis approach and results, and the conclusions. It is important to include key assumptions, uncertainties, and omissions to the extent that these are significant to the conclusions of the analysis.

The background on the problem describes what is understood about the significance, extent, and causes of the health, safety, or environmental problem being addressed. This includes information on vulnerable populations and resources.

Exhibit 5.1. Typical table of contents for an RIA technical report.

1. Executive summary
2. Background on the health, safety, or environmental problem
3. Regulatory or policy options selected for assessment
4. Analysis baseline
5. Response to policy options
6. Cost assessment
7. Benefit assessment
8. Comparison of benefits and costs
9. Conclusions

The regulatory or policy options are selected based on legal and technical considerations, as well as effectiveness in alleviating the identified problem. Considering a range of options that are more or less intrusive to society affords the opportunity to find an approach that is effective at reducing the problem (i.e., generating benefits) while minimizing the cost and intrusion to society.

The analysis baseline describes what is expected to occur if no action is taken. This sets parameters that are used in the cost and benefit assessments and is the benchmark against which the cost and benefits of the policy options are calculated.

The response to the policy options includes any analysis of how households or businesses are expected to respond. This may be very straightforward for strict regulations or bans of products.

However, in the case of market incentives or educational guidelines, predicting the response may require technical analysis.

The cost assessment includes subsections on how the costs are likely to be distributed among industries and/or households. Indirect cost effects such as employment losses and key assumptions and uncertainties are also included.

The benefits assessment includes the exposure and risk assessment and the economic valuation of changes in health, safety risks, or environmental effects. The distribution of benefits among different population groups and/or geographic areas and key assumptions and uncertainties are also included.

The comparison of benefits and costs includes summaries of unquantified costs and benefits as well as those that were quantified. Total benefits and costs should be shown as well as net benefits. If key uncertainties have been identified, then results may be shown using alternative assumptions.

Calculations of incremental costs and benefits of increasingly stringent instruments or standards are also useful for decision-makers. Timelines showing benefit and costs over time should be included as well as PV calculations.

The conclusions section incorporates the analysts' assessment of the confidence in the results as well as the magnitude of the results. It is beneficial to articulate needs for future research to reduce uncertainties (e.g., data collection such as monitoring that supports enforcement, performance assessment, and ongoing research) in this section.

5.2 Response to Comments

An important step in the process of finalizing an RIA is to present the draft report and findings and request comments from all interested parties. This may sometimes be part of the formal regulatory development process.

Comments on a draft RIA can be very helpful in identifying areas where the presentation needs to be clarified or where limitations of the analysis need to be acknowledged. Sometimes important issues are raised by reviewers that can be addressed with further analysis. However, often there are questions that cannot be addressed given available data and time. Such limitations can be acknowledged in the final report.

It is also important for decision-makers to know the concerns and comments of various stakeholders who would be affected by the policy actions. The RIA team summarizes comments received and responses made in the analyses and conclusions as part of the final reporting on the RIA.

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Regulatory Impact Analysis Blueprints for Improving the Quality of Regulatory Decision Making[1,2]

Table of Contents

1. This document was prepared by Dr. Richard B. Belzer, Regulatory Checkbook (Mt. Vernon, VA USA), on contract to the Policy Research Initiative (PRI) and should not be construed in any way as reflecting its views.

2. Revised August 15, 2010.

1.0 Summary

This report sets out a framework for improving the quality of regulatory impact analysis through the use of Regulatory Impact Analysis (RIA) Blueprints. An architectural blueprint provides the detailed plan for constructing a house. It provides a guide for the building contractors and craftsmen to follow. An RIA Blueprint provides departmental officials and analysts a guide for constructing an informative RIA. By following the RIA Blueprint, analysts can be more confident of providing the information officials need to make well-informed decisions. By contributing to and supporting the Blueprint process, department officials can obtain better quality information at an earlier date.

The RIA Blueprint framework utilizes existing RIA guidance and adheres to established regulatory development processes. Departments and agencies differ with respect to the nature and scope of their regulatory activities; hence, departments and agencies should adapt the RIA Blueprint framework to their specific needs.

A RIA Blueprint makes clear at the beginning of the regulatory development process how various analytic elements are prepared, reviewed, and used for decision making. Most elements are normal parts of the process, but the Blueprint provides a scheme for organizing their production and securing effective consultation in a timely and better-organized fashion. Where a component is new, it is a "best practices" technique for ensuring quality and compatibility with departmental objectives.

2.0 RIA Staging

Most regulatory development schemes envision an iterative process in which regulatory impact analysis begins at an early stage to determine where approval processes can be streamlined and where resources should be focused. Beginning the analysis process early establishes and sustains an active and constructive dialogue between analysts and officials; between the department and other Government departments and agencies; and between the Government and the public. The RIA Blueprint provides a structured format for organizing these relationships and ensuring that they stay on task and on time.

The Blueprint includes three main stages, each of which includes provisions for consultation and information quality review. A fourth stage—Ex Post Review whose purpose is to assess the accuracy of the RIA—is highly desirable but optional.

2.1. Pre-Analysis Stage

Certain tasks should be performed before work begins on producing the RIA. Effort expended early reduces the risk of future controversy and the potential for remediation, which is expensive to the department or agency in terms of both expenditure and delay.

Although the Pre-Analysis Stage is dominated by data collection, it also includes significant analytic tasks whose purpose is to identify information gaps, determining which gaps if filled could materially affect decision-making, and conduct value of information (VOI) analyses to rank the relative contributions research can make to aid decision-making.

Activities in the Pre-Analysis Stage are discussed below.

2.2. Proposed Regulatory Stage

The major analytic effort—estimating social costs, social benefits, and other impacts—occurs in this stage. Ensuring adherence to established norms is a key objective, which is made easier by appropriate commitment to the Pre-Analysis Stage. Many RIA errors result from proceeding too quickly to the Proposed Regulatory Stage.

At the end of this Stage, decision makers must make tentative choices concerning which suite of regulatory and non-regulatory alternatives they propose to adopt. It is very helpful if they clearly link their proposed decision to elements in the RIA. By doing so, they enable consultation to focus on questions that might be amenable to analytic resolution. If they propose tentative decisions that do not appear to have any linkage to the RIA, however, they may unintentionally signal to the public and affected parties that the RIA did not contribute meaningfully to the proposed decision.

