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地域保健分野における規制影響分析の方法論に関する調査研究

平成17年度　総括・分担研究報告書

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厚生労働科学研究費補助金（健康科学総合研究事業）
総括研究報告書

地域保健分野における規制影響分析の方法論に関する調査研究

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研究要旨
規制影響分析を，地域保健分野での規制政策の策定時に実施するための方法論を確立するために，諸外国での先行する取り組みを我が国の地域保健分野および保健医療セクターでの規制政策の文脈に応用するという観点から比較検討を，文献調査および渡航してのヒアリング調査を通じて行った．諸外国には，保健医療セクターに特有な問題点に対処した規制影響分析のガイドライン，ガイダンス，マニュアル等は見いだせなかった．今後は，研究目標である規制影響分析書のフォーマットに従ったとりまとめの方法論の確立を目指して，諸外国での事例の内容にまで踏み込んだ分析を進める．

A．研究目的

本研究の目的は，我が国の規制改革の文脈のなかで，試行的実施が進んでいる規制影響分析を，地域保健分野での規制政策の策定時に実施するための方法論を確立することである．規制とは厚生労働行政のあらゆる側面でとられる可能性のある手法であり，その新設や改廃は行政の大きな役割のひとつである．こうした行政手法をとる場合に規制影響評価という事前評価が義務づけられることは，よりよき行政，よりよき政策の実現にとっては，望ましいことであるとは考えられるが，この新たな分析という手続きを，厚生労働行政の実務の中でどのように運用していくのかということには，明らかではなく，地域保健分野の規制を中心とした保健医療セクターでの多様な規制に対して規制影響分析をどのようにとりまとめていくのかという方法論を確立することはきわめて重要である．

B．研究方法

規制政策の事前評価という規制影響分析は，諸外国での先行する取り組みを受けて我が国に導入されつつあるものであるので，本研究では，先進的な取り組みが見られる諸外国の事例を，我が国の地域保健分野での規制改革の文脈に応用するという観点から，比較検討することを通じて，我が国での試行的実施で提示されている規制影響分析書のフォーマットにしたがってとりまとめる方法論を確立するという方法をとった．2 年計画の 1 年目である本年度は，具体的には，諸外国において，保健医療分野の特殊性に対応したかたちで規制影響分析のとりまとめ方を示した方法論が存在するか否か，また，保健医療行政の実務の中でどのような形で実践しているのか，という 2 点

を中心に，文献調査および渡航してのヒアリング調査を行って収集したデータを質的に分析した．

C．研究結果

まず，我が国に先行して規制影響分析に取り組んできている諸外国においては，規制影響分析一般に関してのとりまとめの方法論は，ガイドライン，ガイダンス，マニュアル等の形で存在しているが，保健医療セクターに特有な問題点に対処するという形ではまとめられてきていないことが明らかとなった．

保健医療行政の実務の中でどのような形で実践しているのか，という点に関しては，特に，イギリスでの事例が示唆的であった．イギリスの保健省では，担当官が経済系技官とともに規制影響分析を実施するが，実践的には，内閣府から提示されたフォーマットに従って，政策決定過程を通じて利害関係者等からインプットされるデータを中立的な立場からにまとめるという形がとられていた．

D．考察

保健医療セクターに特有な問題点に対処するガイドライン，ガイダンス，マニュアル等が見いだせなかったのは，諸外国では方法論のとりまとめにおいて規制政策の仕組みの多様性が個別のセクターの特殊事情よりも優先されてきたためではないかと考えられる．

一方で，イギリスでの，能動的なデータ収集や規範的な判断を行うことなく業務の一環として規制影響分析を行うという取り組み方を見ると，規制影響分析を精緻な費用便益分析を収穫とした一連の学術的な研究分析と類似した営みとしてとらえ，行政の実務になじみにくいのではないかというような予断を払拭して，方法論の確立を目指すことができると考えられる．

E．結論

こうした 1 年目の結果をふまえて，2 年目には，研究目標である規制影響分析書のフォーマットに従ったとりまとめの方法論の確立を目指して，諸外国での事例の内容にまで踏み込んだ分析が必要であると考えられる．

F．健康危険情報

なし

G．研究発表

1．論文発表

なし

2．学会発表

なし

H．知的財産権の出願・登録状況（予定を含む）

1．特許所得

なし

2．実用新案登録

なし

3．その他

なし

厚生労働科学研究費補助金（健康科学総合研究事業）
分担研究報告書

保健医療セクターでの規制影響分析の方法論に関する国際比較調査

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研究要旨
規制影響分析の方法論について，保健医療セクターでの分析の方法論に焦点を当てて，国際的に比較検討するための基本的な情報収集を行った．文献調査では，諸外国での規制影響分析を一般的な観点から検討した文献は見られたものの，保健医療セクターへの応用に焦点を合わせたものを見いだすことができなかった．このため，規制影響分析の国際的動向を継続的にモニターしてきているOECDにおいて専門家に対する聞き取り調査を行い，イギリス，カナダ，オーストラリア，ニュージーランドなどでの保健医療セクターにおける分析の進め方を深く分析することを示唆された．次年度には，これら諸国を対象として，ガイドライン，マニュアル，事例などの情報をさらに収集分析していく予定である．

A．研究目的

本研究は，規制政策の策定時に事前評価として行われる規制影響分析の方法論について，保健医療セクターでの分析の方法論に焦点を当てて，国際的に比較検討するための基本的な情報収集を目的とする．

より具体的には，保健医療セクターも含むあらゆるセクターでの規制政策の実施時に事前に行うことを義務づけることを意図しつつ進んでいる試行的実施の実施要領(図表1)に示されているような規制影響分析書をまとめるためのマニュアル作りのための基礎資料の収集である．

我が国の規制影響分析に関しては，1990年代まで十分には実施されていない(OECD 1997)との国際的な指摘も受けつつ，規制改革や政策評価の潮流のなかで政策決定過程に取り入れられるようになってきているが，当然，国内でのノウハウの蓄積が極めて乏しい，従って，諸外国でとられている方法論を比較検討することが有意義であると考えられる．

B．研究方法

具体的には，以下の3つ方法をとった．

1．規制影響分析に関する国際的レビュー文献の検討．
2．OECDでの規制影響分析担当部局であるRegulatory Policy Divisionでの聞き取り調査．
3．諸外国のガイドラインやマニュアル等の収集．

C．研究結果

1．レビュー文献の検討

規制影響分析に関する 1990 年代の主要な国際的レビューである"Regulatory Impact Analysis. Best Practice in OECDcountries." (OECD1997)および我が国での規制影響分析に関する最新の包括的な文献である「規制評価のフロンティア」(行政管理研究センター 2004)を本研究の基礎文献と位置づけ，その上で,規制影響分析の保健医療セクターへの応用に焦点を合わせたレビュー文献を，各種オンラインデータベースやインターネットを通じて検索した．その結果，規制影響分析に関しては，行政学の分野も含めて学術論文や専門書籍等による論孜は乏しく，保健医療セクターに焦点を合わせてまとめられた文献は同定できなかった．保健医療セクターに限定せず，検索の範囲を規制影響分全般に広げても，この主題に関する情報の収集・蓄積・普及は，主にOECDが継続的に取り組んできていることが明となり，近年の国際的な動向を調査に基づいてまとめたレビューとして"Regulatory Impact Analysis (RIA) Inventory: Note by the Secretariat." (OECD2004)が同定できた．(図表 2)

このレビューのなかでも保健医療セクターでの規制影響分析の取り組みに関する記述も比較的乏しいものであり，フィンランド，ベルギー，カナダなどでの取り組みの存在が示唆されているのに限られた．

2．OECD, Regulatory Policy Division での聞き取り調査

上述のレビュー文献の検討のみでは，その後の本研究の目的であるマニュアル作りのための情報収集の出発点としては不十分であることは否めなかったので，規制影響分析に関する国際的な情報センターとなっている OECD の Regulatory Policy Division を訪問し，保健医療セクターへの応用に関わる方法論上の問題点に対する対処や，近年の日本の文脈への応用を考えた場合に参考になると考えられる諸外国での取り組みの事例の有無などを中心に聞き取り調査を行った．

まず，保健医療セクターへの応用に関わる方法論上の問題点に対する対処についての取り組み，特に,OECD 諸国で，本研究が目標としている保健医療セクターでのマニュアルやガイドラインとしてまとめられているものがある否かという点に関しては，10 年以上にわたって国際的に規制影響分析の仕組みや手法の変遷をモニターしてきているものの，思い当たるものはないということであった．この理由に関しては,各国での方法論の開発では規制政策の内容や仕組みの多様性を扱うことを目指した開発の方が，保健医療セクターも含めたセクター別の特殊性よりも大きな課題としてとらえられてきたためではないかということであった．

近年の日本の文脈，特に保健医療セクターへの応用を考えた場合に参考になると考えられる諸外国での取り組みの事例については，先に同定した文献で指摘されていたブインランド，ベルギー，カナダの特定の事例というよりは，規制影響分析の仕組みと方法論が体系的に整備されていて，比較的の情報蓄積も豊富になされてきているイギリス，カナダ，オーストラリア，ニュージーランドのガイドラインや事例を収集し，保健医療セクタ

ーへの応用という観点から分析することを示唆された.

