

BRAZILIAN  
GOVERNMENT

**Guidelines and  
Guidebook for  
Regulatory Impact  
Analysis - RIA**

JUNE 2018



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Initially drafted with a focus on Federal Regulatory Agencies, the Guidelines and Suggested Analytical Roadmap for Regulatory Impact Analysis - RIA Guidelines and the Guidebook for the Preparation of Regulatory Impact Analysis - RIA Guidebook were approved by the Interministerial Governance Committee - CIG as a recommendation of best practice for all the Federal Public Administration.

This publication is the result of technical discussions coordinated by the Chief of Staff of the Presidency of the Republic of Brazil in partnership with the Ministry of Finance, the Ministry of Planning, Development and Management and the Federal Regulatory Agencies. The common objective is to formulate evidence-based regulation and strengthen the dissemination of best practices on regulatory quality.

The common goal is to encourage evidence-based regulation and to strengthen the dissemination of practices that improve regulatory quality.

The discussions were also joined by the National Institute of Metrology, Quality and Technology - Inmetro.

RIA is a tool designed to ensure that decision-making is supported by the systematic and transparent analysis of the best evidence available, based on the definition of the problem to be solved and the objectives to be achieved.

The RIA Guidelines define the concepts, basic stages and minimum standards to be observed when preparing a Regulatory Impact Analysis. The RIA Guidebook details the key elements that should be present in the RIA Report, highlighting important aspects and presenting recommendations based on best practices internationally observed.

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# FOREWORD

Regulation is a contemporary form of State action that refers, in a broad sense, to the set of legal and regulatory instruments (laws, decrees, and other rules) available to governments to establish obligations that the private sector, citizens and the government itself must fulfil. It is therefore one of the main instruments whereby governments advance the social and economic well-being of their citizens. However, regulation may become an obstacle to these very purposes. When it is excessive and disproportionate, it may hinder innovation or create unnecessary barriers to trade, competition, investment and economic efficiency.

Why regulate? What for? How does one define the best rule to adopt in a given situation? The answers to these questions should be present whenever preparing rules designed to change people's behaviour. Making rules is a seemingly inexpensive activity for those who perform it, but it has the potential to result in high costs for those who will have to comply with them. Therefore, it is vital to improve the quality of the assessments of regulatory options, and consequently, the cost of conducting them, so that rules are better planned and do not burden business and society unjustifiably.

In this regard, a Regulatory Impact Analysis (RIA) is a systematic process of evidence-based analysis that starts with the definition of a regulatory problem and then assesses the possible impacts of the alternatives available to meet the intended objectives, with the purpose of guiding and supporting decision-making. As a tool to improve regulatory quality, it provides more technical and analytical foundation to the regulatory authority during its decision-making process, especially when it entails the imposition of rules.

For guiding the preparation and implementation of RIA in the Federal Government, we are introducing the RIA Guidelines and RIA Guidebook. The RIA Guidelines contain directions for the implementation of RIA by any public administration entity and introduces a set of common minimum standards for the application of this tool. The RIA Guidebook is in accordance to the RIA Guidelines and provides advice and technical assistance to anyone carrying this analysis. The purpose of the Guidebook is to introduce the basic key contents and the general

orientations that should steer the RIA process, but without getting into detailed discussions about specific techniques or methodologies.

Both the RIA Guidelines and the RIA Guidebook are based on the principles that is essential to start the RIA in the early stages of the regulatory process, in other words, prior to drafting laws, decrees, regulations and other rules, and that it is paramount to integrate stakeholder engagement mechanisms during the preparation of the RIA.

Both documents were the outcome of a technical group created in January 2017 and coordinated by the Office for Public Policies. It consisted of representatives of Federal Regulatory Agencies, Ministry of Finance and Ministry of Planning, Development and Management, as well as Inmetro. As a result, we now have the present documents containing minimum standards for the effective implementation of RIA in a uniform, transparent and participatory manner. Please note that these guidelines have no aspiration of exhausting the methods and techniques available to suit each individual case.

The Regulatory Agencies were the preliminary focus of the RIA Guidelines and the RIA Guidebook. They were formulated in accordance with Bill nº 6621 / 2016, which provides for the management, organisation, decision-making process and social control of these bodies. Nevertheless, other institutions that publish rules with the potential to amend rights or create obligations for third parties may perfectly use them.

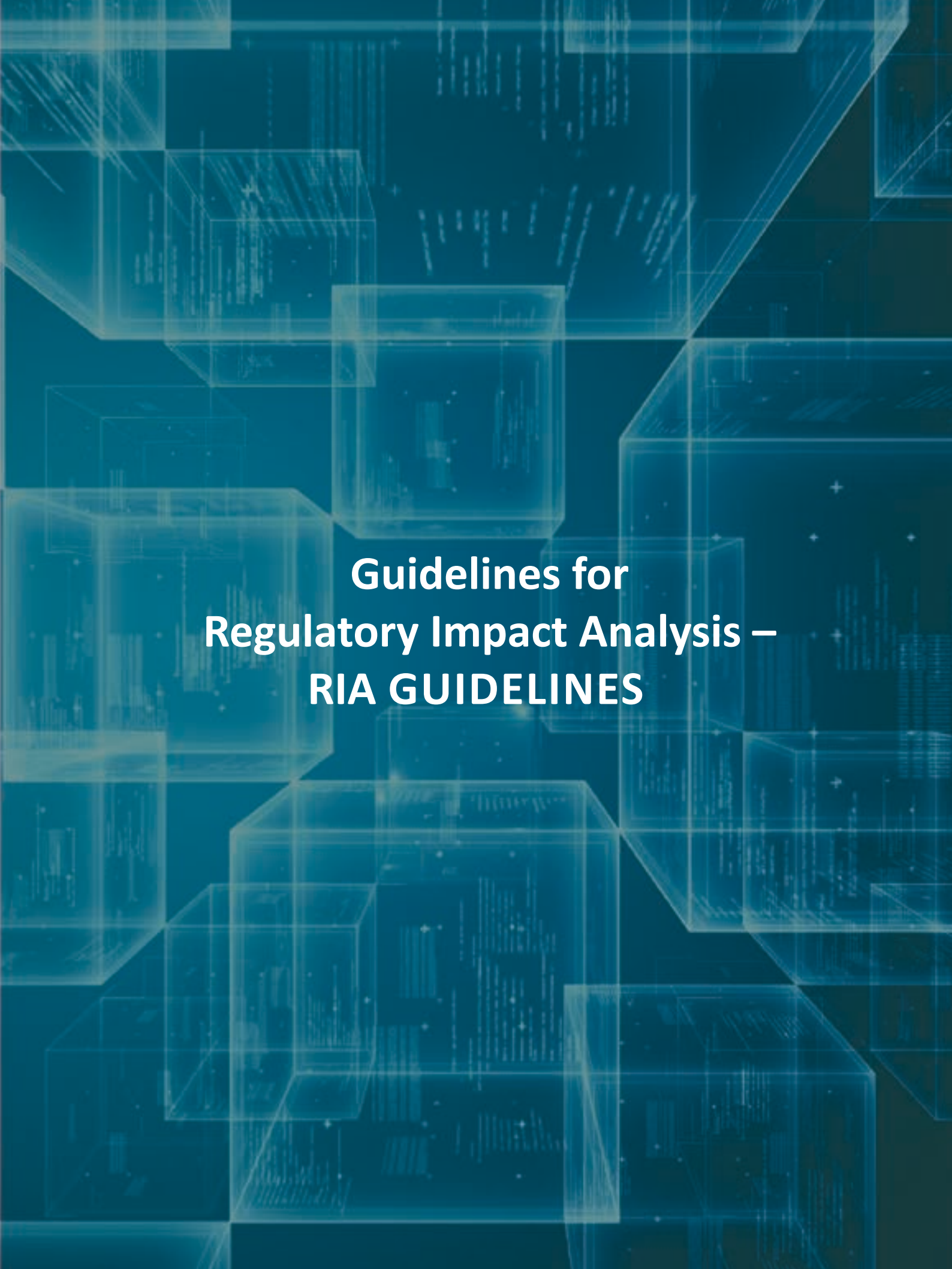
Such flexibility allowed both documents to be submitted, on June 11<sup>th</sup>, to the Interministerial Governance Committee (CIG), formed by the State Ministers of Finance; Planning, Development and Management; Transparency and Comptroller General of the Union, under the coordination of the President's Chief of Staff. The CIG endorsed the recommendation to use the RIA Guidelines and the RIA Guidebook throughout Brazil's federal public administration, acknowledging these documents as important tools for regulatory improvement, which is a principle of public governance recognized by the Public Governance Decree.

We therefore hope this is the beginning of a change in the institutional culture of our public administration, so that rules will be prepared more carefully and adequately according to their purpose, while achieving the desired results with the lowest possible costs to society, and contributing to the economic development of the country.

**MARCELO PACHECO DOS GUARANYS**

Deputy Minister of the Office for Public Policies

Office of the Chief of Staff



**Guidelines for  
Regulatory Impact Analysis –  
RIA GUIDELINES**



# RIA GUIDELINES AND PROPOSED ROADMAP FOR REGULATORY IMPACT ANALYSIS – RIA GUIDELINES<sup>1</sup>

<b>GENERAL GUIDANCE</b>	Please note that although the Guidelines were originally developed with a focus on Federal Regulatory Agencies, any public administration bodies or entities enacting rules with potential to amend rights or create obligations for third parties may use the recommendations gathered. <sup>2</sup>
<b>CONCEPTS</b>	<p><b>Regulatory Impact Analysis – RIA</b> is the systematic process of evidence-based analysis which, following the definition of a regulatory problem, seeks to assess the possible impacts of the alternatives available to reach the intended objectives, with the purpose of guiding and supporting decision making;</p> <p><b>Regulatory Outcome Assessment – ROE</b> is an instrument that evaluates the performance of the adopted or amended regulation, considering the achievement of desired objectives and outcomes, as well as other impacts observed on the market and society, resulting from its implementation;</p> <p><b>Rule of general interest to the economic agents, consumers or users of provided services</b> is one which may potentially influence their rights or obligations;</p> <p><b>RIA and ROE Implementation</b> in the context of regulatory entities means defining the organizational units involved in undertaking analysis and their respective legal authority.</p>
<b>OBJECTIVES</b>	<p><b>The RIA objectives are:</b></p> <p>I – to guide and support the decision-making process;</p> <p>II – to provide greater efficiency to regulatory decisions;</p> <p>III – to provide regulatory coherence and quality;</p> <p>IV – to provide technical robustness and predictability to relevant regulatory decisions;</p> <p>V – to increase transparency and understanding of the regulatory process as a whole, raising the awareness of stakeholders and the society in general regarding regulatory problems, stages of the analysis, techniques used, alternative solutions envisioned and the criteria considered to substantiate relevant regulatory decisions; and</p> <p>VI – to contribute to the continuous improvement of regulatory activity.</p>
<b>APPLICABILITY</b>	Given that it contains information and data regarding the possible effects of the rule, RIA will precede the adoption of new regulations or the amendments to existing ones that may affect economic agents, consumers or users of services, proposed by regulatory entities.

<sup>1</sup> Translation support of the original document was provided by IPEA's research fellow Cristina Toth Sydow.

<sup>2</sup> In this document we will refer to the regulatory agencies, ministries, bodies and other public entities with powers to enact regulatory rules as regulatory entities.