2.3. Final Regulatory Stage

Formal consultation on the proposed regulatory action can yield significant insight, particularly about impacts that had not been previously identified or fully appreciated. Sometimes, however, consultation will show that the draft RIA displayed an unwarranted level of concern about certain impacts. Analysts should expect to make adjustments as a result of consultation. It is unrealistic to expect the RIA to "get it right" the first time.

After these adjustments have been completed, the RIA should return to the department or agency decision maker with a transparent and reproducible summary explaining how the analysis changed as a result of consultation. The summary should highlight those each material analytic change that may be significant enough to justify a different decision than the one proposed.

2.4. Epilogue: The Post-Regulatory Stage

The formal RIA process ends with promulgation of a final regulation. However, much can be learned by conducting an ex post review to ascertain how accurately the RIA predicted actual impacts. Inevitably, predictive accuracy will vary. Ex post review is the best way to ascertain which analytic tools worked well and which need improvement.

Ex post review has additional benefits in any case where a department or agency reasonably expects that a regulatory action will need to be followed by one or more future actions. Indeed, regulatory practice worldwide suggests that this is likely even when department or agency officials are convinced that a particular regulation has finally "solved" the problem.

3.0 Division of Analytical Labour

A well-conducted RIA relies on the contributions of several different groups of analysts, each with different types of education and expertise. Some activities cross group boundaries, so it is important to have systems in place that encourage multi-disciplinary thinking and collaboration, and to avoid the creation of analytical "silos".

3.1. The Science and Technology Team (S&T)

The Science and Technology Team (S&T) are responsible for developing most of the technical inputs on which the RIA relies. These include, for example, the preparation of a quantitative risk assessment (RA) in cases where the problem to be addressed involves human health, safety, environmental, or financial risk. Integral to risk assessment is the identification, estimation, and presentation of uncertainties.

The information available to S&T inevitably will be limited, so vital "state of the art" tasks are the determination of information gaps and estimation of the value of obtaining new information. Value of information (VOI) analysis has been part of the regulatory analyst's toolbox for decades,[1] but it tends not to be practiced as often as it should.

All scientific and technical information must be carefully reviewed to ensure that it meets information quality standards appropriate to the decision. These standards include such criteria as objectivity and practical utility for decision-making. When an RIA relies on information that is not objective, departmental officials' ability to trust the results is undermined. Similarly, not all information has practical utility for decision-making. Practical utility will be context dependent.

3.2. The Economics Team (Econ)

The principal tasks of the Economics Team (Econ) are to identify a broad range of alternatives to be considered in the RIA and conduct an objective cost-benefit analysis (CBA) of each alternative. It is generally accepted that the benefit side of the CBA will rely on the risk assessment prepared by S&T. However, the ubiquity of uncertainty will result in risk assessment being relevant to the cost side as well.

As in the case of other scientific and technical information, the Econ Team will face limited data and thus need to identify information gaps and conduct VOI analysis of prospective data acquisitions. Similarly, economic information must be reviewed to ensure that it meets information quality standards appropriate to the decision.

3.3. The International Trade and Harmonization Team (IT&H)

Canadian regulatory practice is sensitive to the practices of other nations and potential effects on international trade. The International Trade and Harmonization Team (IT&H) are responsible for learning how similar regulatory problems are addressed elsewhere and evaluating their propriety and applicability to Canada.

Information gaps will arise here, as well, and VOI analysis can be used to estimate the value to decision-makers of conducting research to fill these gaps. In addition, information quality assurance also will be important. For example, nations vary not just with respect to the regulatory standards they set, but also with respect to how they enforce these standards. For this reason, it is important to learn about both, to assess levels of compliance, and to be cognizant of the potential for unintended consequences. Every nation that already has regulatory standards relevant to a proposed decision in Canada is a partially controlled experiment from which Canadian regulators can learn at relatively little cost.

3.4. The Law and Administrative Practice Team (L&AP)

The Law and Administrative Practice (L&AP) Team is responsible for ensuring that regulatory actions stay within the bounds of statute, and that the regulatory process actually followed adheres to established regulations and procedures. This includes such tasks as identifying consultative parties and ensuring that they participate appropriately, at each relevant stage of the process that yields the RIA.

3.5. Overlapping Contributions

It is incorrect to interpret each of the four Teams as operating on its own, as if its work can be contained within a "silo". The purpose of teaming is to establish accountability, not to create fiefdoms or barriers to collaboration. To reduce these problems, work under the RIA Blueprint should be organized so that every Team is able to participate effectively on each of the other Teams. Effective participation goes beyond merely being aware of, or even being consulted about, the work products of other Teams. It means being able to ensure that inputs received from other Teams meet analytic requirements and that outputs from other Teams appropriately utilize the information provided to them.

4.0 The Pre-Analysis Stage

The Pre-Analysis Stage is dominated by the rigorous identification of the problem to be solved and the collection of available data. State-of-the-art practice is to evaluate the quality of available data, first to establish e applicable quality metrics and then to determine which data sets satisfy them. Data that do not meet minimum quality standards should be excluded.

Analysts can be resistant to discarding data in the belief that all data have value. However, early exclusion of low-quality information is often essential to prevent an RIA from becoming captive to prejudgment and prone to error. A high-quality RIA can never be produced from low-quality data. Indicators of low quality include such phenomena as insufficient precision for decision-making,

discarded uncertainty, poor or unknown sample representativeness, and bias, particularly if the magnitude of bias cannot be ascertained.

After full elaboration of the available data, information gaps will become apparent. These gaps do not necessarily signal that there is insufficient information to make decisions; rather, they indicate that the outcomes of decisions will be more uncertain than decision-makers want them to be. Each information gap can be evaluated to discern whether it is feasible to fill it not all unknowns can be answered at any price), and if so, how much value the new data have for decision-making (new data that are inexpensive to obtain have little or no value if they cannot change the regulatory decision).