また，我が国の試行的実施で示されているテンプレートについては，上述の諸国でのガイドライン等に示されているものと比較するとシンプルな作りであり，盛り込むべき情報量も少ないが，導入の出発点としては違和感のないものである，と指摘された.

3．諸外国のガイドラインやマニュアル等の収集

上述の聞き取り調査の結果を受けて，研究初年度である平成17年度末には，イギリス，カナダ，オーストラリア，ニュージーランドの各国における規制影響分析のガイドラインやマニュアルなどを収集している.

D．考察

本年度は規制影響分析書をまとめるためのマニュアル作りのための基礎資料の収集を図ったが，以前より政策決定過程の中で規制影響分析を行ってきている先進諸国の中には，直接的に参考になるようなものとして確立した資料がなさそうであるということが明らかとなった.

本研究の目的達成のための次年度の戦略としては，収集を進めている規制情報分析全般を対象としたガイドラインやマニュアルの分析に加えて，さらに現場での実際に分析を行っている担当者へ，実践的なノウハウに関する聞き取り調査を行ったり，諸外国での類似した規制政策の事例に関する規制影響分析書を比較検討してとられている手法の選択肢を明らかにしたりする分析が考えられる.

E．文献

OECD (1997), Regulatory Impact Analysis. Best Practice in OECD countries, Paris.
行政管理センター (2004) 規制影響分析のフロンティア，東京.
OECD (2004) Regulatory Impact Analysis (RIA) Inventory: Note by the Secretariat, Paris.

F．健康危険情報

なし

G．研究発表

1．論文発表

なし

2．学会発表

なし

H．知的財産権の出願・登録状況（予定を含む）

1．特許所得

なし

2．実用新案登録

なし

3．その他

なし

図表１　規制影響分析(RIA)の試行的実施

【参考】規制影響分析（RIA）の試行的実施に関する実施要領
（平成16年8月13日）

1　目的等

規制影響分析（RIA）の試行的実施は、規制に係る政策評価についての評価手法の開発及び規制改革の一層の推進に資することを目的として行う。

この実施要領は、RIAについて、その試行的実施のための基本的な指針を定めるものである。

2. 実施細則

(1) 対象

RIAは、可能な限り全ての規制の設定又は改廃に際して行うものとする。ただし、政省令等については、軽微等の理由により「規制の設定又は改廃に係る意見提出手続」（平成11年3月23日閣議決定）（以下「パブリック・コメント手続」という。）を行わなかったものについてはこの限りでない。

(2) 実施時期

① RIAは、以下に定める時期までに行わなければならないこととする。

ア　法律の制定・改廃により設定・改廃される規制については、当該法律の公布（廃止）時

※ ただし、できる限り当該法律案の国会提出時までに行うことが望ましい。

イ　政省令等の制定・改廃により設定・改廃される規制については、パブリック・コメント手続における意見の募集時

※ あわせて、パブリック・コメント手続における意見等を踏まえて規制の実施時までに当該規制を修正する場合は、その時点で改めてRIAを行うものとする。

ウ　法律による見直し等の検討が加えられている規制については、当該検討結果の公表時

② RIAを行った規制については、当該RIAに記載するレビュー時期までの間にレビューを行わなければならないこととする。

(3) 分析項目

当面、分析項目は、規制の内容・目的、期待される効果、想定される負担、想定できる代替手段等との比較考量、レビューを行う時期等とし、上記 (2) ①については別添1の様式により、②については別添2の様式により行うものとする。

各分析項目についての具体的な分析事項例は以下のとおり。

① 規制の内容・目的

当該規制についての簡単な内容、また導入の目的・必要性を記載するとともに、当該規制の根拠条文を明示。

（規制緩和の場合は、当該規制緩和の内容・目的等を記載するとともに、緩和後の規制について、なおその規制が必要である理由を記載。）

※ 分析の単位は、当面、「○○事業の許可」といった行政行為ごとを原則とする。

② 期待される効果

当該規制に関し、規制実施による関連業界や国民への便益、社会的便益という観点から、その効果について、影響の帰着先を特定しつつ、想定され得る効果の要素を可能な限り列挙するとともに、可能な限り当該効果を定量化し推計。

なお、「効果」は、現状維持とした場合と比べた増分で表現するものとする。

③ 想定される負担

当該規制に関し、規制実施による行政コスト、遵守コスト、社会コストという観点から、国民等への負担について、影響の帰着先を特定しつつ、想定され得る負担の要素を可能な限り列挙するとともに、可能な限り当該負担を定量化し推計。

なお、「負担」は、現状維持とした場合と比べた増分で表現するものとする。

④ 想定できる代替手段との比較考量

想定できる代替手段を提示し、当該代替手段についても上記②、③の分析を行い、設定・改正しようとする規制案と当該代替手段を比較考量。

なお、代替手段については、可能な限り規制以外の代替手段も提示するものとする。

また、規制緩和の場合は、当該規制の撤廃も想定できる場合は代替手段として提示するものとする。

⑤ 備考

設定・改正しようとする規制に関し審議した審議会等において示された有識者の見解その他関連資料がある場合は、必要に応じそれを明示。

⑥ レビューを行う時期

規制は、社会経済情勢の変化に応じ、不断に見直されるべきであることから、規制の導入から一定期間が経過した後に、当該規制がその時点での社会経済情勢に照らしてなお最適であるか否かを判断することが望まれる。

この観点から、当該判断を行う時期として、当該規制の施行後5年を超えない期間を設定。

(4) 分析の程度

分析の程度については、RIAの試行的実施等を通じて検討すべき事項であることから、当面、定量的／定性的という点も含め、RIAを実施する府省の判断にゆだねるものとする。

なお、総務省は、内閣府規制改革・民間開放推進室と連携しつつ、分析手法の開発・向上に資するような知見・情報等を各府省に対して提供することとする。

(5) RIAの公表等

RIAを実施した府省は、速やかにその結果を内閣府規制改革・民間開放推進室に通知（※）するとともに、原則としてインターネットにより公表しなければならないこととする。

なお、内閣府規制改革・民間開放推進室は、RIAの結果等を各府省より得たときは、速やかにこれを総務省にも回報することとする。

（※）e.kisei@cao.go.jpあてに、件名を「【RIA】○○省（庁）」として、RIAを付した規制案（規制改正案）とともにメール送信願います。

3. 附則

RIAの試行的実施は、平成16年10月1日より行うものとする。また、本実施要領については、平成17年3月31日までの間に必要な検討を加えるものとする。

規制影響分析書（新設・改正時）

（別添１）

規制の名称	○○に関する届出制の導入（○○に関する認可制の緩和）				
担当部局	○○省○○局○○課 △△省△△局△△課	電話番号：03-****-**** 電話番号：03-****-****		e-mail：******@****.go.jp e-mail：******@****.go.jp	
評価実施日	平成○○年○○月○○日				
規制の内容・目的					
	根拠条文等：				
想定される選択肢	今選択肢１	○○に関する届出制の導入			
	今選択肢２	○○に関する規制の強化			
	今選択肢３	○○について税制支援を行う			
	今選択肢４	○○について予算措置を講じる			
期待される効果	効果の要素	選択肢１の場合	選択肢２の場合	選択肢３の場合	選択肢４の場合
想定される負担	負担の要素	選択肢１の場合	選択肢２の場合	選択肢３の場合	選択肢４の場合
	実施に要する負担（行政コスト）				
	実施により生じる負担（遵守コスト）				
	その他の負担（社会コスト）				
各選択肢間の比較					
備　考	○○等調査等中において△△となっている。				
レビュー時期	平成○○年○○月末までに行う。				

規制影響分析書（レビュー時）

（別添２）

規制の名称	○○に関する届出制の導入（○○に関する認可制の緩和）		
担当部局	○○省○○局○○課 △△省△△局△△課	電話番号　03-****-**** 電話番号　03-****-****	e-mail　******@****.go.jp e-mail　******@****.go.jp
評価実施日	平成○○年○○月○○日		
規制の内容・目的			
	根拠条文等		
期待される効果	効果の要素	事前分析	レビュー時
想定される負担	負担の要素	事前分析	レビュー時
	実施に要する負担（行政コスト）		
	実施により生じる負担（遵守コスト）		
	その他の負担（社会コスト）		
備　考		○○等調査等中において△△となっている。	
事前分析で規制案を選択した理由			
結　論	引き続き○○に関する届出制を維持することが適当である。		
次回レビュー時期	平成○○年○○月末までに行う。		