<p><b>NON-APPLICABILITY</b></p>	<p>I – <b>administrative rules</b> whose effects are restricted to the entity itself;                  II – <b>decisions intended to regulate specific situations</b> and applicable to specific individuals/companies;                  III – <b>decisions that correct errors</b> involving syntax, spelling, punctuation, typography and numbering of previously published regulations;                  IV – <b>rules that revoke or update obsolete standards</b>, without any change of merit;                  V – <b>rules that consolidate other regulations</b>, without changing their merit.</p>
<p><b>STARTING THE RIA/</b></p>	<p>RIA shall initiate as soon as the regulatory entity undertakes actions to solve an identified regulatory problem.</p>
<p><b>WAIVER POSSIBILITIES</b></p>	<p>Mandatory RIA may be justifiably waived by decision of the regulatory entity authority/ies in the following cases:                  I - <b>urgency</b>;                  II - <b>rules aimed at regulating rights or obligations defined in a superior legal instrument that does not allow the possibility of different regulatory alternatives</b>; and                  III - <b>rules of manifest low impact</b>.                  In urgent cases when the mandatory RIA is waived by a substantiated decision of the regulatory entity authority/ies, it will be necessary to prepare a technical note or equivalent document identifying the regulatory problem to be solved and the objectives to be achieved, in order to subsidise the future preparation of the Regulatory Outcome Evaluation (ROE).</p>
<p><b>RIA REPORT</b></p>	<p>RIA shall be presented as a report - the RIA Report - and shall contain some essential elements.</p>
<p><b>RIA LEVEL I – BASIC ELEMENTS</b></p>	<p>(a) objective and concise executive summary, using plain language accessible to the general public;                  (b) identification of the regulatory problem to be solved, presenting its causes and extent;                  (c) identification of stakeholders or groups affected by the regulatory problem;                  (d) identification of the legal basis supporting the action of the regulatory entity in the subject matter;                  (e) definition of the objectives to be achieved;                  (f) description of possible alternatives to address the identified regulatory problem, considering the option of no-action in addition to regulatory solutions and, whenever possible, non-regulatory options;                  (g) description of the possible impacts of identified alternatives;                  (h) comparison of the options considered, indicating and justifying the most appropriate alternative or combination of alternatives to achieve the intended objectives;                  (i) description of the strategy to implement the suggested alternative, including monitoring and supervision methods, as well as the need to amend or repeal existing rules;                  (j) considerations regarding information, contributions and comments received for preparing RIA in stakeholder engagement to receive inputs on the subject under analysis;                  (k) full name, position of civil servants who took part in the RIA and signature of the responsible for the Report.</p>

<p><b>RIA LEVEL II – BASIC ELEMENTS</b></p>	<p>If the regulatory problem under analysis is significantly complex or the alternatives to address it have significant impacts, the regulatory entity shall undertake the following analysis, in addition to items "a" to "k":</p> <p>(l) survey the international experience in addressing the regulatory problem under analysis;</p> <p>(m) measure the possible impacts of the identified options on relevant stakeholders; and</p> <p>(n) risk assessment.</p>
<p><b>MINIMUM CONTENT AND COMPLEMENTATION</b></p>	<p>Whenever possible, the minimum analytical content listed above must be detailed and complemented by additional elements, according to the degree of complexity, scope and impact of the regulatory problem.</p>
<p><b>METHODOLOGY</b></p>	<p>The methodology used shall be described clearly and objectively in the RIA Report, and shall be justifiably defined on a case-by-case basis, to adapt to concrete cases, according to the characteristics and complexity of the subject under analysis and the available information and data. All sources of consultation must be cited.</p> <p>Whenever possible, RIA Level II shall include quantitative analyses to measure and compare costs and benefits of the identified alternatives.</p>
<p><b>DECISION-MAKING AND STAKEHOLDER ENGAGEMENT WITHIN THE SCOPE OF RIA</b></p>	<p>In order to improve transparency in the regulatory process and increase the available sources of information, the partial or full RIA Report shall be subjected, whenever possible, to a specific public consultation process to encourage comments, suggestions and contributions from stakeholders and the general public.</p> <p>The specific public consultation shall be concluded before the preparation of a draft rule to address the regulatory problem identified.</p> <p>The regulatory entity shall use the means and channels it deems most appropriate, ensuring the deadline for public manifestations is proportional to the complexity of the subject.</p> <p>The decision-making authority/ies may manifest their opinion during the preparation of the RIA Report, in order to advise the strategy and streamline the decision-making process in the respective regulatory entity.</p>
<p><b>DECISION-MAKING AND STAKEHOLDER ENGAGEMENT WITHIN THE RULE ADOPTION OR AMENDMENT</b></p>	<p>The decision-making authority/ies shall manifest their opinion on whether the proposed rule is appropriate, indicating whether its adoption is recommended given the expected impacts whilst offering any necessary complementation where applicable.</p> <p>Should decision-making authority/ies decide to move on with the administrative procedure, either their opinion and the RIA Report will be part of the documents available to stakeholders for public consultations or public hearings.</p>
<p><b>PUBLIC CONSULTATION</b></p>	<p>In cases where the RIA is not undertaken, at least a technical report or an equivalent document must be available to stakeholders, showing what substantiated the decision.</p> <p>The drafts and proposed amendments to rules of general interest to economic agents, consumers or users of services shall be made available for public consultation prior to the decision of the regulatory authority/ies.</p>

**PUBLIC HEARING**

Except in case of different deadline defined in specific legislation or in international treaty or agreement, the public consultation period will begin after the publication of the relevant order or notice of opening in the Official Gazette and on the website of the regulatory entity. The consultation will have a minimum length of 45 (forty-five) days, unless in exceptional cases of urgency and relevance, properly motivated.

Notwithstanding other access solutions it deems convenient, the regulatory entity shall enable contributions to be sent over the Internet in their entirety, without limitations of size or format, while taking into account the technical limitations of the entity. At the beginning of the public consultation, the regulatory entity shall provide access, at their headquarters and on their respective website in open format, to the RIA Report, studies and data, along with any related technical material used to substantiate the proposals submitted to public consultation, with the exception of those that are confidential.

Comments and suggestions submitted by interested parties should be made available at the regulatory entity headquarters and on their respective websites up to 10 (ten) business days after the public consultation period has ended.

The regulatory entity's opinion regarding the comments or contributions received during the public consultation process must be made available at their headquarters and on their respective website within 30 (thirty) business days of the final decision on the matter by the decision-making authority/ies.

When deemed appropriate, the Ministry of Finance will express its opinion about the regulatory impacts of drafts and proposed amendments to rules of general interest to economic agents, consumers or users of provided services, submitted to public consultation by the regulatory entity.

The decision-making authority/ies may convene a public hearing on matters considered relevant.

The opening of the public hearing period will be preceded by an order or opening announcement published in the Official Gazette and other media with at least 5 (five) working days' notice.

The regulatory entity shall make the following documents available at a specific location and on their respective website, at least 5 (five) working days prior to the start of the public hearing:

I - for the proposals of new rules and amendment to rules submitted to public hearing: the RIA Report, studies, data (in open format whenever possible) and the technical material that substantiated them, with the exception of those that are confidential;

II - for other proposals submitted to public hearing: the technical report or an equivalent document substantiating the proposals.

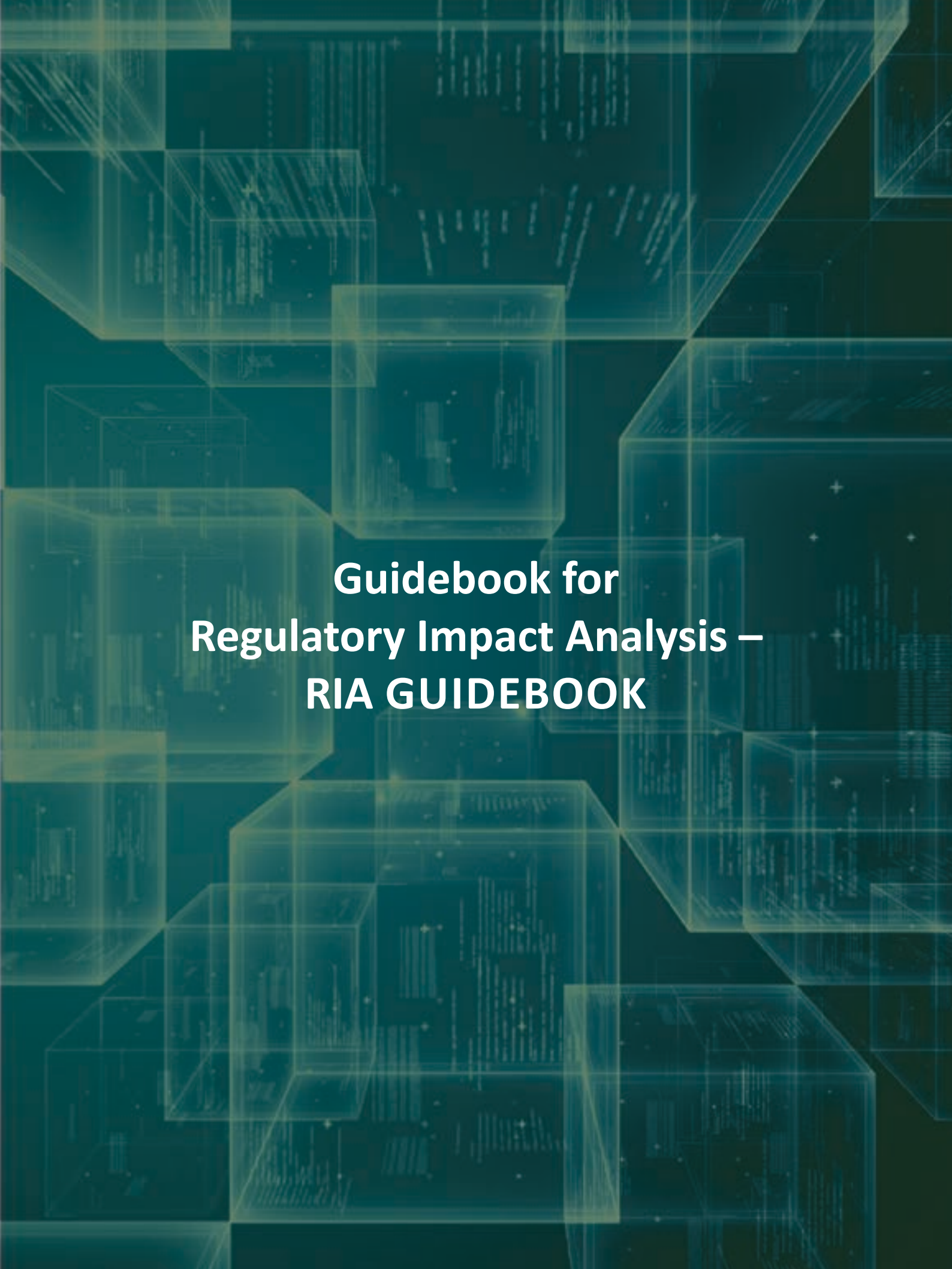
The regulatory entity shall establish the procedures for the consultations and public hearings.

The regulatory entity may establish other means of stakeholder engagement, either directly or through legally recognised organisations and associations.