VOI analysis is the state-of-the-art practice used for determining whether to invest in acquiring new information prior to decision-making (and, in this case, prior to the preparation of an RIA that would inform decision-making). Whereas information quality assurance is a relatively new practice, VOI analysis has been part of policy analysis for decades,[1] though often not implemented. The typical reason given for foregoing VOI analysis is the decision context lacks sufficient time to conduct the research that VOI analysis indicates would be beneficial. When this is true, VOI analysis does not pass the VOI analysis test. However, the belief that there is insufficient time often is mistaken. In any case, the RIA Blueprint focuses attention on the Pre-Analysis Stage so that limited time will rarely be a legitimate reason not to conduct VOI analysis.

The subsections below identify Pre-Analysis Stage tasks for which each Team is primarily responsible.

4.1. Shared or Common Tasks

4.1.1. Describe the types of information needed to produce the RIA, including scientific, technical, statistical, and economic data

Several Pre-Analysis Stage tasks are common to multiple teams, or they require joint contributions to complete. For example, no RIA can be performed without first collecting and evaluating available information. Similarly, not all information collected has practical utility for decision-making.

At the earliest stages, each Team should assemble lists of the types of information needed to perform the RIA. This is different than assembling the information available. Very often (if not always), there will be information that is needed which is not available, and information that is available which is not needed.

4.1.2. Review the scientific, technical and economic literature relevant to the issue, including data needed to complete the RIA

The next task is to use these informational "wish lists" lists to determine whether relevant information already exists that can be used to inform an RIA. Existing information can be subjected to triage and assigned into one of three categories: (a) information that is essential for the RIA, (b) information that appears to have some potential value, and (c) information that has no discernible practical utility for the task. This triage helps overcome the analyst's natural desire to find a use for everything and the temptation to find a way to use information that has recognized high value but was collected for a different purpose. In a similar vein, analysts often have difficulty applying the principle of sunk costs, and are thus resistant to discarding information that was obtained at high cost but which has little or no practical value for the purpose at hand.

4.1.3. Identify information gaps that could be supplanted by knowledge prior to decision-making

Inevitably, the review and triage of existing information will disclose important knowledge gaps. Thus, the major product of the review and triage is the identification of these information gaps and a preliminary assessment of the value of information that, if obtained, could have a material effect on the analysis of an alternative or a decision maker's rational choice.

A simple strategy for making this preliminary assessment is to imagine that the missing information could be obtained at no cost and ask a pair of questions:

- "If we had this information today, what effect could it have on the analysis?"
- "If we had this information today, could it change the preferred rank order of alternatives taking into account the decision-maker's stated values and preferences for trading off competing policy objectives?"

This approach treats the missing information as a free good, and thus it establishes the most generous possible threshold for deciding *not* to obtain it. If the answer to either question is "yes", then it may be worth the expenditure of effort to obtain the missing information. But if the answer to either question is "no", then there is no practical value for decision making in closing the information gap.[3]

3. An exception might be made for information that cannot be used in decision-making because of a statutory constraint, but the collection of the information and its subsequent inclusion in the RIA can put a shadow price on the constraint. Parliament could find very useful the quantification of this shadow price, and consider whether to relax the statutory constraint.

4.1.4. Perform value-of-information analyses of additional data

There are well-established principles and methods for determining the value of information (VOI) for which the answer to one of these questions is "yes" [1,2,3]. Armed with this information, an analyst can determine how much it is worth spending to obtain new information that would result in a change in the decision maker's choice of intervention alternative. If actually obtaining this information is more costly than this figure, then there is no value to the decision-maker in bearing the cost of obtaining it. If it is less costly, however, then the decision-maker is better off if the information is first obtained.[4]

The use of VOI methods enables the search for additional data to be focused on only those research activities that add real value. It also provides a rational basis for declining to conduct additional research. For the analyst pressed for time, VOI methods provide a relatively simple (and very inexpensive) tool for determining whether it is worth spending scarce resources to resolve specific uncertainties.

VOI methods are essential for an ethical use of the precautionary principle, which specifically invites risk-averse decision-making in the absence of reasonable certainty about (usually) the likelihood and severity of adverse effects. The stated justification for precaution comes with a commitment to revisit a decision as new information becomes available. But if no revisitation will occur in fact, then there is no decision-making benefit to gaining additional knowledge and the initial precautionary decision will have been made on false pretenses.

4.2. S&T Team Tasks

4.2.1. Review relevant evidence-based assessments relevant to the scope, scale, and magnitude of the problem to be addressed

It is an exceedingly rare public policy problem that no one has ever experienced before. Learning how the problem previously arose, and what was done about it, can provide crucial insight of two forms. First, it can provide ideas concerning potential regulatory and non-regulatory interventions that have been considered (or attempted) in the past. Second, if the previous attempt failed, learning about it can help the department avoid making the same mistake. Each of these activities should be scheduled early in the development of an RIA.

Frequently there is a great deal of available information that can be used to understand a potential public policy problem's nature, scope, and magnitude, and learn about the array of possible available remedies, by examining what others have experienced and done. This is not the same thing as merely accepting at face value RIAs that were produced, say, by other Governments. It is easy to

4. Slightly more complex calculations are required if the information imperfectly addresses the question at hand.

turn such RIAs into defaults or templates without giving appropriate consideration to crucial legal, cultural, or factual differences.

Ex post analyses (see Sec. 2.4) are especially useful for gaining the broadest possible perspective about a public policy problem. Such program evaluations can be revealing about which approaches have worked in the past and which have not.

4.2.2. Describe the scientific and empirical evidence, uncertainties, ethical considerations, and public views of the public policy issue

Established RIA practice calls for assembling scientific and empirical evidence concerning the problem to be solved, and supplanting it with information about uncertainties, ethical considerations, and public attitudes. This is especially important if the decision-maker is instructed by statute to rely on precautionary approaches when crucial evidence is lacking and there is a risk of serious or irreversible harm. Even so, the policy judgments necessary for precautionary decision-making can be informed by even rudimentary regulatory impact analysis.

The RIA should fully account for what is known as well as what is unknown. Precaution may be necessary when crucial information is lacking, and for that reason, the RIA Blueprint includes VOI analysis, a tool drawn from decision theory that is neutral with respect to risk aversion, which can be used for estimating the value of resolving uncertainty through the production of new evidence.