（出典：規制評価のフロンティア）

Unclassified　　GOV/PGC/RD(2004)1

Organisation de Coopération et de Développement Economiques
Organisation for Economic Co-operation and Development　　15-Apr-2004

English - Or. English

PUBLIC GOVERNANCE AND TERRITORIAL DEVELOPMENT DIRECTORATE
PUBLIC GOVERNANCE COMMITTEE

GOV/PGC/RD(2004)1
Unclassified

Regulatory Impact Analysis (RIA) Inventory

Note by the Secretariat

29th Session of the Committee
15-16 April 2004
International Energy Agency, Paris

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English - Or. English

EXPLANATORY NOTE FOR A SURVEY OF RIA SYSTEMS IN OECD COUNTRIES

1. Regulatory Impact analysis is a tool to assess systematically the negative and positive impacts of proposed and existing regulations. Interest in RIA is strong and growing, including in developing countries. It is a strategic tool for regulatory management and reform, but it is not a panacea. The OECD Secretariat developed best practices on RIA in 1997 and also a set of good principles. Whilst these have helped many member countries to establish RIA systems, the implementation of regulatory reform calls for continued efforts to improve the capacity for high quality regulation. Ten years from now, the status and quality of RIA should be far better than today.

Getting maximum benefit from RIA: best practices

1. Maximize political commitment to RIA.
2. Allocate responsibilities for RIA program elements carefully.
3. Train the regulators.
4. Use a consistent but flexible analytical method.
5. Develop and implement data collection strategies.
6. Target RIA efforts.
7. Integrate RIA with the policy-making process, beginning as early as possible.
8. Communicate the results.
9. Involve the public extensively.
10. Apply RIA to existing as well as new regulation.

Source: OECD (1997), *Regulatory Impact Analysis. Best Practice in OECD Countries*, Paris.

2. Many government officials in charge of drafting and reviewing RIA are facing more practical problems, rather than conceptual or basic principles. Many member countries supported the RIA Inventory Project at the Working Party held on 23-24 September 2003. A primary objective of the RIA Inventory is to provide member countries with practical information on RIA. This paper is an explanatory note for the fact sheet **"Survey of RIA Systems in OECD Countries"**, which is a main result of the RIA Inventory. This paper compares key elements of RIA systems in OECD countries such as type of analysis, scope of coverage, public disclosure, quality control, cost-benefit analysis, social discount rate, risk assessment, effects on competition and market openness, and ex-post monitoring.

3. This paper should be reviewed by member countries, to check the fact sheet of their RIA systems. Replies have been received from 14 countries and the EU.

1. Type of Analysis and the Legal Basis of RIA

4. In theory, there are many types of impact analyses, such as cost-benefit analysis, cost-effectiveness analysis, cost assessment, benefit assessment and risk analysis. Cost-benefit analysis that counts the net benefit is the most desirable. In practice many countries do not adopt the rigorous cost-benefit analysis due to the difficulty of quantifying costs and benefits, and so have adopted a more flexible impact analysis system.

5. Many countries have a similar impact analysis system in terms of scope of coverage, quality control, cost-benefit analysis, and consideration of the effects on competition and market openness.

Although the names given to impact analysis systems differ, e.g. RIA (Regulatory Impact Analysis or Regulatory Impact Assessment), RIS (Regulatory Impact Statement), RIAS (Regulatory Impact Analysis Statement), the key elements of these systems are similar. The group of countries that adopt this style of RIA system includes: Australia, Canada, Denmark, Germany, Italy, Japan, Korea, Mexico, New Zealand, Norway, Poland, the United Kingdom, and the United States.

6. There are different types of RIA systems. Some are more focused on a special area, others are partially analysed, or have a simple checklist.

- The Netherlands adopts a Business Effects Analysis, which appears focused on the impacts arising from businesses.
- The Czech Republic adopted Analysis of Financial Impacts and Impacts on the Economy, which has expanded to cover other socio-economic impacts. Implementation of a formalised RIA into the law-making process is being prepared.
- France has General Impact Analysis with specific addresses of employment and fiscal impacts.
- Austria and Portugal have Fiscal Analysis, which focus on the direct budget costs for government administration.
- Finland has a wide range of partial impact analyses covering budget, economy, organisation and manpower, environment, society and health, regional policy and gender equity. These partial analyses are not integrated, and are carried out by various ministries.
- Belgium only carries out the risk assessment in case of health, safety and environmental regulations.
- Ireland, Spain and Sweden have a checklist on the impacts arsing from regulations.

7. The European Union has adopted the Integrated Impact Assessment since Jan. 2003. In the past, the EU had a system under which sector impact assessments were carried out by various departments of the EU. This was inefficient because various impact analyses, such as small businesses, consumer rights, employment, gender equality and environment, overlap in some way or contradict each other resulting in a more burden than integrated impact analysis. A considerable number of countries like Australia, Canada, Finland, Korea, Mexico, New Zealand, Norway, U.K and the U.S.A adopt RIA systems that cover multiple impacts including economic, social and environmental impacts.

8. A legal basis for an RIA system is a good indicator by which we can understand how well the RIA system can be implemented. The OECD countries adopt various legal forms such as a Law, Presidential Decree, Executive Order, Cabinet Directive, Guidelines of the Prime Minister, etc. These legal forms can be classified into four groups. It is believed that the higher the legal basis, the more powerful is its implementation. However, implementation also depends on historical background, administrative culture and the commitment of high level officials.

- Based on a law: the Czech Republic, Korea and Mexico
- Based on a presidential order: U.S.A
- Based on a prime ministerial decree or guidelines of the prime minister: Australia, Austria, France, Italy and Netherlands

- Based on a cabinet directive, cabinet decision, government resolution, policy directive, etc.: Canada, Denmark, Finland, Ireland, Japan, New Zealand, Norway, Poland, Germany, Portugal, Sweden and the United Kingdom

2. Scope of Coverage.

9. Drafting RIA is a sophisticated and time consuming exercise. It is therefore important to determine the circumstances when RIA is required. The scope for RIA may be limited to the primary laws that are made by the legislative, or may also include the subordinate regulations, such as presidential decree, directives and guidelines that the executive makes in order to implement primary laws. RIA is usually required in the case of newly introduced regulations or strengthened regulations. In some countries, RIA is also required in the case of reviewing existing regulation. RIA is rarely used at regional or local levels, with the exception of a few federal countries, such as Australia, where it is used widely at state level and Mexico, where it is also used in some states. Uneven coverage of RIA programs seriously reduces effectiveness. Given that laws and lower-level regulations can have similar impacts, there is no reason *a priori* to distinguish between them; hence, the differences seem to be related to institutional relationships and historical circumstances rather than to rational program design.

10. Most OECD countries require RIA for primary laws and subordinate regulations. Denmark require RIA only for primary laws. The Czech Republic and Ireland require RIA for primary laws and major subordinate regulations, the Netherlands for major laws and major subordinate regulations, Portugal for selected laws and subordinate regulations and Sweden for primary laws and subordinate regulations that might have an effect on small businesses.

11. Australia requires RIS for primary laws, subordinate regulations, international treaties and quasi-regulations that have an impact on business or competition. The impact on business arises in the following cases: (i) govern the entry or exit into or out of market, (ii) control prices or production levels, (iii) restrict the quality, level, or location of goods and services available, (iv) restrict advertising and promotional activities, (v) restrict price or type of input used in the production process, (vi) are likely to confer significant costs on business and may provide advantages to some firms over others. It is notable in the case of Australia that proposing ministries contact the Office of Regulation Review (Quality Control Body) early in the policy development process in order to decide whether RIS is required or not.

12. Canada has a particular scope of RIAS (Regulatory Impact Analysis Statement). Canada requires RIAS only in subordinate regulations. Memorandum to Cabinet (MC) similar to RIAS is required for primary laws and policies. It should be noted that adoption of primary laws typically involves consultation with stakeholders, discussion of policy proposals among government ministries with different mandates and discussion of the proposal by Cabinet and public debate in Parliament during the legislative process. Canada does not require RIA for primary laws because all of these elements promote the development of high quality legislation.

13. The United Kingdom requires RIA in primary laws and subordinate regulations which have a non-negligible impact on business, charities, and the voluntary sector. It is notable in the case of the UK that regulations affecting only the public sector are currently subject to a Policy Effects Framework (PEF) assessment. From 2004, however, they will also be brought within the RIA system.