	<p>The regulatory entity must make their position available at their headquarters and on their respective website up to 30 (thirty) working days after a decision is made on the matter.</p> <p>Any reports from public hearings or other means of stakeholder engagement must be made available at the headquarters of the regulatory entity and on their respective website up to 30 (thirty) business days of their conclusion.</p> <p>The public hearing reports must contain at least an attendance list, a summary record and the number of statements presented.</p> <p>In highly complex cases, the consultation period may be extended only once and by an equal amount of time, as long as it is justified.</p>
<b>REGISTER OF STAKEHOLDERS</b>	Regulatory entities may keep a register of stakeholders in order to send (preferably) e-mail alerts about stakeholder engagement opportunities, notices of new public consultations, deadline for contributions, and the schedule of public hearings.
<b>DECISION-MAKING PROCESS NOT BOUND TO RIA REPORT</b>	The RIA report does not bind the final regulatory decision.
<b>REASONED DECISIONS BY THE DECISION-MAKING AUTHORITY/ IES</b>	Any decision contrary to RIA recommendations must be duly reasoned by the Decision-Making Authority/ies.
<b>RIA AND ROE IMPLEMENTATION</b>	The bylaws of each regulatory entity shall detail the procedures of RIA and ROE. <b>RIA and ROE Implementation</b> is hereby understood as the definition of which organisational units are going to be involved in the preparation of both the RIA and ROE, and their respective powers. Such detailed procedures shall be established in a specific rule.
<b>REGULATORY STOCK REVIEW</b>	If the regulatory entity decides that issuing or amending a regulation is the best available alternative to address the regulatory problem, the new or updated rule shall include a deadline for its future review.
<b>REGULATORY OUTCOME EVALUATION - ROE</b>	Regulations or amendments to regulations exempted from RIA due to urgency or which were subjected to RIA Level II, shall be object of a Regulatory Outcome Evaluation - ROE, based on the effects observed: I - within a period of two years from the date of its entry into force, in cases of urgency; II - within the deadline defined in the rule itself, for RIA Level II cases.
<b>STRATEGIES FOR DATA COLLECTION AND PROCESSING</b>	The regulatory entity shall implement specific strategies to collect and treat data in order to enable quantitative analyses of costs and benefits, if applicable.
<b>AVAILABILITY OF RIA REPORT INVENTORIES AND LIST OF WAIVED RIA CASES FOR ELECTRONIC CONSULTATION</b>	The regulatory entity shall keep an inventory of RIA reports and a list of waived RIA cases available for consultation on their respective websites, ensuring their contents can be easily located and identified by the public, except for confidential cases.





**Guidebook for  
Regulatory Impact Analysis –  
RIA GUIDEBOOK**



# 1. INTRODUCTION

## 1.1 Purpose of this Guidebook

The purpose of this Guidebook is to assist civil servants responsible for conducting Regulatory Impact Analyses - RIA. Our purpose is to present a basic roadmap for RIA, with the directives that shall guide the analysis, without entering into detailed discussions about specific techniques or methodologies.

For a more detailed knowledge of each RIA stage and the applicable techniques and methodologies, it is undeniably important to consult the available literature, manuals or specialised publications, some of which are mentioned throughout this document.

**Considering the advisory nature, the procedures presented herewith are not binding.** The more or less comprehensive application shall be defined on case-by-case basis, according to the complexity of the subject under analysis and the experience accumulated by the regulatory entity.

Please note that although the Guide was initially developed with a focus on Regulatory Agencies, the recommendations compiled may be used by any public administration bodies or entities enacting rules with potential to amend rights or create obligations for third parties<sup>3</sup>.

The Glossary at the end of this document provides definitions and concepts used in this Guide.

## 1.2 Better Regulation Principles

A regulation is an instrument whereby the State intervenes in the behaviour of agents in order to improve efficiency, safety, economic growth and social welfare.

However, if used arbitrarily and disproportionately, it can have substantially harmful effects on markets and on the society as a whole, such as higher prices of products or services,

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<sup>3</sup> In this document we will refer to the regulatory agencies, ministries, bodies and other public entities with powers to enact regulatory rules as regulatory entities.

reduced investments, barriers to entry, barriers to innovation, high costs of conformity to the regulated sector, increased risks and market distortions. In addition, regulations also impose **inspection** and **monitoring** costs to regulators. Therefore, they shall only be created when it is justifiable.

Most developed countries recognise the costs and consequences of poor regulation, so that they have been directing efforts, since the early 1990s, to implement mechanisms and tools to improve regulatory quality and performance.

The Organisation for Economic Co-operation and Development - OECD has dedicated its attention to studying and writing about this subject. In the Recommendation on Improving the Quality of Government Regulation, the Organisation proposes a roadmap according to which good regulation shall:

- aim to solve problems and achieve clearly defined objectives, while being effective in achieving them;
- be evidence-based and proportional to the problem identified;
- be based on a sound legal basis;
- create benefits which outweigh its costs;
- consider the distribution of its effects among different stakeholders and groups;
- minimise administrative costs and possible market distortions resulting from the implementation;
- be clear and understandable to regulated agents and users;
- be consistent with other regulations and policies;
- be transparent in its preparation, with adequate procedures for effective and timely manifestations by stakeholders and groups; and
- consider the incentives and mechanisms to achieve the desired effects, including implementation strategies that maximise the results.

As Carlos Ari Sundfeld highlights:

*“regulation, as a form of state intervention, manifest itself both as strength and action with stated economic objectives (control of market concentration, repression of violations to the economic order, control of prices and fees, admission of new agents in the market) and as other objectives with multiple justifications and inevitable economic effects (environmental measures, urban planning, standardisation, regulation of professions, etc.). Regulations are issued not only by authorities whose mission is to watch over a specific field of activities (the stock market, telecommunications, energy, health insurance,*

*oil), but also by those those with powers over the majority of economic agents. (e.g.: environmental agencies). (Direito Administrativo Econômico. 2002, p. 18).<sup>4</sup>*

In Brazil, despite the existence of several regulatory agencies for specific sectors, several other bodies and entities carry out regulatory activities, as for the Brazilian Central Bank (Bacen), the Securities and Exchange Commission (CVM), the Superintendence of Private Insurance (Susep), etc<sup>5</sup>. The Federal Direct Administration also exercises a regulatory function. For example: increasing and reducing the IOF (financial tax) rate to intervene in foreign currency trading (Federal Revenue Service); regulating levels of compulsory deposits by financial institutions to increase or reduce the amount of currency in circulation (Bacen); regulating the quantity, quality and funding rules for higher education student loans to increase the offer of or access to this service (Ministry of Education); regulating the production and trading of animal products and of beverages and plant products (Ministry of Agriculture, Livestock and Food Supply).

### 1.3 What is RIA

RIA is one of the key instruments focused on improving regulatory quality. **It consists of a systematic process of evidence-based analysis that starts with the definition of a regulatory problem and then assesses the possible impacts of the available alternatives to reach the desired objectives. Its purpose is to advise and subsidise decision-making, and ultimately contribute to the efficiency, efficacy and effectiveness of regulatory actions.**

**Figure 1** - Regulatory Impact Assessment Process



Source: Prepared by the author/s

<sup>4</sup> CONSTANTINO, Giuseppe Luigi Pantoja. Regulação de serviços públicos: conceitos e evolução histórica. Conteúdo Jurídico, Brasília-DF: 20 de agosto de 2014. Available at: <http://www.conteudojuridico.com.br/?artigos&ver=2.49487&seo=1>.

<sup>5</sup> These entities, along with the independent regulatory agencies, are part of the indirect administration that has regulatory powers.

In many cases, regulatory decisions are based on limited information and without proper consideration to which groups will be affected and how. RIA wants to change this practice. The mere identification of a problem is not a justification for governmental intervention.

RIA shall not be understood as a mere comparison between intervention alternatives. Prior to this, a RIA must understand the nature and dimension of the regulatory problem, define what are the regulator’s intended objectives, and analyse whether any kind of intervention is actually necessary. It is only after this initial reflection that one can start to identify and analyse possible alternatives so that a decision about the best choice may be made. After examining all relevant information and considerations, RIA may even indicate that the best possible alternative is to not to regulate.

Additionally, a RIA shall briefly outline an implementation strategy for the recommended -alternative and inform how its effects can be monitored. Therefore, a RIA contributes not only to drafting the regulation, but also to the remaining regulatory cycle, as shown in Figure 2.

**Figure 2** - Regulatory Cycle



Source: Prepared by the authors

The RIA analyses and results shall be presented in the RIA Report, available to decision makers and to the general public.



The Report will allow decision makers to:

- (a) have better knowledge of the real need for intervention;
- (b) identify possible alternatives, their advantages and disadvantages; and
- (c) make better-informed decisions and be more confident about the possible effects.

For the general public, the RIA Report shall be able to communicate clearly:

- (a) the identified problem and the need for intervention by the regulatory entity;
- (b) the expected benefits from the recommended action and why it was chosen among other options available; and
- (c) the constraints or obligations generated by the recommended alternative and how it will be implemented.

**Both the decision makers and the civil servants involved in its preparation shall keep in mind that the RIA Report is a non-binding document.** It is a technical analysis intended to subsidise decision makers and give them more confidence.

**Thus, RIA does not take away the jurisdiction of the decision-making authority/ies of the regulatory entities to take action or not, nor does it replace their judgement over which is the best intervention. However, to ensure transparency in the regulatory process, any deliberations contrary to RIA recommendations shall be specifically substantiated by the decision-making authority/ies.**

## 1.4 When to conduct a RIA

RIA shall be conducted whenever the regulatory entity identifies a **regulatory problem** that may require issuing or amending rules, or taking any other action with the potential to influence the rights or obligations of economic agents, consumers, or users of services provided by companies in the regulated sector.

In keeping with the principles of rationality and proportionality, **RIA is not applicable** in the following cases:

- I – **administrative rules** with effects restricted to the regulatory entity itself;
- II – **decisions intended to regulate specific situations and applicable to specific individuals/companies;**
- III – **decisions that correct errors** involving syntax, spelling, punctuation, typography and numbering of previously published regulations;
- IV – **rules drafted to consolidate other regulations** on a certain subject, without changing their merit.

V – **rules drafted to revoke or update obsolete rules**, without any change of merit.

**The mandatory RIA may be waived in the following cases by a reasoned decision of the decision-making authority/ies of the regulatory entity:**

I – **urgency**;

II – **rules intended to regulate rights or obligations defined in a superior legal instrument that** do not allow the possibility of different regulatory alternatives;

III – **rules of manifest low impact**.

Any rule or amendments to rules exempt from a prior RIA due to urgency, as decided by the decision-making authority/ies or subjected to RIA Level II, shall undergo a **Regulatory Outcome Evaluation - ROE**, based on the effects observed:

I – within a period of up to 2 years from its entry into force, in cases of urgency;

II – within the deadline defined in the normative rule itself, for RIA Level II cases.

It is important to remember that the outcome of an action can only be evaluated when the expected effects are compared to the actual effects observed after implementation. Therefore, **in urgent cases where the RIA is waived, while drafting the regulatory rule it is important to identify the regulatory problem that needs to be addressed and the objectives to be achieved. They shall be presented in a technical note or an equivalent document in order to subsidise the future preparation of the ROE.**

In order to improve transparency and social control, **the regulatory entities shall keep their inventory of RIA Reports as well as a list of cases of waived RIA available for consultation on their respective websites**, ensuring easy location and identification of contents by the general public, except for confidential cases.