4.2.2.1 Scientific and empirical evidence

All available scientific and empirical evidence should be gathered. This step is prerequisite to both conventional and precautionary decision- making. It cannot be said that precautionary decision-making is justified because crucial evidence is lacking if effort is not expended first to ascertain what is known.

Scientific evidence is generally limited to forms of knowledge that are capable of being refuted by the application of the scientific method. Information that is not capable of being refuted belongs in the category of beliefs, values, and perhaps ethics, none of which can be refuted.

Empirical evidence consists of data obtained from the observation of a physical, chemical, biological or economic system. Data obtained from observation is not fixed, however, but always subject to measurement error and potential bias.

Uncertainty is the absence of full knowledge and can take several different forms [4], including:

- Random error and statistical variation
- Systematic error and subjective judgment
- Linguistic imprecision

- Variability
- Randomness and unpredictability
- Disagreement
- Approximations[5]

Strictly speaking, like market failure, uncertainty is always present and never can be eliminated. Thus, a proper understanding of the purpose of precautionary decision-making is to accommodate situations in which the consequences of waiting until significant new knowledge is obtained are greater than the benefits of learning.

4.2.2.2 Risk assessments and other secondary, synthetic works

Many RIAs will require important technical inputs, such as scientific studies and synthetic risk assessments. Each can be valuable provided that the resource is genuinely evidence-based, relevant to the analytic task at hand, and subject to refutation through the application of the scientific method. For example, the estimation of human health risks often is predicated on high-dose testing in laboratory animals. The value of these experiments is not obvious. Results have to be converted across species and extrapolated to the low doses characteristic of human exposure. The conventional practice involves making assumptions that generally are not testable. Best practice in cost-benefit analysis (CBA) calls for at least performing a sensitivity analysis or uncertainty analysis when results hinge on untestable assumptions.

The use of risk assessments of this type also is problematic for the RIA itself. CBA requires the use of unbiased inputs, which requires that the objectivity of a risk assessment be verified before use. Similar technical problems bedevil the estimation of social costs and benefits of alternatives that are expressly precautionary.

The reliance on secondary and synthetic works also can result in bias because the preparation of any such product typically requires that subjective choices be made concerning what weights to explicitly or implicitly assign to information of various forms and types. Evidence that is excluded, for example, implicitly receives a zero weight. Evidence that is essential for the support of a particular decision implicitly receives 100% of the weight of evidence.

So-called "weight of evidence" (WoE) methods typically are not transparent enough to be considered science, even when the subjects of the weighting are scientific in nature. This is because of the refutability requirement noted above. When weights are not disclosed, it is impossible to refute an inference or conclusion derived from WoE schemes. When weights are disclosed, it then becomes apparent that the weights themselves are actually policy judgments. The RIA Blueprint provides for the explicit use of a decision support tool ("multi-attribute decision analysis") in which

5. To this list can be added uncertainty about uncertainty—that is, a lack of certainty about what is *not* known.

department officials specify the value judgments the want to guide decision-making. This has the dual utility of circumscribing the function of analysts to their proper roles (so that analysts are neither tempted to nor compelled by circumstance to make policy) and ensuring transparency in the weighting of competing policy objectives.

4.3. Econ Team Tasks

4.3.1. Rigorously define the policy objective expected to be achieved

Clarity about the public policy objective is essential for ranking alternatives with respect to their effectiveness. Alternatives that do not (or cannot) substantially achieve the policy objective have little to recommend them irrespective of other regulatory impacts.

Sometimes, the purpose of regulation can be reduced to a single objective. Far more typically, departmental officials are directed by statute to weight several factors in their determinations but not instructed as to what weights to use. This trade-off across objectives unavoidable and invites a loss of clarity in the RIA. Multi-attribute decision analysis provides a clear solution to this conundrum.

4.3.2. Analyze the public policy issue, its causes, and context, including its urgency and immediate and long-term impacts

This task is one that should occur at the very beginning of the regulatory process. An important part of it involves identifying the "baseline" for the RIA—the conditions expected to exist if no action is taken. Careful attention to ascertaining an unbiased characterization of the baseline is a prerequisite for developing credible estimates of social benefits, social costs, and other impacts of interest.

4.3.2.1 What is the public policy issue?

Generally, issues do not become matters for *public policy* by accident. Clear thinking is needed to frame the problem correctly and completely. A well-posed problem may have answers, but a poorly posed problem does not.

Perspectives often differ concerning the definition of a problem. For example, from the perspective of farmers, pesticides are intended to increase net income by protecting crops from insect infestation and disease. From consumers' perspective, however, the problem consists of weighing chemical risks against the benefits of food that is less expensive and has higher quality. Environmentalists worry about risks to endangered species and habitats resulting from unintended consequences. Each of these perspectives is a valid way to conceptualize "the problem". Cost-benefit analysis is the tool used to count up all the social costs and social benefits exactly one time so that decision-makers can compare alternatives and make informed decisions that take account of

every perspective. Where policy objectives conflict, multi-attribute decision analysis captures the exchange rate for trade-offs across objectives.

4.3.2.2 What are the causes of the problem?

A common justification for government intervention, whether through regulatory or non-regulatory means, is the existence of "market failure":

> In a perfectly competitive market, the outputs of the goods and services of the economy and the set of prices for these outputs are determined in the marketplace in accordance with consumers' preferences and incomes, as well as producers' minimization of cost for a given output. In this market, the outcome is efficient and social welfare is maximized. However, in some situations, markets fail to achieve such efficient outcomes. *Market failure* refers to situations in which the conditions required to achieve the market-efficient outcome are not present [5, p. 2].

Strictly speaking, departures from perfect competition are always present. Therefore, it is important not to rely reflexively on the economic definition or simply assert the existence of market failure as an all-purpose justification for regulatory action. Analysts should carefully examine a market failure's nature (e.g., is it a characteristic feature of human decision-making or an isolated phenomenon?), scope (e.g., is it local, regional, national or international?), and magnitude (e.g., it is a nuisance to, a hindrance on, or a constraint limiting social welfare?).