14. RIA is a useful tool for the reviewing of regulations already in place, as well as new regulations. Many countries seem to require RIA in the case of strengthening existing regulations. However, RIA is not usually required for the reviewing of existing regulations, even thought the drafting of RIA of existing regulations is easier than that of new regulations because regulators already have data to be used for RIA. It is noteworthy that countries such as Australia, Canada, Germany, Netherlands, Switzerland and the United Kingdom also apply the RIA system to the reviewing of existing regulations.

3. Public Disclosure

15. A consultation process with interest groups, other ministries and civil groups is a necessary step in the regulatory formation process. RIA is a good tool for consultation because it has a wide range of information on costs and benefits. It is desirable for consultation purposes that RIA be publicly disclosed as early as possible. Many countries disclose their RIA for consultation, but some OECD countries disclose their RIA only after consultation or do not release at all.

16. The countries which disclose their RIA for consultation include Canada, Denmark, EU, Finland, Italy, Mexico, New Zealand, Norway, Poland, Sweden, Switzerland, the UK and the United States. Japan and Portugal disclose their RIA for consultation only in the case of major regulations or in selected cases. Australia, France, Iceland and the Netherlands disclose their RIA when regulations are submitted to their Parliament or the Council of Ministers. Italy circulates RIA to affected groups in draft form but does not publicly disclose for consultation. Other countries which do not disclose their RIA include, Austria, Hungary, Ireland, Korea, Spain and Turkey.

4. Quality Control

17. Quality control is needed to maintain good quality regulations. Quality control bodies perform various functions including consultation on the drafting RIA, technical assistance, reviewing the quality of RIA and reporting on ministerial compliance with RIA. The quality control body issues a guideline for drafting RIA in most cases. The relationship between the control body and regulating ministries is an important factor understanding a country's RIA system.

18. In Australia, Canada, EU, Hungary, Korea, Mexico, Sweden, UK and the USA, an independent control body can advise ministries to revise the drafted RIA. Preliminary RIA is required for all the proposed regulations in the EU and the quality control body of the EU select the major regulations which are required to draft an extended RIA. In the case of Australia, initiating regulatory agencies should contact the quality control body early in the policy development process in order to decide whether RIA is required or not.

19. Many other countries have an independent quality control body whose role is not as well defined as that of the above mentioned. These are: the Czech Republic, Italy, the Netherlands, Poland and Switzerland. Countries such as Austria, Denmark, Finland, Germany New Zealand and Norway do not have an independent quality control body. The quality control level may be compromised when RIA is controlled by the regulators themselves or by Ministries such as Finance, Justice, etc. In the case of France, Iceland, Ireland, Japan, Portugal, Spain and Turkey, there is no quality control body in place.

5. Cost-Benefit Analysis

20. Cost-benefit analysis is the most important and difficult part in RIA. Research has been carried out on how well the Cost-benefit analysis was carried out from 1982 to 1992 and 1996 to 1999 in the Environmental Protection Agency (EPA) of the United States [1]. The ratio of calculating net benefits is very low: 26% under the Reagan administration, 13% under the Bush (Senior) Administration and 39% under that of Clinton. This means that in most cases quantification of all costs and benefits is not carried out. This implies that adequate criteria to screen the cases which require a fully quantified RIA are needed.

21. The Office of Management and Budget (OMB) in the USA issued detailed guidelines on Cost-Benefit Analysis in an effort to cope with the difficulties often faced in the process of Cost-Benefit

[1] How have government Cost-Benefit Analyses Changed Over Time? Robert W. Hahn and Patrick M. Dudley, Dec. 2002

Analysis. Although the guidelines are not complete, it shows an alternative way of facing difficult cost/benefit analysis.[2]

- If monetization of the effects is impossible, explain why and present all available quantitative information along with the timing and likelihood of the effect.
- If quantification of the effect is difficult, present any relevant quantitative information along with a description of the unquantifiable effect, the timing and the likelihood.
- If monetizing of benefits is difficult, "Cost-Effectiveness Analysis" rather than Cost-Benefit Analysis can be used.
- If costs and benefits are not traded in the market, use willingness-to-pay measures to monetize the effects.
- If cost and benefit estimates depend heavily on certain assumptions, make those assumptions explicit and carry out analyses sensitively, using plausible alternative assumptions.

22. Cases on cost/benefit analysis are various. Some countries cover all the cost and benefits, while others cover selected costs and benefits, some countries require that benefits be greater than cost, while others not, some countries require quantification of all the costs and benefits while others require quantification only in the case of significant or selected regulations. An important factor in cost/benefit analysis is the criteria by which a regulation required to make a full quantification analysis is selected. Many advanced countries adopt this kind of threshold criteria as a strategy of targeting efforts on RIA.

- The EU adopts a two-step approach method. Preliminary RIA is required for all the proposed regulations and the quality control body selects the major regulations which are required to draft an extended RIA, including quantification of cost and benefits.
- In Canada, all significant regulatory proposals must undergo a cost/benefit analysis. A significant regulation is defined as one with a present value of cost greater than $50 million, or if it has a lower present value of costs and a low degree of public acceptance.
- In Korea, major regulations are required to make quantification of cost and benefit. A major regulation is defined as: (i) the annual cost affected by a regulation is more than 10 billion Won in a year; (ii) the number of regulated people is more than 1 million on a yearly basis; (iii) regulation that explicitly prohibits competition; or (iv) disproportionate or unreasonable regulation that does not fit well with international standards.
- In Mexico, there are three types of RIA: "High Impact RIA", "Ordinary RIA" and "Periodic regulation RIA". High impact regulations must provide detailed quantification of costs and benefits.
- In the USA quantification of cost and benefits is required for major regulations. Major regulations are defined as regulations that impose annual costs exceeding US$100 million, possibly impose major increases in costs for a specific sector or region, or have significant adverse effects on competition, employment, investment, productivity or innovation.

6. Social Discount Rate

23. A social discount rate is a key element in calculating cost and benefits because it is a discounting factor of future costs and benefits. In the European Union the discount rate is expressed in real terms,

[2] Guidelines to Standardise Measures of Costs and benefits and the Format of Accounting Statements, OMB, 2002. For more details, see the web page: http://www.whitehouse.gov/omb/memoranda/m00-08.pdf

taking account of inflation. This rate corresponds approximately to the average real yield on longer term government debt in the EU since the early 1980s[3].

24. In the United Kingdom, the discount rate is determined by three factors: (i) time preference of individuals; (ii) annual growth in per Capita consumption and (iii) elasticity of marginal utility of consumption[4]. The "HMT Green Book" published by the UK Government explaining in detail how to determine the discount rate.

25. The United States determines the discount rate based on the marginal pre-tax rate of return on an average investment in the private sector in recent years. This rate is usually the same rate as the interest rate on Treasury Notes and Bonds. Significant changes in this rate are updated by the OMB Circular which is updated around the time of the president's budget submission to Congress. The OMB Circular shows the nominal and real discount rate depending on the time period[5]. It is also recommended that the sensitivity analysis using other discount rates should be added, if the use of such an alternative rate can be justified.

7. Risk Assessment

26. One important analytical method in RIA is risk assessment, which allows regulators to understand more clearly the human and environmental risk arising from regulation. As more social and environmental regulations are subjected to RIA, questions of assessing and balancing risks are further complicating the question of appropriate analytical methods. Many countries adopt risk assessment in health, safety and environmental regulations, some in all cases, while others require it only for major regulations.

27. In Canada, regulatory authorities proposing new regulatory requirements or regulatory changes must have evidence that a problem has arisen, that government intervention is required and that new regulatory requirements are necessary. In addition, when health, safety and environmental risks are involved, regulatory authorities must consider whether the relative and absolute risks posed are such that intervention is required at this time. Australia, Belgium, Denmark, EU, Mexico, New Zealand, the United Kingdom and the U.S.A require risk assessment in all cases. Austria, the Czech Republic, France, Germany, Hungary, Norway, Iceland, Poland, Sweden and Switzerland require risk assessment only in selected cases. Some countries such as the Finland and Japan require risk assessment on environmental regulations in all cases, while only in selected cases in the area of health and safety.

8. Effects on Competition and Market Openness

28. The effect on competition and market openness of regulation is an important factor to be considered in RIA. The EU, Hungary and New Zealand require effects on competition and market openness to be considered, where relevant, for individual proposals. Many member countries including

3 How to assess impacts–Guidelines for Commission staff, the Strategic Planning and Programming Unit in the Secretariat General of the EU.