## 2. GENERAL GUIDANCE

**The RIA shall not be understood as a questionnaire or a list of items to be filled in to justify the creation of a regulation. In order to serve its purpose, it must consist of a process to diagnose the problem, reflect on the need for regulation, and investigate the best way to achieve it.**

As highlighted by OECD, RIA's most important contribution to the quality of regulatory decisions is not the precision of the calculations, but the analysis itself, questioning and understanding the potential impacts of regulation and exploring the possible alternatives (OECD, 2008).

The methods, techniques and methodologies applied shall be defined on a case-by-case basis. However, **a good RIA shall begin in the early stages of the regulatory process** and shall follow some minimum necessary stages, detailed in Chapter 3 of this guidebook.

Every analysis shall be conducted with a delimiting reference period (5 years, 10 years), which shall be expressed in the RIA Report.

To ensure the quality of the analysis and the consideration of different perspectives, it is important that different areas of the regulatory entities are involved in the preparation of RIA, especially those responsible for its implementation, inspection and monitoring. If they cannot be directly involved throughout the development of RIA, they shall at least be consulted in order to bring their contributions to the analysis.

**The roadmap to this guidebook shall not be understood as a hermetical or exhaustive logical sequence. On the contrary, the stages listed here will often be interactive, so that information provided during more advanced phases will require a review or adaptation of previous phases.** In other cases, stages and processes that are more limited in detail or are not described in this guidebook may be necessary because of the specific or complex nature of the subject.

Despite the specificities of each case, a good RIA shall observe some fundamental characteristics, described as follows.

## 2.1 Proportionality and levels of analysis (RIA Level I and RIA Level II)

RIA shall always observe the principle of proportionality, which means that the time, effort and resources invested in the analysis, shall be proportionate to the relevance of the problem investigated and to the potential impacts of government intervention.

In order to fulfil its purposes, the RIA shall include at least the following stages - **RIA Level I:**

- (a) executive summary;
- (b) identification of the regulatory problem;
- (c) identification of stakeholders or groups affected by the identified regulatory problem;
- (d) identification of the legal basis supporting the regulatory entity's intervention regarding the subject under analysis;
- (e) definition of the objectives to be achieved;
- (f) description of possible alternatives to address the identified regulatory problem, including the no-action option, as well as regulatory solutions and, whenever possible, non-regulatory options;
- (g) explanation of the potential impacts of the identified alternatives;
- (h) comparison among the considered alternatives, pointing out the most adequate alternative or combination of alternatives to achieve the intended objectives, and justifying this choice;
- (i) description of the implementation strategy for the suggested alternative, including ways to monitor and inspect its results, as well as any need to amend or revoke existing regulations;
- (j) considerations regarding information, contributions and participants' manifestations received throughout the RIA preparation in the stakeholder engagement processes;
- (k) full name and position of the civil servants that took part in the RIA and signature of the civil servant responsible for the analysis.

**The proportionality principle is not connected with the need to conduct a RIA in full or in part. It is related to the detail or the depth of the analysis and shall be considered in each of its stages.**

Practice and experience will reveal cases that require further analysis, even during preparation of the RIA. In more complex cases, a basic analysis level will not be able to appropriately identify and investigate all factors relevant to decision-making.

**When this initial analysis is insufficient, the most relevant impacts shall undergo a more detailed analysis - RIA Level II, if possible, using quantitative methods. Apart from**

**the extra effort of using quantitative techniques, the analysis of more complex cases will require at least the following elements, in addition to those previously mentioned:**

- (l) international benchmarking of experiences on dealing with regulatory problems similar to the one under analysis;
- (m) measurement of the potential impacts of identified alternatives on consumers or users of services, and on other affected major segments of society; and
- (n) risk assessment.

A few criteria that most commonly influence the depth and level of analysis are:

- type, dimension, duration and distribution of impacts among stakeholders or groups;
- uniqueness of the problem or the limited experience with it;
- degree of innovation or the irreversibility of the impacts of the considered alternatives;
- sensitivity of the issue among relevant stakeholders (the regulated sector, consumers, other public entities, legislative branch, etc.);
- risks type or level involved in the problem or in the considered alternatives considered; and
- degree of uncertainty or results sensitivity in relation to relevant components of the analysis (impacts, assumptions, data, etc.);

Some countries opted for the publication of rules defining quantitative or qualitative criteria or parameters that, once noticed, compel to more advanced analysis. A few examples of variables used as parameters to define the level of analysis in OECD countries are:

- Type of impacts involved: for example, on health, safety, environment, competition, etc.;
- Total costs imposed to stakeholders by the considered alternatives;
- Amount or percentage of the population impacted by the considered alternatives;
- Budget impact of the considered alternatives for the regulatory entity or for the government as a whole.

## 2.2 Plain Language

The language and form at RIA Report presentation are key elements for its practical use in the regulatory process.

The Report shall provide a logical reasoning, enabling an easy sequencing of facts, arguments and conclusions.

The Report shall focus on relevant issues, avoiding the inclusion of secondary aspects, because excessively long documents are a hindrance and a discouragement to the reader. It is important to keep in mind that the RIA Report is not an academic document, but a working one. At each stage, the most relevant questions and arguments shall be presented first. Overly technical analyses, in-depth details about the methodology, assumptions or scenarios adopted can be on the annexes of the document if they do not affect the analysis comprehension.

It is also important to remember that in addition to advising the decision-making authority/ies, the RIA Report shall substantiate and communicate the actions of the regulatory entity to the external public (regulated companies, consumers, associations, trade unions, other government bodies, the media, etc.). It shall also encourage the stakeholders' participation in the regulatory process.

Therefore, the language used shall be as simple as possible, making sure the various interested parties can understand the Report. The excessive use of technical jargon or unfamiliar expressions shall be avoided, and when they are necessary, their definitions shall be included to avoid ambiguities or questionings.

## 2.3 Data and information sources

Since the RIA is an evidence-based analysis process, a crucial element for its preparation is to collect data and information that can guarantee its reliability, thereby reducing the degree of subjectivity.

Other sources of information can be used in addition to internal data available to the regulatory entity, such as other public institutions, public or private databases, academic papers and studies, specialised publications, researches, consultation and social participation processes, and information obtained from data exchange processes or technical cooperation agreements with foreign Governments.

The RIA Report shall be transparent in its methods, data and information sources, except for those that are confidential. It is recommended that qualified third parties can replicate the analyses, in order to grant external legitimacy to the RIA.

It is advisable that the collection of information or data used in the RIA has the following characteristics:

- Public accessibility;
- It shall be accurate and impartial to enable its confirmation by other sources or by empirical evidence and not only reflect particular values and interests;
- Reputable source with recognised reliability or credibility, or one that shows no reason to anticipate future questionings or reviews of data or information used; and
- It shall be up-to-date and relevant.

The RIA shall also take into consideration the data and information that will be needed to monitor and evaluate the results of the implemented alternative.

The regulatory entities shall implement specific strategies to collect, organise and process data, in order to enable quantitative analyses, and subsequently, proper Regulatory Outcome Evaluation (ROE) and monitoring.

## 2.4 Stakeholder engagement and transparency

International experience demonstrates that dialogue and consultations with external players are essential to a high-quality RIA. When conducted properly, stakeholder engagements processes not only reduce information asymmetry, but also substantiate and legitimise decision-making.

Public consultation and public hearing are already common practice among Federal Regulatory Agencies, which follow the rites and procedures defined by law or other specific regulations on the matter, and among a few bodies and entities of the direct federal administration. However, these processes are often held after the decision about the alternative to be implemented is taken, to collect contributions and opinions on the draft rule text.

**Good regulatory practice recommends that consultations and dialogue with stakeholders shall begin as soon as possible, in the early stages the RIA.** The objective is to invite relevant stakeholders to contribute to the quality of the analysis that will guide the decision. When they are involved after the decision made, they tend to focus only on the regulation draft text, without considering the analysis that culminated in the proposal, even when the RIA is available for consultation together with the draft rule.

The **stakeholder engagement** processes conducted to gather information and receive contributions can occur:

- throughout the entire RIA process;
- at predefined milestones;
- when there is need for additional specific information; or
- after the RIA Report has been concluded, as a mean to validate evidences, diagnoses, premises and assumptions that have underpinned the analysis.

While respecting all general or internal regulations addressing the matter, stakeholder engagement processes held to develop a RIA can take different forms and have different scopes, depending on the nature of the information that needs to be obtained<sup>6</sup>.

<sup>6</sup> Decree No. 8,243/2014 establishing the National Social Participation Policy (PNPS) and the National Social Participation System (SNPS) contains minimum guidelines for consultations and public hearings. Available on: [http://www.planalto.gov.br/ccivil\\_03/\\_ato2011-2014/2014/decreto/d8243.htm](http://www.planalto.gov.br/ccivil_03/_ato2011-2014/2014/decreto/d8243.htm)

A few basic precautions shall be in place when conducting stakeholder engagement processes:

- clearly define the purpose of the consultation: whether to identify the problem, to map alternatives, identify impacts, collect data, validate assumptions and hypotheses, etc.;
- define the target consultation group: regulated companies, consumers, employees, other government bodies, experts, etc.;
- organise the demand for information: avoid asking for data or posing unnecessary questions, which can reduce encouragement to participation or take the focus away from relevant information;
- define the best consultation method to reach the target audience, using channels that facilitate participation: meetings, debates, consultations, opinion polls, questionnaires, letters, face-to-face meetings, electronic platforms or other means of communication, etc.;
- use language that is adequate for the targeted audience;
- use adequate means of communication or publicity to ensure that the target audience has adequate information timely;
- ensure an appropriate deadline for the consultation process, according to the complexity of the subject under review and the information desired, so as to enable and encourage stakeholders to prepare effective contributions;
- conduct the consultation during a favourable period, avoiding vacations, public celebrations, public holidays, etc. whenever possible; and
- ensure the confidentiality of sensitive information.

In order to improve communication with relevant stakeholders, regulatory entities may keep a register of stakeholders in order to send them alerts, preferably by e-mail and in advance, about stakeholder engagement, including the publication of new public consultations or public hearings.

When preparing stakeholder engagement processes and also when analysing the received contributions, stakeholder representation shall be guaranteed.

Typically, not all groups affected by the problem or the alternatives considered are sufficiently organised or are in condition to express their opinions. The regulatory entity shall, therefore, make special effort to make sure the rights and interests of these groups are also taken into consideration.

When analysing the manifestations received, it is also important to note whether they reflect a wide range of interests in order to avoid undue influence by any particular groups.



Another important aspect in stakeholder engagement processes is to distinguish opinions from facts and evidence. The regulatory entity shall also verify the quality and reliability of the data received and make it clear in the RIA Report who provided it and how the information was used in the analysis.

Finally, the RIA Report shall contain a **specific section containing information on stakeholder engagement processes**, offering the regulatory entity's considerations on information, manifestations, contributions and criticism received in these processes.

It is important to clarify that dialogue with external audiences does not imply in a process of negotiation with them, nor does it imply in loss of authority or autonomy of the regulatory entity in the decision-making process.