Externalities are the chief example of market failure, but other phenomena also may be relevant. For example, efficient prices and resource allocation may be lacking because property rights do not exist or are ambiguous. Common property resources have special problems in this regard, and the creation of property rights may be a reasonable alternative to consider and analyze.

On occasion, an underlying cause of the problem may be previous Government action. For example, regulated entities or program beneficiaries (or both) may have responded to a previous Government action in unexpected and undesirable ways.

Discerning when this is the case is an important discipline in regulatory impact analysis—both at the Pre-Analysis Stage, when attention is focused on developing a clear description of a problem, and during the examination of alternatives in the Proposed Regulatory and Final Regulatory Stages, some of which may have unintended consequences that can be avoided if predicted in advance. For these reasons, it is a best practice not to assume that markets are imperfect but government is not, but instead to examine the outcomes of each scenario under realistic conditions [6].

4.3.2.3 What is the context in which the problem presents itself?

The context in which a public policy problem arises may matter a great deal. "Context" is shorthand for the collection of beliefs, assumptions, definitions, and values that lie behind Government action. Clarity about context reduces uncertainty within the department or agency, across the Government, and among interested and affected members of the public concerning what each party understands and considers important. It is especially valuable to decision-makers to be able to know "what might otherwise be buried in the analyst's mind" [1, p. 20].

4.3.2.4 How urgent is it to respond to the problem?

Some problems require immediate action, and regulations to deal with them may be exempt from the RIA requirement. But a problem that may look urgent when first presented often turns out to be less serious after a bit of reflection. Similarly, regulatory responses to seemingly urgent problems often have unexpected consequences that even a limited RIA would have identified.

4.4. IT&H Team Tasks

At the Pre-Analysis Stage, the IT&H Team is primarily responsible for surveying the extent to which the problem to be addressed has arisen in other jurisdictions and, if so, what they have done about it.

4.4.1. Has the problem to be addressed arisen in other jurisdictions?

The main Pre-Analysis stage task for the IT&H Team is to collect information about whether the problem to be addressed has been manifest in other jurisdictions.

4.4.2. If so, what did they do about it?

If the problem to be addressed did arise in another jurisdiction, learning what they did about it can provide great insight to departmental decision-makers. This is not to say that they must (or should) mimic what another jurisdiction did, though they might want to do so to achieve harmonization.

4.4.3. What were the consequences?

For each jurisdiction that has acted to address the same problem, learning about the consequences also gives departmental decision-makers targeted insights otherwise not available to them. Some of this information can be gleaned from government documents, but the Team also should carefully review the comments provided by consultative parties and published literature.

All information must be vetted for accuracy and completeness through consultation.

4.5. L&AP Team Tasks

4.5.1. What does the enabling legislation or other law authorize the department or agency to do?

Departments and agencies may not act outside the scope of their legislative authorities, of course. Sometimes, however, it can be desirable and informative for an RIA to include alternatives that are not permitted by law. These alternatives can highlight, and put a shadow price on, a department or agency's legislative constraints. Given this information, Parliament might prefer to modify the law to authorize an alternative that the department or agency is currently is prohibited from adopting. RIAs thus can provide a welcome body of insight that can guide legislation as well as examine alternative ways to implement it.

This part of the legal analysis component of the RIA should be performed very early in the regulatory process.

4.5.2. Is the regulatory objective within the scope of the department's statutory authority?

Typically this condition is assumed to be satisfied, but sometimes it is not clear which Government department or agency has practical jurisdiction because more than one department has a valid claim. Alternatively, the actions of one department to address an issue can result in adverse effects on another department's mission.

Where conflicts across departments can be identified early, procedures can be adopted to resolve interdepartmental issues amicably. Sometimes, inter-departmental collaboration can yield the most effective remedies.

4.5.3. Prepare a reasonably comprehensive list of interested and affected parties for consultation, and a plan for ensuring that consultation is effective

Consultation is an integral part of the regulatory process. The RIA Blueprint incorporates consultation at each Stage of the RIA. Consultation may be most critical at the Pre-regulatory Stage, because errors made early in the process are difficult and expensive to repair. However, conventional practice appears to delay consultation until the Proposed Regulatory Stage. At this point, the RIA is largely completed. Errors cannot be fixed except at significant expense in departmental resources and delay.

4.5.4. Organize and implement pre-analysis consultation

As early as possible, affected and interested parties (and the public) should be identified and, in accordance with a well-crafted plan, brought into each aspect of the RIA process. Affected and interested parties may be aware of data and previously conducted research that are unfamiliar to

departmental analysts. Affected parties may possess, or have the ability to collect, data that would yield a superior RIA.

5.0 Proposed Regulatory Stage

5.1. Shared or Common Tasks

Each of the shared or common tasks listed in the Pre-Analysis Stage (see Sec. 4.1) may recur in the Proposed Regulatory Stage. For example, information that has value but was not available at the Pre-Analysis Stage might now be had at modest or no cost. Technical literatures change over time, so valuable peer-reviewed studies might be available that could not be obtained earlier. Information gaps may be somewhat different, and VOI analyses that previously argued against collecting new data may reverse direction once they are updated.

For these reasons, each of the tasks listed in Sec. 4.1 also should be conducted at he Proposed Regulatory Stage. Typically, this does not involve a major new effort but rather a fine-tuning of previous work.

5.2. S&T Team Tasks

Tasks performed at the Pre-Analysis Stage must be reviewed and revised, but only as needed to account for new information. This includes:

5.2.1. Review relevant evidence-based assessments relevant to the scope, scale, and magnitude of the problem to be addressed

5.2.2. Describe the scientific and empirical evidence, uncertainties, ethical considerations, and public views of the public policy issue

After these preliminary tasks are complete, the S&T Team now proceeds to conduct its major Proposed Regulatory Stage analytic product:

5.2.3. Conduct a rigorous information quality review of the information that might be used for risk assessment

The time to perform information quality assurance is *before* it is used in a risk assessment. If this task is delayed, it may result in the risk assessment needing to be repeated.