4 The formula is: $R = p + e \times g$, where R is the discount rate; p is time preference of individuals; e is elasticity of marginal utility of consumption; g is annual growth in per Capita consumption. For more details, see "HMT Green Book" in web address: http://greenbook.treasury.gov.uk/annex06.htm

5 The following are the rates to be used through January 2005 when making cost/benefit calculations:
The nominal interest rates are: 3-year (3.0%); 5-yearss (3.7%); 7-year (4.2%); 10-year (4.6%); and 30-year (5.5%).
The real interest rates are: 3-year (1.6%); 5-year (2.1%); 7-year (2.4%); 10-year (2.8%); and 30-year (3.5%).
See more details in the web page: http://www.whitehouse.gov/omb/circulars/a094/a94_appx-c.html

Australia, Canada, Denmark, Finland, Germany, Iceland, Ireland, Italy, Korea, Mexico, Poland, Sweden, Turkey and the United Kingdom require the effect on competition and market openness in all cases. The Netherlands, Norway, Switzerland and the United States require these effects only in the case of major regulations. Austria, the Czech Republic, France, Japan and Portugal require the effects only in selected cases.

29. The United Kingdom has a very detailed guideline for effects on competition. The Office of Fair Trading prepared "Guidelines for competition assessment" in February 2002. According to the guideline, there are two steps in the competition assessment process. The first step is a competition filter that identifies regulations required to make a detailed competition assessment. If the number of the answer 'yes' to the nine filter questions is more than half, those regulations are required to make a detailed assessment[6]. The second step is carrying out a detailed assessment along the lines of :

- **Identifying the affected markets:** First, define more precisely which economic markets are affected by a regulation. These markets may follow Standard Industrial Classification definitions or may differ. It is important also to identify indirectly affected markets.
- **Understanding the current nature of competition:** Before investigating how a regulation will change competition, policy makers should understand how competition currently operates in the relevant markets. This involves exploring in more detail supply and demand factors, market outcomes, and the competitive process.
- **Identifying the impacts of the regulation:** Having understood how competition currently takes place in the affected markets, identify the supply and demand impact and market impacts of a regulation, and the direct and indirect impacts on the competitive process resulting from that regulation, for each policy option presented.

9. Ex-post Monitoring

30. The ex-ante analysis of a regulation is difficult. There are too many factors to be considered and many items are difficult to quantify. Although one of the important lessons about RIA is avoid using it as an ex-post justification of a regulation; government officials tend to use it in that way. This increases the importance of the ex-post monitoring which can feedback into ex-ante analysis. Ex-post monitoring is also a good way to prevent regulatory failure. Leading countries in this field are recently paying much attention to ex-post monitoring.

- In Australia, RIA should include implementation and review section. It should state how the recommended option will be monitored, with a view to its amendment or removal when circumstances change.
- In Canada, departments are required to use the *Manual on Review, Internal Audit and Evaluation*, to structure the review process and identify performance measurements in the evaluation of their application of the *Regulatory Policy*. Furthermore, the central body of Canadian regulatory reform has initiated a number of initiatives in recent years to achieve meaningful and relevant performance measurement and reporting of federal regulatory programs, responsive to transparency and accountability expectations of Canadians, Parliamentarians and the public sector.
- In Denmark, every year the government chooses approximately 15 new laws that must be reviewed 3 years after their introduction.

6 See "Guidelines for competition assessment" Feb. 2002, Office of Fair Trading, UK
Reference web page: http://www.oft.gov.uk/nr/rdonlyres/a7138977-6fc2-45de-be32- 3ab6e767664a/0/oft355.pdf

- In the EU, services are asked to provide detailed plans for monitoring and evaluation of proposals. New legislative proposals should consider review clauses, where appropriate, in particular in areas subject to rapid technological change.
- Germany has created a concept of retrospective RIA. The retrospective RIA is done when operational experience is available after implementation. The key questions of retrospective RIA are: Were regulatory objectives achieved? Should the regulation be revised or up-dated?
- In Hungary, the Act on Legislation states that regulatory bodies have to follow the realisation of regulations and must take the experience into consideration when preparing new laws or the program on legislation.
- In Mexico, ex-post evaluation of the quality of RIA is done internally by a central body of Mexican regulatory reform and data is shared with individual agencies. There is an internal "score card" for RIA that is used for monitoring RIA quality.
- Norway also requires ex-post evaluation at intervals of central government institutions and policy instruments, especially concerning the pre-supposed social effects. Environmental regulations have been evaluated ex-post a number of times.
- In the Swedish Checklist, one question refers to the follow-up of effects on small businesses caused by regulation.
- In the UK, each RIA must state how the effectiveness of the regulation is to be measured and when. In addition to internal evaluation by a central body of British regulatory reform, the independent National Audit Office considers a sample of RIA each year.

10. Other Information to Contribute to the Development of RIA Systems

31. Having a high level commitment to the RIA system is necessary for its successful implementation. In the case of the U.S.A, legislators use RIA to judge the quality of new laws and regulations. The United States' regulatory agencies are instructed not to publish regulations unless the RIA is attached. Canada, Mexico and the UK require a minister or deputy minister to sign RIA to demonstrate his/her responsibility on RIA.

32. The generally poor performance of OECD countries in implementing data collection strategies means that the data essential to conducting good analysis is often lacking, while *ad hoc* strategies for data collection often fail on grounds of both timeliness and cost. A particular problem is the failure to utilize fully the potential of consultation strategies as data sources and means of verifying data quality and the quality of assumptions.

33. It is worthy of note that Denmark's efforts in the area of data collection in cost-benefit analysis. Denmark set up the Business Test Panels to assess the burden of regulations with businesses. The Business Test Panels are used to request information on the administrative burdens of approved legislation. There are three panels consisting of 500 firms in each panel. Ministries have discretion about using the test panel procedure but most have used it for legislation having significant business impact. Denmark also has Focus Panels which are used to obtain information on the impact of bills, with effects only on specific sectors of the economy. However, experience has shown the precision of test panel data to be low and the system is largely seen as an "early warning system" for unanticipated major impacts[7]. The Model Enterprise Program has also been introduced to provide more statistically robust data. Model Enterprises consisting of representative businesses in the industry sector are used to measure actual administrative burdens on business. The identified burdens by Model Enterprises can be applied to similar regulatory proposals.

[7] Regulatory Policies in OECD Countries – From Interventionism to Regulatory Governance p. 131, Dec. 2002

SURVEY OF RIA SYSTEMS IN OECD COUNTRIES

Explanation of key Elements

1. Type of analysis, date begun, and required by refer to the following:
   - The kind of analysis, for example: Regulatory Impact Analysis, Regulatory Impact Assessment, Business Impact Analysis, General Impact Analysis, etc.
   - When was it started and developed?
   - Is the analysis required by a law, presidential decree, cabinet instruction, or guidance, etc.?
2. Scope of coverage refers to the following:
   - In which case is RIA required? For example:
     - In all the primary laws
     - In all the subordinate regulations
     - Only in major regulations
   - What is the definition of major regulations?
   - Is RIA required in the review of existing regulations?
3. Public disclosure refers to the following:
   - Is the RIA publicly disclosed for a consultation?
   - If not, when is it publicly disclosed?
4. Quality control refers to the following:
   - Is the quality of RIA controlled by a quality control organisation?
   - What is the function of the quality control body? And what is the relationship between the control body and ministries?
   - Does the control body issue a guideline?
5. Cost/Benefit Analysis refers to the following:
   - Quantification of cost/benefit is required in all the regulations or only in major regulations?
   - What is the definition of the major regulation?
   - Cost/Benefit covers all the costs/ benefits or selected costs/benefits?
   - What are the selected costs/benefits?
   - The benefit should justify the cost?
   - Are there any other alternatives than counting the net benefits?
   - When is sensitivity analysis done?
6. Social discount rate refers to the following:
   - How is the social discount rate determined?
   - Is the same discount rate applied to all the regulations?
7. Risk Assessment refers to the following:

- Is quantitative risk assessment done in all the cases or only in selected cases?
- What are the selected cases? Is there a guideline for risk analysis?

8. Effects on competition and market openness refer to the following:

- Are the effects on competition and market openness considered in all the cases or in selected cases?
- What are the selected cases?

9. Ex-post monitoring refers to the following:

- Is ex-post monitoring done on RIA?
- How is ex-post monitoring done?

10. RIA contact point refers to the following:

- Who is in charge of RIA?
- What is his/her e-mail address?