### RECOMMENDED READING

CANADA (s.d), Treasury Board of Canada Secretariat. Guidelines for Effective Regulatory Consultations. Available on: <https://www.canada.ca/en/treasury-board-secretariat/services/federal-regulatory-management/guidelines-tools/effective-regulatory-consultations.html>

EUROPEAN COMMISSION (2015). Better Regulation "Toolbox", Chapter 7. Available on: [http://ec.europa.eu/smart-regulation/guidelines/docs/br\\_toolbox\\_en.pdf](http://ec.europa.eu/smart-regulation/guidelines/docs/br_toolbox_en.pdf)

ISRAEL (2013), Governance and Social Affairs Department, Prime Minister's Office. Regulatory Impact Assessment: Governmental Handbook. Version 1.0. Available on: <http://www.pmo.gov.il/SiteCollectionDocuments/mimshal/Regulatory%20Impact%20Assessment.pdf>

OECD (2017) Draft Best Practice Principles on Stakeholder Engagement in Regulatory Policy (the Principles), Minutes for Public Consultation, Directorate for Public Governance. Available on: <http://www.oecd.org/gov/regulatory-policy/public-consultation-best-practice-principles-on-stakeholder-engagement.htm>

OECD (2015) Stakeholder engagement and regulatory policy. OECD Regulatory Policy Outlook 2015, Chapter 3. Available on: [http://www.oecd-ilibrary.org/governance/oecd-regulatory-policy-outlook-2015/stakeholder-engagement-and-regulatory-policy\\_9789264238770-8-en](http://www.oecd-ilibrary.org/governance/oecd-regulatory-policy-outlook-2015/stakeholder-engagement-and-regulatory-policy_9789264238770-8-en)

UNITED KINGDOM (2016). UK Cabinet Office. Consultation principles: Guidance. Available on: <https://www.gov.uk/government/publications/consultation-principles-guidance>



# 3. RIA REPORT

## RIA Level I

### 3.1 Executive Summary

In order to improve transparency and favour understanding, the RIA Report shall start with **an objective and concise Executive Summary, written in plain language and accessible to the general public.**

The summary shall be written after the RIA has been completed, and shall express a synthesis of the analysis and the conclusions reached.

In spite of its brief format, the summary shall make sense even when the reader does not read the RIA Report in full. Therefore, it shall highlight the most important issues regarding the following matters:

- the identified regulatory problem;
- the defined objectives;
- the considered solution alternatives;
- the suggested alternative and the reason it was chosen;
- possible impacts of the proposed alternative.

### 3.2 Identifying the problem

**This stage consists of presenting the problem that drew the attention of the regulatory entity to the possible necessity for a regulatory intervention.**

**The phase in which the regulatory problem is identified is essential to develop a high-quality RIA. It requires special dedication from civil servants who conduct the RIA, since it is only after the problem is correctly identified that it will be possible to find effective solutions.**

**The problem identification shall begin with a broad perspective, considering it under many different points of view.**

**After this initial investigation, the problem shall be clearly defined, to avoid ambiguity. The nature, causes and consequences of the problem, its extent and its expected evolution in the absence of intervention shall also be identified and presented.**

**The following terms shall be avoided when defining the problem: ABSENCE, LACK, OBSOLESCENCE, INSUFFICIENCY, LACK OF CAPACITY, INADEQUACY, LACK OF COORDINATION, LOW QUALITY, DELAYS and INEFFICIENCY, RELIABILITY, LOSS, FRAGILITY and others.**

A key component in any RIA is the correct understanding and definition of the problem that initially drew the regulatory entity’s attention. This is the starting point of the entire analytical work that will be carried throughout the RIA. Only with a clear problem definition, its causes and consequences, it will be possible to identify the possible solutions and choose the best alternative to achieve the desired objectives.

A **regulatory problem** may involve different elements such as price, market entry, information, quality, quantity, etc. with different natures, such as market failures, regulatory failures, institutional failures, need to guarantee conditions or fundamental rights to citizens or to promote public policy objectives.

**Table 1** - The Nature of Regulatory Problems

<p><b>Market Failure</b></p>	<p>It occurs when efficient economic result is not achieved by the market, causing sub-optimal allocations of resources and preventing the maximum social welfare. The most common market failures are market power (monopoly, natural monopoly, and imperfect competition), positive or negative externalities, information asymmetry and the existence of public or merit goods.</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Information asymmetry among health market agents; and</li> <li>• Entry barriers to oil exploration market due to high initial investments required.</li> </ul>
<p><b>Regulatory Failure</b></p>	<p>It occurs when an action taken to solve a regulatory problem is not effective or is inconsistent, creating new problems or aggravating existing one(s). This can occur for numerous reasons, such as poor defined problems or objectives, failure when implementing or inspecting regulation, unpredicted consequences, inconsistencies between competing or complementary regulations, disruptive innovations, etc.</p>

	<p>Examples:</p> <p>Regulation edited to stimulate new electric power plants near consumer markets in order to reduce power losses in transmission and distribution. Soon after rule edition, one verified that remote power plants were also stimulated, creating an undesired effect.</p>
<b>Institutional Failure</b>	<p>It occurs when institutions act in a dysfunctional manner or their performance is unsuitable, thus jeopardizing efficiency or preventing desired objectives from being achieved. Lack of clarity, duplicated or overlapping institution powers, rigidity towards changing rules or structures to adapt to new realities, institutional capture are examples that can cause institutional failures.</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Complex language in rules lead to diverging interpretations about obligations to be followed by third parties;</li> <li>• Overlapping powers or lack of competency clarity involving two or more regulatory entities or lack of coordination can result in conflicting rules, making it difficult or even impossible to the regulated stakeholders to comply with.</li> </ul>
<b>Unacceptable Risks</b>	<p>It occurs when there are risks considered intolerable or that can only be justified in exceptional circumstances. This kind of risk can vary according to local culture, country's income level, etc.</p> <p>Example:</p> <p>Risk of financial system failure: can lead to the enactment of prudential regulations.</p>
<b>Contribute to ensure fundamental rights</b>	<p>It occurs when regulation is needed to secure or preserve citizen's fundamental rights, for example, life, freedom, integrity, safety, privacy, etc.</p> <p>Example:</p> <p>Regulation on personal data to protect citizen's privacy: regulation for access, use or sale of personal data, etc.</p>
<b>Contribute to policy objectives</b>	<p>It occurs when there is an urge for intervention to secure public policy objectives such as equality, housing, health, protection of domestic industry.</p> <p>Example:</p> <p>Regulation issued to pursue broadband massification, contributing to fulfil public policy objectives such as digital inclusion and productivity improvement, with consequences for economic development, as well as the massification of educational and health policies.</p>

Source: Prepared by the author/s

A good problem definition shall provide clear and objective answers to the following questions:

- What is the context surrounding the problem? In other words, what are the circumstances in which the problem is being considered?
- What are the nature and consequences of the problem?
- What are the causes or problem triggers?
- What is the extent or magnitude of the problem, in other words, where does it occur (local, regional or national level), how often, and what is the size of the affected groups?
- What is the expected problem evolution in case of no intervention?

In many cases, problems are multifaceted, with many causes or origins, and affect various groups or stakeholders in different ways and with different intensities. In such cases, it is important to consider and investigate as many aspects as possible. Eventually, the different causes and different groups affected will need some balancing, either to define objectives or to analyse the alternatives.

This stage demands special attention to identify the problem root cause/s – its primary and fundamental causes. They are conditions, scenarios and behaviours that need to be changed to prevent the problem from happening again. Investigating the root cause is important to treat the problem real causes and not its symptoms. Very often, the cause initially identified has actually been created by another factor. A logical way to trace the root causes is to try to build a backward sequence of events, trying to understand the links between contributing and primary factors. It is only by treating the root causes that one can prevent the problem from happening again. Literature presents several techniques to analyse the root cause, for example: 5 Whys; the Problem Tree; the Ishikawa Diagram (also known as Fishbone Diagram); QC Story; Kepner-Tregoe Method and the Theory of Constraints.

The problem shall not be defined as a “lack of something” or a “need for something”. This could direct the definition of objectives and, consequently, the choice of the best alternative to face the problem. Castro and Renda (2015) highlight that it is essential to avoid describing the problem as “lack of public intervention”, because this intervention can, indeed, be one of the possible solutions to the problem, but it is not “the problem itself”.

The problem definition shall include an assessment of its scope and consequences. One shall investigate and demonstrate that the problem is relevant and has sufficient repercussions to justify an intervention by the regulatory entity, and that it is not an isolated or circumstantial fact.

This stage shall also include a brief description of the expected evolution of the problem if no intervention is made. One shall investigate whether the problem will continue to exist or escalate during the period considered for the analysis, and whether its consequences will

be irreversible. The no-action scenario (or the maintenance of ongoing actions or regulation in force) is known as the baseline scenario.

### RECOMMENDED READING

ALVAREZ, R. dos R. (1997). Métodos de Identificação, Análise e Solução de Problemas: uma Análise Comparativa. In: XVII Encontro Nacional de Engenharia de Produção, Gramado. Anais - ENEGEP 97. Porto Alegre: ABEPRO, 1997. Available on: [http://www.abepro.org.br/biblioteca/enegep1997\\_t1109.pdf](http://www.abepro.org.br/biblioteca/enegep1997_t1109.pdf)

AUSTRALIA (2003). Department of the Treasury, Practice Guide for Preparing Regulatory Impact Statements. Available on: [http://www.treasury.act.gov.au/documents/regulatory\\_impact\\_statement\\_guide.pdf](http://www.treasury.act.gov.au/documents/regulatory_impact_statement_guide.pdf)

CASTRO, R J., RENDA, A. (2015). Guía al Estudio de Impacto Regulatoria em la República de Ecuador. Documento preparado para la Secretaría Nacional de Planificación y el Desarrollo (SENPLADES) del Gobierno de Ecuador.

EUROPEAN COMMISSION (2015). Better Regulation “Toolbox”, Chapter 2. Available on: [http://ec.europa.eu/smart-regulation/guidelines/docs/br\\_toolbox\\_en.pdf](http://ec.europa.eu/smart-regulation/guidelines/docs/br_toolbox_en.pdf)

UNITED KINGDOM (2018). HM Treasury, Green Book: Central Government Guidance on Appraisal and Evaluation. Available on: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/685903/The\\_Green\\_Book.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/685903/The_Green_Book.pdf)

SERRAT, O. (2009). The five ways technique. Washington, DC: Asian Development Bank. Available on: <http://www.adb.org/publications/five-whys-technique>

SUBIRATS, J. (2006). Definición del problema. Relevancia pública y formación de la agenda de actuación de los poderes públicos em políticas públicas. In: SARAVIA, E.; FERRAREZI, E. Políticas públicas. Coletânea Volume 1– Brasília: ENAP, 2006. 199-218

### 3.3 Identifying the stakeholders or groups affected by the regulatory problem

**This stage shall clearly identify the main stakeholders or groups affected by the regulatory problem under analysis.**

**These stakeholders’ vision about the regulatory problem in question is an important input to understand its causes and extension properly. Therefore, it is important to define a strategy for stakeholder engagement.**

A fundamental part of understanding and treating the problem is to identify the stakeholders affected by it. The analysis shall clearly state how the problem impacts individuals, companies, groups or sectors, and describe how they are affected.

This stage shall answer the following questions:

- Which stakeholders or groups are being affected by the regulatory problem?
- How does the problem affect each stakeholder or group directly or indirectly?
- What is the relevance of the observed effects for each stakeholder or group?
- Do the affected stakeholders or groups contribute to the continuity or intensification of the problem? Are there any changes in behaviour or measures that these stakeholders or groups could take to avoid or minimise the effects?
- How the problem effects are evolving for each stakeholder or group?
- What are the prospects for these effects if nothing is done?