The Econ Team, which must use the risk assessment as an input to the BCA, must participate in the process so that the product meets the needs of CBA. It is essential, for example, that the risk assessment be objective—that is, free of embedded regulatory policy preferences.

5.2.4. Prepare the draft quantitative risk assessment or other technical support document expected to be used as an input to the CBA for the proposed regulation

As noted above, the conventional wisdom holds that risk assessment is an input to the benefit side of the CBA. While true, this notion is incomplete. The cost side of the CBA is never certain, even though it is conventional to assume that costs are fixed. For this reason alone, risk assessment should be performed with respect to cost-side phenomena. Moreover, some costs may be manifest in the form of health, safety, or environmental risks. It is inappropriate to ignore these risks.

5.3. Econ Team Tasks

Tasks performed at the Pre-Analysis Stage must be reviewed and revised, but only as needed to account for new information. This includes:

5.3.1. Describe the nature, scope, magnitude, and duration of the problem that needs to be addressed

5.3.2. Explain fully to decision makers and Canadians the nature of the issue and how its impacts change over time

After these preliminary tasks are complete, the Econ Team now proceeds to conduct its major Proposed Regulatory Stage analytic products.

5.3.3. Conduct a rigorous information quality review of the information that might be used for estimating economic effects

The Econ Team also should perform quality assurance *before* economic information is used in a CBA. If this task is delayed, it may result in the CBA needing to be repeated.

The S&T Team, which provided scientific and risk information as an input to the CBA, must participate in the process so that the information is used properly in the CBA.

5.3.4. Select, design, and assess regulatory and non-regulatory alternatives for analysis

An RIA should consist of both regulatory and non-regulatory alternatives styled in accordance with the nature, scope, and magnitude of the problem. Oftentimes, little attention is devoted to non-regulatory alternatives because they depart from a department's or agencies conventional practice. This is unfortunate, because non-regulatory approaches, such as the provision of information that can improve private decision makers' incentives, may have significant advantages over conventional command-and-control regulation. No single approach is always best, and often a mix of instruments is desirable

5.3.4.1 Considering types of regulatory alternatives

Three types of regulatory alternatives dominate the literature. Some approaches specify to regulated parties exactly what they must do to comply. Others specify the objectives to be achieve and encourage diversity and creativity in the choice of methods. Finally, some regulatory tools strive only to change behavioral incentives in the private market and do not disturb either means or ends. The choice of instrument may be substantially determined by the nature of the problem to be solved and the public purposes to be served.

5.3.4.2 Design standards

The term "design standards" encompasses the broad range of regulatory approaches in which the regulatory agency prescribes exactly what regulated parties must do to comply. These approaches often include detailed technical specifications. When evaluated using conventional cost-benefit analysis, design standards often fare poorly because they cannot account for the diversity of conditions in the private economy.

Design standards fell out of favor perhaps 30 years ago. Nonetheless, they persist in regulatory culture because much of the legislation that departments and agencies are directed to implement was written long ago and has not been updated to reflect improved understanding of regulatory tools.

5.3.4.3 Performance standards

Performance standards elevate ends over means in regulatory design. Instead of prescribing *how to comply*, they prescribe *what to achieve*. This frees regulated parties to think more creatively. In virtually every case, performance standards will be able to achieve policy objectives at less cost.

When design standards fell out of favor, performance standards took their place. Beginning roughly in the 1980s, legislation increasingly was written to permit or require departments and agencies to use performance standards.

5.3.4.4 Economic incentives

Where the underlying problem motivating regulation is a substantial market failure, economic incentives have become increasingly popular alternatives to both design and performance standards. Economic incentive schemes endeavor to "get prices right," by which it is meant to eliminate the gap between private and social cost of a market activity, and otherwise refrain from intervening. This gap arises because of an externality in production or consumption. This is the logic behind modern schemes for the control of air pollution and the UN Global Environment Facility management of climate change. However, economic incentive schemes have been used for a variety of smaller public policy problems.

5.3.5. Consider various non-regulatory alternatives

Sometimes the problem to be solved suggests alternative tools for achieving public policy objectives.

5.3.5.1 Provision or mandated disclosure of information

Asymmetric information between buyers and sellers in the market is a ubiquitous phenomenon. Before the Internet Age, it was difficult to overcome this because obtaining information entailed significant search costs and information was expensive to archive. The Internet has dramatically reduced both of these costs. What used to be a form of market failure has become a vibrant market, and government intervention was not necessary to make it happen.

Still, some information that is relevant to private decision-making may not be available because it is not collected. If it were, however, market participants could be given the opportunity to be fully informed. Because marginal buyers and sellers set price and quantity, not everyone must be fully informed for a market to perform efficiently.

5.3.5.2 Assignment or clarification of property rights

The theory of externalities is over 100 years old, dating from the work of Arthur Cecil Pigou (1877-1959). About 50 years ago, however, a revolutionary change in economic thinking began to emerge as the result of a paper published by Ronald Coase (1910-) in the inaugural issue of a new scholarly journal [7]. Coase's key insight, which greatly extended work he had published in 1937,[8] was that if property rights were completely assigned and there were no transactions costs, externalities would not occur. Furthermore, it did not matter who owned the assigned property rights. The same market equilibrium would occur.

Transactions costs are not zero, of course. Nonetheless, estimating the market equilibrium that would arise absent transactions costs provides valuable information concerning the most stable of all natural outcomes. To the extent that departments and agencies can craft regulations that approximate this condition, they have a much better chance of solving the problem instead of postponing resolution to a future date or creating new problems to solve.

Furthermore, regulatory action can reduce transactions costs instead of increasing them. The intermediate goal of reducing transactions costs can guide the development of a non-regulatory alternative.

5.3.6. Impartially estimate the likely effects of all reasonable alternatives

A classic temptation in the genre is to analyze an odd number of alternatives (e.g., three or five) in which all but the department's preferred option (usually the middle one) have one or more fatal defects. The department's preferred option is usually self-evident. When this occurs, the public tends to lose confidence that the department has considered all the alternatives fairly.