11. Other remarks refer to other useful information to be noted in relation with RIA.

1. AUSTRALIA

Key Elements	Brief Explanations
1. Type of analysis, date begun, and required by	• 1985 to 1997 Regulation Impact Statement (RIS) required in certain circumstances, required by Cabinet decision. • March 1997 RIS process strengthened and new guidelines were released in 1998. This RIS Guide may be updated in 2004. • The RIS takes a community-wide focus and covers economic, social and environmental impacts. RIS should also highlight impacts on small business and Ecologically Sustainable Development where appropriate. • All Australian States and Territories also have RIS systems.
2. Scope of coverage	• Primary laws, subordinate regulations, international treaties and quasi-regulations that have business or competition impacts. The Australian Government and inter-governmental regulatory forums make approximately 2000 regulations each year, with about 150 of these being subject to the RIS process. • Business impacts arise in the case that proposed regulations (1) govern the entry or exit into or out of market (2) control prices or production levels (3) restrict the quality, level, or location of goods and services available (4) restrict advertising and promotional activities (5) restrict price or type of inputs used in the production process (6)are likely to confer significant costs on business, or may provide advantages to some firms over others. • Reviews of existing regulations should adopt the RIS framework.
3. Public disclosure	• Federal Government RIS are not required for community consultation. Publication of such RIS is required for regulation that is tabled in the Australian Parliament and is encouraged in other cases. • For RIS applying to Ministerial Councils and national standard setting bodies, a draft RIS should be publicly available as part of the community consultation process.
4. Quality control	• For Australian Government, Ministerial Councils and National Standard Setting Bodies, RIS are reviewed by the Office of Regulation Review (ORR) which is part of the Productivity Commission. The Commission has statutory independence from the executive arm of government. • RIS Guidance issued via *A Guide to Regulation* (1998). • Proposing departments/agencies should contact the ORR early in the policy development process to decide whether a RIS is required. • One of the ORR's key roles is to ensure that the level of analysis in a RIS is commensurate with a regulation's potential impact on business and the broader community. This is part of the Government's policy of regulatory best practice. A key tenet of the policy is to ensure that regulation provides the greatest net benefit to the community, and that it is the most efficient and effective way of addressing a problem. • The RIS Guide and ORR training sessions are used to promote the RIS process and enhance cooperation with departments/agencies. When a RIS is being prepared, drafts of the RIS are exchanged between these bodies and the ORR. The ORR endorses a RIS once it meets the requirements of the RIS Guide. • If a RIS fails to meet the minimum requirements, the ORR will advise the department/agency and decision-maker accordingly. Other sanctions for RIS non-compliance include identification of non-compliance within the ORR's Annual Report, "Regulation and its Review". • Regulation review units within State and Territory governments provide RIS quality control in their respective jurisdictions.
5. Cost/Benefit analysis	• The RIS should show a net benefit to justify the preferred option. • Quantitative and qualitative information about impacts, benefits and costs of feasible options is required. The level of quantification of costs and benefits depends on the scale and scope of the impacts. • Data collection and analysis is undertaken on a case-by-case basis.
6. Social discount rate	• While no social discount rate is specified in the RIS Guide, the ORR recommends, where applicable, the social discount rate endorsed by the Australian Government Department of Finance and Administration.

7. Risk assessment	• Quantitative and qualitative risk assessment undertaken on a case-by-case basis. Risk assessment is included within RIS, where applicable. Risk assessment is outlined in *A Guide to Regulation*.
8. Effects on competition and market openness	• Likely effects on competition and market openness are considered in RISs in all cases.
9. Ex-post monitoring	• RIS should include implementation and review section. It should state how the recommended option will be monitored, with a view to its amendment or removal should circumstances change. • Ex-post monitoring is usually undertaken on a case-by-case basis.
10. Contact point	• Chris Toyne [ctoyne@pc.gov.au].
11. Other Remarks	• Australia has a separate RIS process for Australian Government taxation measures, focusing on implementation options. • RIS should include a subsection that assesses the impact on small business compliance costs and paper work burdens. • Where a proposed regulation has a direct bearing on export performance, a Trade Impact Assessment should be incorporated in RIS. • States/Territories have their own different and separate set of RIS requirements. • Australian Government RIS requirements are broadly consistent with the RIS requirements which apply to inter-governmental forums (such as Ministerial Councils and national standard setting bodies). However, for inter-governmental decision making forums a draft RIS is assessed by the ORR before being released for public consultation. The final RIS is assessed by the ORR to ensure it meets the RIS requirements. The RIS is then considered by the decision making body. • Regulatory Plans are part of the Government's strategy to improve regulation. These are prepared by departments/agencies and record their previous year's regulatory activity and their intentions for the year ahead. • Regulatory Performance Indicators are designed to facilitate an assessment of the effectiveness of regulation, including compliance costs. **(Useful web addresses)** ➢ This is the web site of the Australian Government Office of Regulation Review (ORR). You can get the information on the functions of the ORR, government policy on regulation, specific regulation reform initiative, etc. • http://www.pc.gov.au/orr/orrintro.html ➢ This is the web address in which you can find Guidelines for preparing Australian Government Regulation Impact Statements (RISs), and RIS check list. • http://www.pc.gov.au/orr/reports/guide/reguide2/index.html ➢ The COAG *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies* is available from: • http://www.dpmc.gov.au/publications.cfm

4. CANADA

Key Elements	Brief Explanations
1. Type of analysis, date begun, and required by	• Socio-economic Impact Analysis in 1978, required by Cabinet Directive. • Regulatory Impact Analysis in 1986, required by Treasury Board Policy, under authority of Financial Administration Act. • RIAS in 1999, required by Cabinet Directive – lead challenge function by Privy Council Office, as of 1999. • The *RIAS Writer's Guide* of 1992 states that "drafters should quantify estimates for impacts on inflation, employment, distribution of income, operating costs, international trade, including global competitiveness and direct benefits". Also, the guide requires that, "whenever there are possible environmental effects, drafter should summarize the results of an assessment of the environmental implications. • Further, the *1999 Cabinet Directive on the Environmental Assessment of Policy, Plan and Program Proposal* provides clarification with regard to environmental assessment – it states that "the strategic environmental assessment should contribute to the development of policies, plans and programs on an equal basis with economic or social analysis; the level of effort in conducting the analysis of potential environmental effects should be commensurate with the level of anticipated environmental effects."
2. Scope of coverage	• RIAS is required only for subordinate regulations. Memorandum to Cabinet (MC) similar to RIAS is required for primary laws and policies. •MC constitutes the frame of analysis for primary laws or statutes, and, as such, they are secret documents for internal use of Cabinet and government officials only. The RIAS summarizes the analysis, effects and consultation required by the Regulatory Policy and forms the basis of the Government's decision making and public challenge regarding regulatory proposals. they provide a description of what the government is going to deliver, how Canadians have been consulted, and what they have said, hence the public nature of RIAS. • It should be noted that adoption of primary laws typically involves consultation with stakeholders, the discussion of policy proposals among government ministries with different mandates, discussion of the proposal by Cabinet, and public debate in Parliament during the legislative process. All of these elements promote the development of high quality legislation. RIAS is also applied to the review of existing regulations
3. Public disclosure	• All RIAS are published in draft form in Canada Gazette Part I and all final RIAS are published in the Canada Gazette Part II. • The Cabinet Directive on Law-Making makes provisions for consultations with affected parties. By tradition, draft bills have been treated with strict confidence before they were introduced in Parliament. However, in keeping with the Government's commitment to openness and consultation, sponsoring Ministers may wish to consult on the basis of draft bills. This consultation is intended to ensure that bills take into account the views of those concerned and it must not pre-empt Parliament's role in passing bills. • Planned regulatory agendas found in departmental and agency annual reports on plans and priorities are tabled in Parliament, as well as on departmental and agency web sites and non-govt sources such as trade and professional publications • Primary legislation is made publicly available through the Parliamentary process and through parliamentary website.
4. Quality control	• Regulatory Affairs and Orders in Council Secretariat (RAOICS) of the Privy Council Office of Canada provides ministries with advice, assistance and can ask them to revise RIAS. RAOICS, assumes, as part of its central regulatory agency review role, a challenge function of regulatory proposal sponsored by departments. • Guidance Issued on all aspects of regulation-making, including specifically on the Regulatory Policy, the Regulatory Process Management Standards and the *RIAS Writer's Guide* - refer to http://www.pco-bcp.gc.ca/raoics-srdc