To help describe the affected stakeholders and draw a distinction between their visions and interests, they may be differentiated as follows:

- directly or indirectly affected by the problem;
- benefited or jeopardised by the problem;
- according to their magnitude or importance;
- according to their location;
- public or private; and
- already active in the market or new entrants.

The identification of affected stakeholders shall be supported by a factual basis. In this stage, any data, information, documents, or available references that can demonstrate the effects and relevance of the problem for the mentioned stakeholders shall be pointed out.

In order to obtain this information, it is important to know the opinion of the affected stakeholders on the matter. They often have the necessary knowledge to identify misconceptions, false assumptions, and incorrect information and to point out elements that have not yet been identified. Another interesting alternative is to consult experts on the matter under analysis. Therefore, there shall be a defined strategy for consultation and dialogue with these stakeholders, either through meetings, memos, letters, electronic messages, or questionnaires available on the website of the regulatory entity.



## RECOMMENDED READING

EUROPEAN COMMISSION (2015). Better Regulation “Toolbox”. Available on: [https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox\\_en](https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox_en)

EUROPEAN COMMISSION (2015). Better Regulation Guidelines – Guidelines on Stakeholder Consultation. Available on: [http://ec.europa.eu/smart-regulation/guidelines/ug\\_chap7\\_en.htm](http://ec.europa.eu/smart-regulation/guidelines/ug_chap7_en.htm)

### 3.4 Identifying the legal basis

**In this stage, one shall analyse whether the regulatory entity has legal support to act on the identified problem.**

**Please also consider whether there are competing and complementary powers with other bodies, entities or levels of government, and whether the regulatory entity is the most appropriate player to intervene.**

Once the regulatory problem is defined and the affected stakeholders and groups are identified, it is necessary to check if the regulatory entity has legal basis to act on the problem in question. The entity mandate shall be demonstrated by means of identifying provisions in laws, decrees or other rules that assign competencies on the subject and jurisdiction over all the affected stakeholders.

At this point, one shall also verify the existence of complementary or competing powers from other bodies, entities or levels of government regarding the problem in question. If they exist, these powers shall be briefly described.

One shall analyse whether the regulatory entity is the most appropriate authority to act on the identified problem, whether it has the powers to deal with the issue or whether articulation with other institutions is necessary.

It is also advisable to look for relevant recommendations or resolutions from other entities related to the identified problem, including line ministries, the Federal Court of Accounts, the Ministry of Transparency and Administrative Council for Economic Defence. If there are, it is important to quote the technical opinions, rulings, recommendations and decisions that formalise their institutional position.

Sometimes, at an advanced stage of the analysis, the complexity of the alternatives or the intensity of the expected impacts, for example, may demonstrate that the initial competency analysis shall be re-evaluated. It is possible to conclude that the regulatory entity is not the

best institution to act on the problem, or that an individual action will not be sufficient to treat the problem properly.

## REFERENCE SOURCES

<http://www4.planalto.gov.br/legislacao>

<http://www.camara.leg.br/buscaProposicoesWeb/pesquisaSimplificada>

<http://www12.senado.leg.br/hpsenado>

<https://contas.tcu.gov.br/pesquisaJurisprudencia/#/pesquisa/jurisprudencia>

<http://www.cgu.gov.br/>

<http://www.cade.gov.br/>

### 3.5 Defining the objectives to be achieved

**In this stage, the regulatory entity shall clearly define the objectives that intends to achieve with regard to the identified regulatory problem.**

**The objectives shall be in line with the public policies defined for the sector and the regulatory entity’s strategic planning.**

**The objectives shall be directly related and proportional to the regulatory problem and its causes.**

**The defined objectives will guide the analysis and comparison of the mapped alternatives and will be the parameter for the implementation, monitoring and evaluation strategies for the chosen alternative.**

Before proposing solutions to the regulatory problem, it is necessary to outline clearly what **objectives** the regulatory entity intends to achieve. Without this definition, it is not possible to identify the possible alternatives and to compare them objectively or to evaluate which is the most effective. In addition, the success of implemented alternative can only be evaluated according to previously defined objectives.

The objectives shall be aligned to the public policies defined for the sector and shall be related with the mission and strategic objectives of the regulatory entity.

A common misunderstanding at this stage is the confusion between the objectives intended (fundamental objectives) and the means of attaining them (means-objectives). For example, “reducing air pollution” is a fundamental objective, achievable by different means, such as

reducing carbon monoxide emissions by motor vehicles, reducing pollution from industrial processes, etc. One way to find out if a proposed objective is a fundamental objective is to ask the question “Why is this goal important?” If the answer is “it is important to achieve another objective”, it means that it is a means-objective.

While fundamental objectives need to be defined after the problem and the affected stakeholders identification, the detailing of desirable objectives may require adjustments as the RIA progresses because of new elements or factors known along the analysis.

Different methods to define objectives can be found in the literature, such as the “Hierarchy of Fundamental Objectives” and the “Network of Means-Ends Objectives” (KEENEY, 1992). Some bibliography for further study is suggested at the end of this section.

After the definition of the key objectives, it is important to describe them qualitatively or quantitatively. For example, the objective “reduce costs” can be described as “amount in currency”, “% of budget”, or in many other ways. The description of the objective can influence how the stakeholders understand them as well as the subsequent analyses.

Once the objectives have been defined and described, it is necessary to assess whether it is possible to set **targets**. While the “objective” is represented by a preferred direction, a “target” is represented by a fixed, measurable level to be achieved. For example, the objective “reduce costs” can be translated into target “reduce costs by \$ 10,000.00 per year”.

The objectives shall be directly related to the regulatory problem and its causes, be proportional to its impact, and shall link the problem to the alternatives.

Both the objectives choice and the target definition set the limits for the alternatives. Objectives and targets that are too wide-ranging may allow for alternatives beyond the context decision. Returning to the example of air pollution, defining an objective such as “reduce the levels of respiratory diseases” would lead to alternatives out of context, such as “fight viruses and bacteria”. Likewise, objectives and targets shall not be too limiting, unnecessarily eliminating alternatives within the context. For example, to define “reduce emissions of pollutants by vehicles” as an objective may eliminate actions related to other sources of air pollutants.

In particular, under no circumstances shall objectives or targets be deliberately restricted in order to narrow the scope for action and drive the analysis towards the choice of a preferred alternative.

#### RECOMMENDED READING

KEENEY, R. L. (1992), Value-focused thinking, Harvard University Press.

### 3.6 Describing possible alternatives

**In this stage, one shall describe alternatives to face the regulatory problem and achieve defined objectives.**

**If RIA is to be useful in the decision-making process, it is necessary to identify the different possibilities of dealing with the problem, excluding those that are not feasible, and analysing in detail those that prove to be potentially effective.**

**The alternatives shall be in line with the institutional mission and guidelines.**

**Besides **regulatory alternatives**, the RIA shall always consider the no-action alternative and, whenever possible, **non-regulatory alternatives**.**

**In order to help the understanding, it is suggested that the alternatives are presented separately, one by one, starting with the no-action alternative.**

**A brief explanation of the alternatives initially considered and later discarded shall be presented at this stage, increasing transparency and stakeholders' confidence in RIA.**

Once a clear understanding of the problem has been achieved and the desired objectives have been defined, it is necessary to map the alternatives to achieve them.

According to the European Commission (2013), this RIA stage is usually the one that attracts more attention from stakeholders. When well prepared, it brings credibility to the analysis and the decision-making process. On the other hand, when poorly substantiated, it tends to attract much criticism and questionings about the quality of the analysis and the effectiveness of the solution pointed out.

The alternatives prospection shall always begin with broadly set of candidates, attempting to bring innovative, “out-of-the-box” approaches to address the problem. In order to increase diversity and innovation when mapping alternatives, it is recommended that different areas of the regulatory entity, with different experiences and perspectives, take part in the process.

Studying the solutions adopted in other countries may also enhance the mapping process.

The identification of the alternatives shall be focused on the options that:

- are reasonable and proportionate to the regulatory problem, in other words, they do not result in an intervention that exceeds what is necessary to achieve the desired objectives; and
- are able to act appropriately on the causes of the problem, in order to promote changes to the conditions or behaviours of agents towards the intended objectives.

**This RIA stage shall always consider the no-action alternative and, if possible, non-regulatory alternatives.** The alternative to “do nothing” or “maintain the status quo” will also serve as a baseline to future effectiveness evaluation of the implemented alternative.

When there is already a regulation in place for the problem under analysis, it shall be evaluated whether there are alternatives to improve its performance, either by improving its design, implementation, monitoring or inspection mechanisms. In some situations, it may be concluded that it is better to deregulate, especially when it appears that the intervention, besides not being effective, is creating new problems.

There is a range of **non-normative** and **normative** alternatives that can be evaluated at this moment, some with more chances of success than others, depending on the factors and characteristics of the problem, the scenario or the sector where they will be applied.

Although there is a growing literature on the matter, there is still no clear or uniform classification of non-regulatory alternatives. It’s possible to find a multitude of ways to treat them based on different approaches (regulation subject, type of instrument used, degree of government involvement, etc.). However, what is most important in this part of RIA is to gather the maximum number of possible solutions, using creativity and innovation, studying similar situations and how they were resolved. Consulting stakeholders affected by the problem is another way to find good alternatives, since they are the main interested to see the problem solved.

The classification used by OECD (2013) is presented as follows:

**Table 2** - Examples of non-regulatory action alternatives

<p><b>Self-regulation</b></p>	<p>Self-regulation takes place when an organised group regulates the behaviour of its own members.</p> <p>The elaboration and monitoring of standards, actions or codes that govern the activities, by the sector itself, increase the acceptance of these rules and make stakeholders feel more responsible for their compliance. The proximity to the market and a good knowledge of their activities gives expertise to the group to evaluate and regulate itself.</p> <p>This approach is recommended when there is no relevant public interest involved, in particular issues that are not related to health or safety, or when the risks and impacts involved are low.</p> <p>It is important to ensure that self-regulation is not captured by the interests of the industry or the sector it is intended for, at the expense of the interests of other agents and or the society as a whole.</p> <p>An example of self-regulation can be found in the advertising market, in which CONAR, a non-governmental institution formed by advertisers and professionals of other areas, developed the Brazilian Advertising Self-Regulation Code and monitors its observance by companies in the sector.</p>
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	<p>Voluntary accreditation systems and voluntary adoption of technical standards or codes of practice are also examples of this type of instrument.</p>
<b>Co-regulation</b>	<p>Co-regulation, or shared regulation, takes place when the industry develops and manages its own standards, but the Government provides legal support to legitimate them. In general, the Government sets quality or performance standards or parameters, allowing players to choose how best to adapt their products, processes, services or technology in order to meet the expected performance.</p> <p>A few examples of co-regulation are codes of conduct or best practices developed with government participation, guides, sector agreements (industry-government) and accreditation systems.</p> <p>The technical standards issued by ABNT are a good example of co-regulation. They consist of rules for standardisation, certification, labelling, etc., issued by a private institution, recognised in several legal instruments and they comply with the strategic guidelines of the National Council of Metrology, Standardisation and Industrial Quality (Conmetro).</p>
<b>Economic Incentives</b>	<p>These instruments aim to change the behaviour of agents through economic incentives. In general, they achieve it by changing the prices or relative costs of products, inputs, technologies and services.</p> <p>This change in relative prices can be achieved through taxes, fees, fines, penalties, subsidies and financial incentives, among others.</p>
<b>Economic Incentives</b>	<p>The creation of markets of trade rights, licenses or permits is also a known instrument based on economic incentives. Practice has shown that creating such markets can be an efficient mechanism when it is necessary to limit the production or consumption of goods or services for the public interest. The benefits arise from the fact that the market will put a price on that right, allocating to agents who may use it more efficiently.</p> <p>The carbon credit market is a classic example of regulation by economic incentives, and so is the possibility of negotiating landing and take-off rights at airports with great demand for flights.</p> <p>Another example are the price-cap mechanisms included in concession contracts, which use economic mechanisms to stimulate companies to obtain efficiency gains or to meet desired standards of product or service performance.</p>
<b>Information and education</b>	<p>These instruments rely on the dissemination of information and education, either to correct information asymmetries among stakeholders or to improve their knowledge about aspects related to the problem.</p> <p>They also include campaigns in which the government seeks to leverage good citizenship values or responsible behaviour, for example.</p> <p>The effectiveness of these instruments depends on the disclosure of the right information accordingly, in order to change agents' behaviours in the desired direction.</p>

Disseminating information or conducting educational campaigns is something that can be done by regulators, companies (voluntarily or by regulation), consumer protection associations, NGOs, international organisations or institutions, etc.