Utilizing consultation early in the process, to solicit input from affected and interested parties and the public concerning alternatives that they believe ought to be considered and examined, can significantly reduce this problem. When a department accepts such advice, it elicits greater trust that its commitment to impartial analysis genuine. That, in turn, motivates constructive participation in the consultation.

5.3.7. Establish a "living," iterative assessment of likely regulatory impacts

A conventional practice in RIA implementation is to disseminate only a completed, final version of the document. This maximizes uncertainty about the contents and quality of the work product, which often can be detrimental to the department's interests. In other arenas, such as scholarly research, the dissemination of drafts for review and comment is standard practice. Final publication is the culmination of the research process, not its unveiling.

The RIA Blueprint provides multiple points for dissemination of and consultation on crucial components. The result of this process is an iteratively improving RIA. By the time the department is ready to make policy decisions, a consensus will have formed—both inside and outside the Government—that the RIA provides an objective and impartial portrayal of the likely effects of each of the prospective alternatives. If there remains a need for Government officials to debate alternative decisions, those debates are much more likely to be focused on substantive policy matters and not on disputes about the merits of the RIA, or the value of applying the discipline of performing RIAs.

5.4. IT&H Team Tasks

At the Proposed Regulatory Stage, the first task for the IT&H Team is to review its Pre-Analysis Stage work and update it to the extent that new information has become available:

5.4.1. Has the problem to be addressed arisen in other jurisdictions?

5.4.2. If so, what did they do about it?

5.4.3. What were the consequences?

Following the completion of these reviews and updates, the Team then embarks on its primary substantive contributions to the RIA.

5.4.4. For each alternative in the RIA for the proposed regulation, evaluate compatibilities and conflicts with approaches taken by other jurisdictions of interest

The extent to which Canadian regulations ought to be harmonized with other jurisdictions is a matter left to the discretion of department decision-makers, unless law settles the question. The

IT&H Team informs that decision by conducting an objective analysis of how each proposed alternative in the RIA conforms to or conflicts with approaches taken by other jurisdictions. This analysis must not prejudge the outcome, however, such as by conveying a policy preference for against harmonization.

5.4.5. For each alternative in the RIA for the proposed regulation, evaluate its international trade implications

Typically, regulatory CBA requires only an accounting of effects that are realized within the water's edge. Canadian CBA guidance invites analysts to "consider" international impacts but does not suggest a means for systematically including it in an RIA [5, p. 9]. Departmental decision-makers often find it useful to have international trade effects clearly portrayed in a separate section.

5.5. L&AP Team Tasks

The first task for the L&AP Team is to review and update work it performed at the Pre-Analysis State to the extent that new information has become available. These tasks include:

5.5.1. What does the enabling legislation or other law authorize the department or agency to do?

5.5.2. Is the regulatory objective within the scope of the department's statutory authority?

5.5.3. Prepare a reasonably comprehensive list of interested and affected parties for consultation, and a plan for ensuring that consultation is effective

After these tasks are complete, the Team then embarks on its principle substantive contributions to the RIA for the proposed regulation.

5.5.4. Are all the alternatives to be analyzed consistent with the *Constitution Act, 1867* and the *Constitution Act, 1982?*

Some alternatives are simply impermissible under any conceivable legislative scenario. This would include alternatives that violate the *Canadian Charter of Rights and Freedoms* and obligations relating to Aboriginal and Treaty Rights arising out of § 35), and the *Canadian Bill of Rights, 1960*.

This part of the legal analysis component of the RIA cannot be performed early. Rather, it must await the articulation of alternatives, for which the Econ Team is primarily responsible.

5.5.5. Is the proposed regulation well drafted and able to operate effectively with other related laws?

Textual coherence with minimal ambiguity is a hallmark of good regulatory practice. In the same vein, potential conflicts or incompatibilities with existing law and regulations must be identified and addressed. Each legislation or directive has unique aspects with implications for both the RIA and the drafting of regulations. Aspects that affect the analysis of the problem, or of alternative ways to solve the problem, should be incorporated into the RIA Blueprint at the outset.

In addition, regulated entities must be able to clearly understand their compliance obligations and rights.

5.5.6. Organize and implement consultation on major components of the RIA for the proposed regulation as they become available

Consultation on the draft RIA is essential, and it should not be delayed until the document is complete. Rather, consultation should be undertaken as early as possible as each major section is completed to a degree sufficient to make consultation effective. Errors that are detected early are much easier to correct.

Consultation on components of the draft RIA also should precede formal consultation on the proposed regulation. Waiting until the formal regulatory consultation period means that technical issues are likely to be subsumed within policy debates. Not only does this lead to inadequate attention to the contents of the RIA, it also raises doubts about the draft RIA's objectivity and neutrality with respect to policy choice.

The key innovation of the RIA Blueprint is the early disclosure of all relevant aspects of its design. This includes disclosure of the regulatory and non-regulatory alternatives to be examined, the data to be relied upon, and the models that will be used to estimate impacts. A department should disclose sufficient information to allow an affected or interested party to perform its own "shadow" RIA. This provides an invaluable means of ensuring that quality standards are met and that the credibility of the RIA is established and sustained.

6.0 Final Regulation Stage

Significant public input should be expected on the draft RIA. If consultation has proceeded in a staged manner as set forth in Sec. 5.5.6, analysts can make corrections and modifications without delay and present the results of this work to department decision-makers for their input and guidance before the draft regulation proceeds to the Final Regulation Stage.

If the analytic effort has been front-loaded into the earlier Stages, as proposed here, most of the analytical work will be complete and effort will consist of fine-tuning the draft RIA.

An exception to this arrangement will arise if department decision-makers choose, after evaluating the work to date and consultative input, to add one or more additional alternatives to the RIA for the final regulation. Provision for such mid-course corrections is essential if the RIA is to gain acceptance as an analytical tool to inform decision-making rather than to justify decisions made on other grounds.

6.1. Shared Tasks

Each of the shared or common tasks listed in the Pre-Analysis and Proposed Regulation Stages (see Sections 4.1 and 5.1) may recur in the Final Regulation Stage. New information may have become available, and consultative input must be given serious consideration befitting the effort expended to provide it.

Some of this input may be useful for closing remaining information gaps. It must be subjected to information quality review, but not required to meet more stringent information quality standards than existing information in the risk assessment, CBA, or RIA.