5. Cost/Benefit analysis	• All significant regulatory proposals must undergo a cost/benefit analysis. This is used to assess the gains and losses resulting from a set of alternative regulatory and non-regulatory actions to help decide whether any of the actions should be undertaken. In carrying out the analysis, four questions must be addressed: (1) What will change as the result of the introduction and operation of each proposed action? (2) What is the estimated value of the benefits that will come about as a result of each proposed action, and who will obtain them? (3) What are the estimated costs of each proposed action, and who will pay them? (4) Given the estimated benefits and costs, should any of the proposed actions be undertaken and, if so, which one? *A significant regulation is defined as one with a present value of costs greater than $50 million or it has a low degree of public acceptance even if the cost is less than $50 million. • The impact assessment should clearly assess: (i) the economic, social, environmental and health impacts of the proposal on Canadian society; (ii) distributional impacts (fairness and equity implications) of the proposal. For example, will the proposal have a disproportionate impact on an industrial sector, area or identifiable social group? (iii) impacts that may affect a region, business and trade, and competitiveness. For example, will a proposal impede competition or promote it? Business Impact Test may be appropriate for regulations that affect business. • The Privy Council Office (PCO) provides guidance documents on measurements. Such documents include a *RIAS Drafter's Guide*, a Guide for Business Impact Testing (BIT), and a Cost-Benefit Guide for Regulatory Programs. * The BIT, as well as the Cost-Benefit Guide, offers a framework for regulators to measure the impact of regulatory proposals on affected businesses. As such, this instrument provides for guidelines on how to survey the potentially-affected industry.
6. Social discount rate	• Departments are encouraged to follow Treasury Board Secretariat's (TBS) guidelines on benefit-cost analysis. For long-term time horizons, TBS suggests using specialists to estimate discount rates and the suggested social discount rate is described as robust around 10%, with a range from 7.5 to 12%. A review of practices in Canada in 2002 suggests that practices in applying social discount rates in Canada are similar to practices in OECD and the US – generally, financial investment analyses use 7.5 to 12% discount rates whereas health/ environment studies use lower discount rates than the suggested 10%. Very short-term impact analyses, where discount rate would have little impact, may not be discounted at all.
7. Risk assessment	• For health, safety, and environmental regulations, regulatory authorities should demonstrate that relative and absolute risks posed are such that intervention is required. • Risk assessment is an intrinsic part in the consideration of alternatives required by a RIAS analysis before arriving at the proposed regulatory direction. The Cost-Benefit Guide for Regulatory Programs- 1995 provides additional guidance for risk assessment.
8. Effects on competition and market openness	• Likely effects on competition and market openness are to be considered in all cases.

9. Ex-post monitoring	• Departments are required to use the *Manual on Review, Internal Audit and Evaluation*, Part 1, to structure the review process and identify performance measurements in the evaluation of their application of the *Regulatory Policy*. • Further, RAOIC has initiated in recent years a number of initiatives to achieve meaningful and relevant performance measurement and reporting of federal regulatory programs, responsive to transparency and accountability expectations of Canadians, Parliamentarians and the public sector. • A study on RIA-RIAS in 2000 assessed the element of instilling discipline in analysis and affecting decision making by providing certain types of information. The study concluded, overall, that the RIA and RIAS requirements have changed the decision-making process; more attention is paid to alternatives and costs and benefits than appeared to exist when the requirements were instituted fifteen years ago; and, officials were sensitive to RIA requirements and departments had systems in place to consider regulatory options and costs and benefits.
10. Contact point	• Jody Aylard : jaylard@pco-bcp.gc.ca • Hélène Quesnel : hquesnel@pco-bcp.gc.ca
11. Other Remarks	• Ministers are accountable for the analysis and sign RIAS. • With respect to primary laws, the Government issued a Directive entitled "Cabinet Directive on Law-making" in March 1999, replacing an earlier Directive from 1981. • With respect to subordinate regulation, the most recent substantive changes to the Regulatory Policy were made in 1995, although this was later updated and reconfirmed by Cabinet in November 1999. • There is no specific formal requirement for different levels of government to co-operate in drafting RIAS, however collaboration in designing and consulting on inter-jurisdictional regulatory proposals is encouraged and in some instances formalised **(Useful web addresses)** ➢ This is the web site of the main regulatory reform organisation in Canada. You can find the information such as the role of the body, departmental regulatory review, and parliamentary regulatory review. • http://www.pco-bcp.gc.ca/raoics-srdc ➢ In this web site there are links to the Cabinet Direction on Law-making, to the Guide to the Making of Federal Acts and Regulations and also international regulatory reform links such as Australia, European Union, Mexico, UK, and U.S.A. • http://www.pco-bcp.gc.ca/raoics-srdc/default.asp?Language=E&Page=links ➢ This is web page where you can find a Directive entitled "Cabinet Directive on Law-making" • http://www.pco-bcp.gc.ca/legislation/directive_e.htm ➢ This is the web page where you can find the most recent substantive changes to the Regulatory Policy of Canada. • http://www.pco-bcp.gc.ca/raoics-srdc/reg-pol/reg-pol_e.htm ➢ This is the web address where you can find RIA cases of Canadian meat regulations • http://www.inspection.gc.ca/english/reg/spprts/2001/93014ria_e.shtml ➢ The web page address for the different regulatory guides offered to Canadian regulators is: • http://www.pco-bcp.gc.ca/raoics-srdc/default.asp?Language=E&Page=Publications&Sub=Current

16. JAPAN

Key Elements	Brief Explanations
1. Type of analysis, date begun, and required by	• Benefits test for permits in 1987
2. Scope of coverage	• Primary laws and subordinate regulations.
3. Public disclosure	• RIA is required to be publicly released for consultation only in major regulations.
4. Quality control	• No. • Guidance is not issued.
5. Cost/Benefit analysis	• Quantification of cost is required in selected cases. • Quantification of benefit is required in selected cases. • Cost covers selected costs. • Benefit covers selected benefits. • Benefit of new regulation should justify cost in selected cases.
6. Social discount rate	• n.a.
7. Risk assessment	• Quantitative risk assessment for health, and safety regulation is done in selected cases. • Quantitative risk assessment for environmental regulation is done in all cases.
8. Effects on competition and market openness	• Likely effects on competition and market openness are to be considered in selected cases.
9. Ex-post monitoring	• n.a.
10. Contact point	• n.a.
11. Other Remarks	

21. NEW ZEALAND

Key Elements	Brief Explanations
1. Type of analysis, date begun, and required by	• RIS have been required since July 1998, extended to include Business Compliance Cost Statement (BCCS) in Apr. 2001, both required by Executive policy. • The RIS must provide impact analysis on all the economic and social costs and benefits, direct and indirect, whether they are quantifiable or not; and include e.g., impacts on business and competition, international obligations, health, environment, culture, and so on, as relevant. The content of the proposal determines the focus that the impact analysis should take – all relevant matters should be covered.
2. Scope of coverage	• Primary laws and subordinate regulations: • All policy proposals submitted to Cabinet which result in government bills or statutory regulations, whether for new regulatory proposals or for amendments or repeals of existing laws (both primary and secondary) need an RIS. Where the proposal has compliance cost implications (i.e., red-tape) for business, the RIS has to include a BCCS. However, there are exemptions from RIS requirements, e.g., for proposals that are minor/machinery, relate to government administration only, for commencement orders etc.
3. Public disclosure	• Yes, all RIS that include a BCCS are published on the responsible department's web site with a link to the Ministry of Economic Development (MED) web site. RIS/BCCS for Bills must be published in the explanatory note to the Bill. Under the Official Information Act, anyone can request a copy of an RIS (i.e., if it is not already voluntarily published on a department's web site) and there are only limited statutory grounds for withholding requested official information.
4. Quality control	• Responsibility of agencies and Ministers. • Guidance issued by the Regulatory Impact Analysis Unit (RIA Unit) in the Ministry of Economic Development. • RIS is a summary statement – unless for high impact proposal, general rule is 3 pages for RIS, or 4 for RIS/BCCS. • All RIS that contain a BCCS must, since August 2002, be assessed for adequacy of the disclosure and analysis by the RIA Unit, and a statement as to its adequacy inserted into the policy paper attaching the RIS/BCCS. • In practice, Ministers rarely, if ever, allow papers to go forward for Cabinet consideration if RIS/BCCS has not been found to be adequate by RIA Unit.
5. Cost/Benefit analysis	• Quantification of costs and benefits is required where that is both possible, an appropriate use of resources in relation to the likely impacts of the proposal, and appropriate. Where data is inherently un-quantifiable, sound qualitative analysis is required. For high impact proposals agencies prepare or commission more formal, comprehensive cost/benefit analysis. • All the relevant costs and benefits need to be addressed, tangible and intangible, and consideration given to impacts on different sectors of society. The content of the proposal will determine what is relevant. Consultation with stakeholders, relevant industry organisations and affected parties is strongly encouraged for the collecting of the data necessary for undertaking robust impact analysis. • Benefits should outweigh costs of any regulatory proposal.
6. Social discount rate	• Discount rates usually only considered when formal cost/benefit analysis undertaken and costs expressed as Net Present Value – usually only in respect of moderately high to high impact proposals. Guidance from RIA Unit in MED suggests a range of discount rates (e.g., 5 – 7% pa for value of avoiding death or serious injury, government bond rate for proposals on government expenditure, a lower (unspecified) rate for environmental values).
7. Risk assessment	• Risk assessment, whether quantified or not, will be undertaken in RIS if appropriate to the subject matter of the regulatory proposal. If risk assessment is thought to be appropriate, it would be incorporated into the cost/benefit analysis in the RIS.
8. Effects on competition and market openness	• Likely effects on competition and market openness are to be considered whenever relevant to the subject matter of the regulatory proposal.
9. Ex-post monitoring	• No formal requirement for ex-post monitoring on RIA.