For example, stamping the fat or sugar content in food labels so that consumers can make their choice individually, can be an alternative to regulating the food ingredients.

Other examples are educational campaigns about the damaging effects of tobacco or designing energy-efficiency labels to rate equipment according to the energy efficiency levels.

Creating rankings of companies or products according to their performance can also be an instrument of encouragement (construction/loss of reputation).

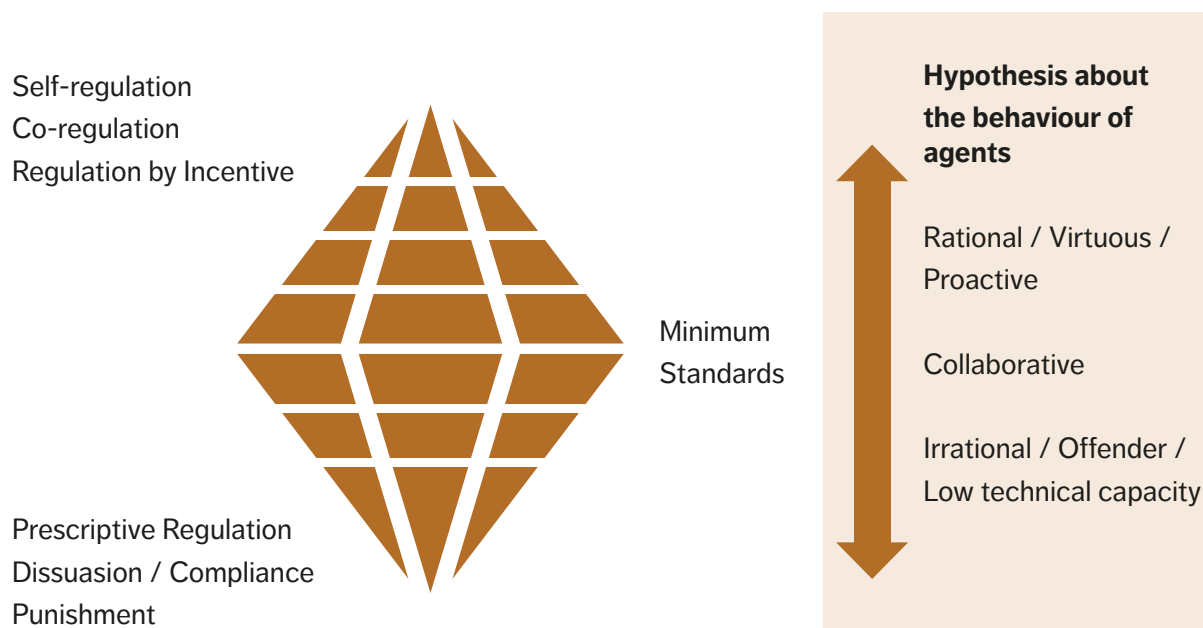
Source: Prepared by the author/s

There is a growing debate about what would be the government optimal approach: by means of deterrence or persuasion (BALDWIN; CAVE; LODGE, 2010). The first model is centred on the prescription, monitoring and punishment of the deviations observed, while the latter emphasises on cooperation, prevention and conciliation. The advocacy of persuasion is supported by the rationality and co-operation of stakeholders, who may act accordingly either through self-incentive or incentives from external sources. Therefore, non-regulatory alternatives shall always be considered.

It is also recommended to design alternatives known in the international literature as “responsive regulation”, that are able to encompass different behaviours dynamically, using the most restrictive and punitive approach on stakeholders who really refuse to cooperate or adjust to the desired behaviour.

The weighting of restrictive, punitive and incentive measures shall be examined on a case-by-case basis, depending on the industry, history of its players, risks involved, etc. The challenge is to be able to identify and implement alternatives that can punish transgressing stakeholders and at the same time encourage others who wish to cooperate and even exceed those minimum standards. Overly prescriptive actions that create barriers or unnecessary costs to cooperative regulated entities can generate a culture of discouragement and resistance to conformity.

Kolieb (2015) proposes a graphical representation of this responsive regulation model in a format he names as Regulatory Diamond, represented as follows.

**Figure 3** - Regulation Diamond

Source: Prepared by the authors, adapted from Kolieb (2015).

The in-depth analysis of all alternatives of action initially mapped can be costly and may unnecessarily extend the RIA period of completion. Thereby, only the alternatives that are feasible and can be effective shall be detailed in the RIA Report.

**Best practice recommends avoiding the inclusion of clearly non-feasible or ineffective alternatives only to justify the no-action alternative or to emphasize the advantages of an alternative that was preferred from the beginning.**

Therefore, once the highest number of possible alternatives have been mapped, it is important to assess them in terms of their feasibility. Some of the criteria that can be used to exclude or prioritize some of the alternatives, thus rationalising the analysis, are:

- low technical feasibility;
- implementation difficulties for the regulatory entity;
- obstacles for compliance;
- legal uncertainty;
- inadequacy, delay or rigidity in relation to technological developments, which could make the rule rapidly obsolete;
- conflict with citizens' fundamental rights;
- conflict or inconsistencies with other rules;



- high degree of complexity in the normative rule text due to the need to differentiate stakeholders' treatment according to their size, regional location, nature, maturity, etc;
- possibility of significant opposition from the public or from important stakeholders, to the point of compromising the expected results.

Considering that stakeholders may have different opinions from the regulatory entity's vision, the alternatives discarded shall be presented at this stage of the RIA report, along with a brief explanation of their exclusion. It is recommended special attention to discarded alternatives known as preferred by stakeholders. This also avoids redoing analysis in the future on undocumented discarded alternatives.

When it is only possible to identify one alternative to be compared to the no-action situation, it is advisable to work on a robust justification to support the absence of other viable alternatives.

### RECOMMENDED READING

AUSTRALIA. Department of the Treasury (2003), Practice Guide for Preparing Regulatory Impact Statements. Available on: [http://www.treasury.act.gov.au/documents/regulatory\\_impact\\_statement\\_guide.pdf](http://www.treasury.act.gov.au/documents/regulatory_impact_statement_guide.pdf)

BALDWIN, R.; CAVE M.; LODGE, M. (2010). The Oxford Handbook of Regulation, Oxford: Oxford University Press.

EUROPEAN COMMISSION (2015). Better Regulation Toolbox, Section 2. Available on: [http://ec.europa.eu/smart-regulation/guidelines/tool\\_15\\_en.htm](http://ec.europa.eu/smart-regulation/guidelines/tool_15_en.htm)

ISRAEL (2013), Governance and Social Affairs Department, Prime Minister's Office. Regulatory Impact Assessment: Governmental Handbook. Available on: <http://www.pmo.gov.il/SiteCollectionDocuments/mimshalRegulatory%20Impact%20Assessment.pdf>

Kolieb, Jonathan (2015), When to Punish, When to Persuade and When to Reward: Strengthening Responsive Regulation with the Regulatory Diamond, Monash University Law Review Vol. 41(1) 2015. Available on: [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2698498](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2698498)

OECD, Alternatives to traditional regulation. Regulatory Policy Division. Available on: <http://www.oecd.org/gov/regulatory-policy/42245468.pdf>

OECD (2002), Regulatory Alternatives, Annex II, Regulatory Policies in OECD Countries: from interventionism to regulatory governance, OECD Reviews of Regulatory Reform. Available on: [http://www.treasury.act.gov.au/documents/regulatory\\_impact\\_statement\\_guide.pdf](http://www.treasury.act.gov.au/documents/regulatory_impact_statement_guide.pdf)

OECD (2013), Alternativas regulatorias y no regulatorias menos restrictivas, División de Política Regulatoria de la OCDE. Presentado en la Oficina de Elaboración y Manifestación de

Análisis de Impacto Regulatorio con Analisis de Concorrência, Ciudad de México, Septiembre de 2013. Available on: <https://www.oecd.org/gov/regulatory-policy/Sesi%C3%B3n-3.2-Presentations.pdf>

UNITED KINGDOM, Environment Agency. Delivering for the Environment: A 21st Century approach to regulation. Available on: <https://www.oecd.org/env/outreach/33947795.pdf>

### 3.7 Analysing possible impacts and comparing the alternatives

**This stage identifies possible positive and negative, desirable and undesirable impacts of the alternatives not discarded in the previous stage.**

**The objective is to assess whether the identified alternatives are likely to create benefits and gains that are superior to their costs and disadvantages, considering all impacted stakeholders.**

**In addition to the impacts on stakeholders, it is important to consider possible impacts of the alternatives on the regulatory entity itself. If these impacts are significant, they shall be included in the comparison of the alternatives costs and benefits.**

**The positive and negative impacts shall be identified and analysed for a predefined period (5 years, 10 years), using the no-action scenario as reference, i.e., the current state of the problem under analysis and the evolution of its impacts in the absence of any action by the regulator.**

**It is necessary to identify which stakeholders or groups are impacted, explaining how these impacts are distributed among them. This analysis shall consider at least three major groups: (a) society; (b) companies; and (c) government.**

**The methodology used to assess these impacts shall be defined on a case-by-case basis, depending on the complexity of the subject, the nature of the variables involved and the quantity and quality of the available data.**

**The methodology used and the reasons for its choice shall be briefly presented in the RIA report. It is also essential to explain clearly the assumptions, parameters, hypotheses and sources of information used in the analysis and comparison of the alternatives.**

**The relevance to include specific types of impacts, for example, on competition, on micro and small businesses, on the environment, on safety, health, etc., shall be decided on a case-by-case basis.**

**In order to add clarity to the text, it is recommended that the RIA Report presents the alternatives individually, ranked from best to worst. When detailing each alternative, the impacts shall be presented in decreasing order of relevance or magnitude.**

This RIA stage has two objectives. The first is to understand the positive and negative impacts of each alternative, and to identify whether their benefits outweigh their costs and

disadvantages when compared to the no-action scenario. Second, this stage aims to create a basis for comparison among feasible solutions, so that it is possible to guide a selection among different alternatives.