6.2. S&T Team Tasks

Each of the Pre-Analysis and Proposed Regulation Stage tasks listed in Sections 4.2 and 5.2 must be updated to account for new information that has become available, as well as consultative input. For convenience, these tasks are listed below:

6.2.1. Review relevant evidence-based assessments relevant to the scope, scale, and magnitude of the problem to be addressed

6.2.2. Describe the scientific and empirical evidence, uncertainties, ethical considerations, and public views of the public policy issue

6.2.3. Conduct a rigorous information quality review of the information that might be used for risk assessment

After these reviews and updates are complete, the Team embarks on its final revisions to its contributions to the RIA:

6.2.4. Prepare the final quantitative risk assessment or other technical support document expected to be used as an input to the final CBA

As noted above, this should be a revise-and-update exercise. Only if departmental decision-makers have made mid-course corrections to add new alternatives should there be any need for de novo scientific investigation and analysis.

6.3. Econ Team Tasks

Each of the Pre-Analysis and Proposed Regulation Stage tasks listed in Sections 4.3 and 5.3 must be updated to account for new information that has become available, as well as consultative input. For convenience, these tasks are listed below:

6.3.1. The nature, scope, magnitude, and duration of the problem that needs to be addressed

6.3.2. Explain fully to decision makers and Canadians the nature of the issue and how its impacts change over time

6.3.3. Select, design, and assess regulatory and non-regulatory alternatives in the final RIA

After these reviews and updates are complete, the Team embarks on its final revisions to its contributions to the RIA:

6.3.4. Impartially estimate the likely effects of each alternative, taking account of variability and uncertainty

As noted above, this should be a revise-and-update exercise. Only if departmental decision-makers have made mid-course corrections to add new alternatives should there be any need for de novo scientific investigation and analysis.

6.4. IT&H Team Tasks

Each of the Pre-Analysis and Proposed Regulation Stage tasks listed in Sections 4.4 and 5.4 must be updated to account for new information that has become available, as well as consultative input. For convenience, these tasks are listed below:

6.4.1. Has the problem to be addressed arisen in other jurisdictions?

6.4.2. If so, what did they do about it?

6.4.3. What were the consequences?

After these reviews and updates are complete, the Team embarks on its final revisions to its contributions to the RIA:

6.4.4. For each alternative in the RIA for the final proposed regulation, evaluate compatibilities and conflicts with approaches taken by other jurisdictions of interest

6.4.5. For each alternative in the RIA for the final proposed regulation, evaluate its international trade implications

As noted above, this should be a revise-and-update exercise. Only if departmental decision-makers have made mid-course corrections to add new alternatives should there be any need for de novo scientific investigation and analysis.

6.5. L&AP Team Tasks

Several of the Pre-Analysis and Proposed Regulation Stage tasks listed in Sections 4.5 and 5.5 must be updated to account for new information that has become available, as well as consultative input. For convenience, these tasks are listed below:

6.5.1. What does the enabling legislation or other law authorize the department or agency to do?

6.5.2. Is the proposed regulatory objective within the scope of the department's statutory authority?

6.5.3. Prepare a reasonably comprehensive list of interested and affected parties for consultation, and a plan for ensuring that consultation is effective

6.5.4. Are all the alternatives in the final RIA consistent with the *Constitution Act, 1867* and the *Constitution Act, 1982?*

6.5.5. Is the draft final proposed regulation well drafted and able to operate effectively with other related laws?

After these reviews and updates are complete, the Team embarks on its contributions to the final RIA:

6.5.6. Have analysts fairly and credibly responded to all significant consultative input?

The public credibility of the RIA process depends on its responsiveness, particularly its responsiveness to legitimate criticism. Public credibility will suffer if the department is dismissive or disrespectful of public input.

7.0 The Assignment of Responsibilities for the Completion of RIA Tasks and Milestones for Evaluating Progress

7.1. Personnel and Milestones

A key feature of the RIA Blueprint is accountability. Each task is clearly assigned at the beginning to personnel with the resources and competence to complete it. Milestones for completion of each task are set forth. The Blueprint is not inflexible to changing circumstances, however, so it contains systems whereby milestones can be changed and, where necessary, departmental resources reallocated.

7.2. Information Quality Assurance

Throughout the RIA development constant vigilance is necessary to ensure that the information used meets quality standards appropriate for how it will be used. Generally, the more crucial specific information is to the outcome the greater must be the attention to quality. There are temptations in any analytic effort to work with what is available rather than what is truly needed. Similarly, virtually all information is uncertain but its uncertainty usually is not carried forward through each stage. The RIA Blueprint establishes a central role for information quality assurance so that the final product neither over- nor underestimates analysts' confidence in their estimates of impacts.

7.3. Reopeners

The RIA Blueprint structures issues in a way that permits them to be settled so that progress is not delayed. At the same time, there may not be satisfying answers to issues that present themselves along the way, and this can lead to a reticence about making decisions. Some participants in the process may be highly resistant to settling an issue if they perceive that it cannot be reopened, whereas others may be quick to judgment in order to shut off useful debate. For these reasons, it is important that explicit provisions be made establishing the conditions under which a previously settled issue can be reopened, and that these conditions are honored. If the conditions are widely regarded as fair and reasonable, enforcement would be much easier than if they appear biased or harsh.

Sometimes reopening conditions may be stated objectively. For example, the VOI analysis step set forth in Section 4.1.4 presumes that the decision to proceed will await the results of a VOI analysis. More generally, a conditional decision to proceed in a certain way can be made for each possible outcome of the VOI analysis, obviating the need for another round of deliberations. Sometimes, a

need to reopen a crucial analytic issue can be foreseen if preliminary estimates of costs, benefits, or other effects depart significantly from prior expectations.

Not all matters of interest can be resolved by resort to objective standards and criteria, of course. For this reason, the Blueprint also should include provisions that admit to frankly subjective reasons for reopening a settled issue. There will be a tradeoff between the ease of reopening and the pace of the process. The absence of a clear process for reopening issues does not, however, generally prevent reopenings from occurring.

8.0 References

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