10. Contact point	• Lisa Barrett [Lisa.Barrett@med.govt.nz]
11. Other Remarks	**(Useful web addresses)** ➢ This is the web page where you can find a Guide to Preparing Regulatory Impact Statements: • http://www.med.govt.nz/buslt/compliance/reginpact/index.html ➢ This is the web page where you can find Guidelines for Departments on Business Compliance Cost Statements: • http://www.med.govt.nz/buslt/compliance/guidelines/index.html ➢ This is the web page which has links to departments' published RIS/BCCSs: • http://www.med.govt.nz/buslt/compliance/risbccs/bydate.html ➢ This is the web page where you can find the Criteria used by the RIA Unit for assessing the adequacy of RIS/BCCSs: • http://www.med.govt.nz/buslt/compliance/adequacy.html#P10_2331

30. UNITED KINGDOM

Key Elements	Brief Explanations
1. Type of analysis, date begun, and required by	• Business compliance cost assessments in 1985, required by government policy. • Regulatory appraisal (including risk assessment and business cost analysis) in 1996, required by government policy. • Regulatory Impact Assessment (RIA) for all significant regulation since 1998, required by government policy. • The RIA must consider not only the obvious costs and benefits, but also a comprehensive analysis of all the wider environmental, social and economic impacts. • New regulations should only be introduced when other alternatives have first been considered and rejected, and where the benefits justify the costs.
2. Scope of coverage	• Any proposal for which regulation is an option – including both primary and secondary legislation - that would have a non-negligible impact on business, charities or the voluntary sector should have an RIA.. • RIA is also applied to reviews of existing regulations. • Regulations affecting only the public sector are currently subject to a Policy Effects Framework (PEF) assessment. From 2004, however, they will be brought within the RIA process.
3. Public disclosure	• The Government is committed to ensuring that RIA is readily available to the public. • Consultation is mandatory for all regulatory proposals that require RIA, with a minimum consultation period of twelve weeks. A partial RIA must be issued alongside formal public consultations. • *Partial RIA follows the same format as a full RIA but the analysis is not yet as complete. . For example, by setting out the Government's analysis to date, a partial RIA sent out with a consultation document can encourage input in the policy-making process, particularly in those areas where further information is particularly needed. In addition, a partial RIA can often contain a broader range in the quantification of costs and benefits than a final RIA. RIA must accompany Cabinet correspondence when seeking Committee clearance for policy changes, for example the publication of a White Paper. In order to secure collective ministerial agreement to proceed with a regulatory proposal, an adequate RIA must have been carried out. • Once a decision has been taken to proceed with regulation, a final RIA must be laid in Parliament alongside legislation. • The final RIA must be placed on the relevant department website as soon as possible.
4. Quality control	• Each department has a Departmental Regulatory Impact Unit (DRIU) responsible for helping policy officials to draw up RIA. • The Cabinet Office Regulatory Impact Unit (RIU) is also on hand to offer help and support and is responsible for scrutinising all RIA. In addition, it has issued guidance on the standard format for RIA. • Ministers must also sign a declaration in the final RIA placed before Parliament stating that they believe the benefits of the proposed regulation outweigh the costs. • The Prime Minister and the Cabinet are committed to ensuring that RIAs accompany any request for collective agreement to a measure. • In addition to internal evaluation by the RIU, the independent National Audit Office (NAO) conducts an ex-post evaluation of a sample of RIAs each year.

5. Cost/Benefit analysis	• Quantification of cost is required in all cases. • Quantification of benefit is required in all cases. • Cost covers all costs. • Benefit covers all benefits. • The benefit of new regulation is required to justify cost in all cases. • No single method of assessment is prescribed, though guidance is available on a number of methods and the general process. • All analysis must be consistent with the guidance set out in the HM Treasury 'Green Book, Appraisal And Evaluation In Central Government' (http://greenbook.treasury.gov.uk). • Policy officials are encouraged to begin informal consultation with interested parties as soon as possible, to inform the process of appraising the various options, and to consult a wide range of sources.
6. Social discount rate	• The discount rate (3.5%) is determined by the following formula. $R = p + e \times g$ Where R is the discount rate; p is time preference of individuals; e is elasticity of marginal utility of consumption; g is annual growth in per Capita consumption. * For more details on the discount rate, see "HMT Green Book" in web address: http://greenbook.treasury.gov.uk/annex06.htm
7. Risk assessment	• The assessment of risk is integrated into the RIA. • The RIA must assess the risk of the problem the proposal is intended to solve happening, as well as flagging up the risks associated with each option and the validity of underlying assumptions.
8. Effects on competition and market openness	• A competition assessment examining the likely effects of the proposed regulation on competition and market openness must be included in all RIA. • The Office for Fair Trading (OFT) has developed a competition filter (included in the Cabinet Office guidance on RIA) to help policy officials determine whether a proposal is likely to have a small or large impact on competition and hence whether a simple or detailed assessment is needed. It also offers expert advice for officials undertaking a competition assessment.
10. Contact point	• Stephen Evans, Regulatory Impact Unit (stephen.evans@cabinet-office.x.gsi.gov.uk) • Alison Kilburn, Regulatory Impact Unit (alison.kilburn@cabinet-office.x.gsi.gov.uk)
11. Other remarks	**(Useful web addresses)** ➢ This is the web site of the Cabinet Office Regulatory Impact Unit. • http://www.cabinet-office.gov.uk/regulation ➢ This is the web address where you can find "Regulatory Reform Act 2001" which is the main framework for regulatory reform in the U.K. • http://www.cabinet-office.gov.uk/regulation/act/index.htm ➢ There is a standard format for RIAs, which is set out in detail in 'Better Policy Making: a guide to Regulatory Impact Assessment', available at • http://www.cabinet-office.gov.uk/regulation/scrutiny/betterpolicy.htm. ➢ All RIA published to date can be found at • http://www.cabinet-office.gov.uk/regulation/ria/regreport.asp ➢ This is the web page where you can find examples of RIA of U.K • http://www.cabinet-office.gov.uk/regulation/scrutiny/exampleRIA_page1.htm ➢ This is the web address about the book "Better Regulation: Making Good Use of Regulatory Impact Assessments", which is the report by the Comptroller and Auditor General of U.K. You can find many examples of good practice for preparing RIA. • http://www.tso.co.uk/bookshop/bookstore.asp?FO=38383&Action=Book&ProductID=0102912238 • ISBN: 0-10-291223-8 ➢ This is the web page where you can find the calculating way of costs and benefits. • http://greenbook.treasury.gov.uk/annex06.htm ➢ An example of a good RIA can be found at: • www.dti.gov.uk/epterprisebill/ria.htm ➢ This is the web page where you can find Guidelines for competition Assessment. • http://www.oft.gov.uk/nr/rdonlyres/a7138977-6fe2-45de-be32-3ab6e7b76b4a/0/oft355.pdf

31. UNITED STATES

Key Elements	Brief Explanations
1. Type of analysis, date begun, and required by	• B/C in 1977; expanded in 1981. • Revised into RIA (Regulatory Impact Assessment) in 1993, required by presidential order and some laws. * The RIA includes various impacts such as on economic, social and environmental impacts.
2. Scope of coverage	• Primary laws in selected cases and all subordinate regulations.
3. Public disclosure	• All RIA are published in draft and final form in national gazette.
4. Quality control	• Independent review by presidential Office of Management and Budget. Guidance issued
5. Cost/Benefit analysis	• Quantification of cost is required in major regulations. • Quantification of benefit is required in major regulations. * major regulation: regulations that impose annual costs exceeding US$100 million, possibly impose major increases in costs for a specific sector or region, or have significant adverse effect on competition, employment, investment, productivity, or innovation. • Cost covers all costs. • Benefit covers all benefits. • Benefit of new regulation should justify cost in all cases (?).
6. Social discount rate	• The discount rate is based on the marginal pre-tax rate of return on an average investment in the private sector in recent years. This rate is usually the same rate as the interest rate on Treasury Notes and Bonds. • Significant changes in this rate are updated by the OMB Circular which is updated around the time of the president's budget submission to Congress. • It is recommended that the sensitivity analysis using other discount rate should be added if the use of such an alternative rate can be justified. * For more details on the discount rate, see the web page: http://www.whitehouse.gov/omb/circulars/a094/a94_appx-c.html
7. Risk assessment	• Quantitative risk assessment for health, safety, and environmental regulation is done in all cases.
8. Effects on competition and market openness	• Likely effects on competition and market openness are to be considered in major regulations.
9. Ex-post monitoring	• n.a.
10. Contact Point	• n.a.