This phase can follow the stages below:

- Identification of likely positive and negative impacts of each alternative;
- Identification of stakeholders and groups affected by the alternatives, considering at least those stakeholders or groups affected by the problem;
- Qualitative analysis to identify the most relevant impacts. It may consider their nature, magnitude and probability of occurrence;
- Definition of the methodology for comparing the alternatives;
- Further analysis of the most relevant impacts, using the methodology chosen; and
- Comparison of the alternatives.

The initial survey of possible impacts shall be as broad as possible, including impacts that are desirable and undesirable, direct and indirect, collateral, tangible and intangible, of short, medium and long term, due to possible regional differences, etc.

The choice and prioritisation of impacts that are going to be more carefully assessed shall be done on a case-by-case basis, since they may vary from sector to sector depending on the problem or the objectives pursued.

Based on the practice observed among OECD countries, it is noticeable that some types of impact are more frequently assessed at this stage of the RIA, whether or not mandatorily.

These include:

- (a) competitive impacts<sup>7</sup>;
- (b) impacts on micro and small businesses (in Brazil, in compliance with the Federal Constitution, article 179, and Law 123/2006, article 1, paragraphs 3 and 4);
- (c) impacts on international trading or the degree of market opening;
- (d) impacts on health;
- (e) impacts on safety;
- (f) environmental impacts;
- (g) impacts on **administrative costs**; and
- (h) budget impacts.

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<sup>7</sup> The following publication can be consulted regarding competitive impacts: OECD (2017), Competition Assessment Toolkit. Available on: <http://www.oecd.org/competition/assessment-toolkit.htm>

An extensive list of different kinds of impacts can be found in the European Commission Guides (2009 and 2015).

Stakeholders or groups affected by the possible impacts shall be identified as well as how those impacts will be distributed among them.

At least those stakeholders or groups identified in stage 3.3 shall be considered at this moment of the analysis, that is, one shall demonstrate the possible impacts of each alternative on stakeholders or groups affected by the problem. In addition, it is important to assess whether groups not affected by the problem can somehow be impacted by the alternatives under analysis. It is also important to take into account the impacts of each alternative on the regulatory entity itself, or on other government institutions or entities.

**The assessment of the impacts of each alternative shall always have the no-action option as reference. In other words, the impacts shall be qualified or quantified as a net gain or cost in relation to the scenario of inaction by the regulatory entity.** The no-action option is not just a current picture of the problem. It shall be understood dynamically, taking into account future projections of the problem evolution and its repercussions, including the possibility that it will be solved or minimised by factors unrelated to the alternatives under analysis.

It is important to conduct at least a qualitative assessment of the advantages and disadvantages, and the benefits and costs of each of the alternatives in relation to each stakeholder. This assessment shall consider the benefits or advantages that significantly improves the condition or well-being of stakeholders or groups against the no-action situation. Similarly, it shall consider costs or disadvantages that worsen the current condition or well-being of stakeholders or groups, also with regard to what would happen in the no-action scenario. This deterioration can occur, for example, through the imposition of financial or administrative costs, new obligations, or by the reduction or removal of an advantage or favourable condition from these stakeholders.

The analysis of the alternatives, including the no-action option, shall be conducted for a predefined reference period that allows for the consideration of the short, medium and long-term impacts. Several countries recommend adopting a 10-year period as parameter. However, this period shall be assessed on a case-by-case basis. In situations where the possible actions are temporary, for example, the analysis shall be associated with this period. In cases where quantitative analyses imply comparing values at different moments in time, these values shall be brought to the same date using adequate discount rate, that shall be clearly specified in the RIA Report.

Although recommended, the monetisation or even the quantification of benefits and costs is not always possible, either due to the very nature of these factors or to the lack of data or

reliable sources of information. In other cases, although possible, this quantification demands disproportionate costs and/or time. In these cases, it is possible to opt for methods and techniques that allow comparison among alternatives using qualitative criteria.

The most adequate methodology shall be defined on a case-by-case basis and shall be presented briefly, along with the reasons for its choice.

The table below summarises the methods most commonly used in OECD countries that use RIA in their policy regulation cycle (OECD, 1997, 2008, 2009):

**Table 3** - Most common RIA methodologies used in OECD countries

<b>Multi-Criteria Analysis</b>	
<b>Definition</b>	Consists on comparing alternatives considering their performance -against various relevant criteria. Each criterion is given a score and a weight according to its expected contribution to fulfil the defined objectives.
<b>Advantages</b>	Not only does it allow for the inclusion of technical and economic aspects to the analysis, but also of other social, political and environmental aspects whose impacts can be difficult to measure, but are relevant to the desired objectives. It makes it possible to define and explicit, objectively and transparently, the criteria that will be used to compare the possible alternatives, even if the criteria are qualitative. It makes it possible to add distributive issues to the analysis.
<b>Disadvantages</b>	The level of subjectivity used in scoring and weighting the criteria used to analyse the alternatives can raise questioning about the obtained result.  It does not always allow the incorporation of costs and benefits values differences over time.
<b>Cost-Benefit Analysis</b>	
<b>Definition</b>	It consists in the comparison of the monetary values (present value) of expected costs and benefits of the intervention. The intervention is considered adequate whenever the present value of its benefits exceeds the present value of the costs incurred by those involved.
<b>Advantages</b>	It offers an objective way to measure the positive and negative impacts of the intervention.
<b>Disadvantages</b>	Not all costs and benefits can be monetized or even quantifiable, due to their nature or to limited data. In addition, a comprehensive cost-benefit analysis does not take into consideration the distributional effects of the alternatives of action. Therefore, an additional analysis may be necessary to verify whether costs and benefits are balanced or centred on certain stakeholders or groups.
<b>Cost-effectiveness analysis</b>	
<b>Definition</b>	It consists of comparing costs among alternatives that result in similar benefits or, alternatively, comparing costs per unit of potential benefit.

	<p>It considers both costs (in monetary terms) and results (in terms of benefits) and it is measured in terms of additional costs per additional success.</p> <p>It is used when the results of the interventions vary, but can be measured in the same unit (e.g. cure of diseases, years of life gained, lives saved, cases avoided).</p>
<b>Advantages</b>	<p>It allows having an efficiency comparison index of the different alternatives, allowing for the elimination of those that are less efficient. It requires less data than the cost-benefit analysis, because there is no need to monetise the benefits created. In some cases, this methodology is used to avoid controversies in the monetisation of certain benefits such as life, health, safety, etc.</p>
<b>Disadvantages</b>	<p>This method assumes benefits as a default parameter, allowing one to find only the less costly way of achieving them. However, the extent of these benefits can be subject to questioning, since they cannot always represent what is best for society as a whole.</p> <p>One limitation of this methodology is that it is not possible to quantify whether its benefits outweigh its costs.</p> <p>In addition, the results in terms of cost per unit of benefit may not provide a definitive answer about which alternative is the best. In some cases, it may be necessary, for example, to set a maximum limit for the costs to bear or to impose to third parties.</p>
<b>Cost Assessment</b>	
<b>Definition</b>	<p>It consists of the direct comparison of costs imposed by the alternatives on companies, consumers, workers, the government, etc.</p> <p>It is used when the focus is on the identification of the lowest-cost option to obtain a particular benefit.</p>
<b>Advantages</b>	<p>It enables to demonstrate directly what is the total cost generated by each alternative.</p>
<b>Disadvantages</b>	<p>It does not consider the benefits generated, therefore it does not allow to differentiate between alternatives that impose the same total cost but generate different potential benefits.</p>
<b>Risk Analysis</b>	
<b>Definition</b>	<p>It is used when the regulatory problem is some kind of risk and the desired objective is to minimise this risk.</p> <p>This assessment shall not be mistaken with the risk analysis presented hereafter in the stage 3.13, which objective is to consider sources of risk and uncertainty of proposed regulation on outcomes.</p> <p>Here it consists in identifying the alternative that mitigate risks or reduce harms more effectively or efficiently.</p> <p>For example: choosing the best alternative to reduce the death rate in auto accidents or to reduce the risk of the financial system failure.</p>

<b>Advantages</b>	It allows identifying whether alternatives will be able to significantly reduce the risk(s).
<b>Disadvantages</b>	It does not consider the costs to reduce risks, nor does it consider other potential impacts of the alternatives.
<b>Risk-Risk Analysis</b>	
<b>Definition</b>	<p>It is similar to the previous methodology, but it takes into account not only the risk(s) directly related to the regulatory problem, but also other risks impacted by the considered alternatives.</p> <p>It is used to assess the net impact of each alternative on overall risk in situations where one type of risk can be replaced by another and the regulator has to consider the trade-off between risks.</p> <p>For example: an action taken to reduce the risk of accidents in civil aviation can have a significant impact on the price of airline tickets, to the point of causing customers to change air travel for land travel, therefore increasing the risk of accidents on highways. A risk-risk analysis could be performed to investigate whether the reduction of the first risk is cancelled by the rise of the second.</p>
<b>Advantages</b>	It enables a broader approach, considering the total reduction of the risk as a result of possible changes in the behaviour of agents in response to the action considered.
<b>Disadvantages</b>	Defining whether the final risk balance is positive or negative is not always a simple task, especially when the risks involved are of different kind.

Source: Prepared by the authors

It is essential that the premises, parameters, hypotheses and sources of information used in this stage be clearly presented in the RIA Report. Whenever the premises or parameters used present a high degree of uncertainty and this can significantly affect the likely impacts of the alternatives, it is important to consider conducting a **sensitivity analysis**.

In some cases, comparing positive and negative impacts, as well as costs and benefits, will clearly indicate that there is one alternative superior to the others to achieve the desired objectives. In others, the best alternative may not be so obvious. In any case, the RIA Report does not necessarily need to point the best choice, but it shall necessarily present a comparison of the alternatives assessed.

By the end of this stage, the RIA Report shall present the results found along the analysis in a brief, objective and accessible way. It is recommended to present a summary table containing the following synthesis for each alternative:

- (a) the extent to which the alternative achieves the defined objectives (effectiveness);
- (b) the relationship between benefits and costs (efficiency); and
- (c) its consistency in relation to the strategic objectives of the regulatory entity.

If possible, the solutions shall be presented in order of preference, based on the conclusions of the analysis.

In addition to presenting the extent to which the alternatives achieve the desired results, their benefits and costs, this final summary shall clearly identify the need for particular attention regarding the considered alternatives. For example: whether there are distributive issues to be considered, in other words, whether there are disproportionate costs that would be supported by any group (companies, small businesses, consumers, workers, the government, region, business partners, etc.); whether there are any issues that can be the object of resistance; whether there are cumulative effects with other regulations, etc. The final results presented in this stage will highlight to decision-makers the advantages and disadvantages, the positive and negative, desirable and undesirable impacts of the alternatives and the trade-offs among the choices available, thus enabling an evidence-based decision.

### RECOMMENDED READING

AUSTRALIA. Australian Government (2006), Introduction to Cost-Benefit Analysis and Alternative Evaluation. Available on: [https://www.finance.gov.au/sites/default/files/Intro\\_to\\_CB\\_analysis.pdf](https://www.finance.gov.au/sites/default/files/Intro_to_CB_analysis.pdf)

AUSTRALIA. Department of the Treasury (2003), Practice Guide for Preparing Regulatory Impact Statements. Available on: [http://www.treasury.act.gov.au/documents/regulatory\\_impact\\_statement\\_guide.pdf](http://www.treasury.act.gov.au/documents/regulatory_impact_statement_guide.pdf)

BRODER, Ivy E. and MORRALL, John F., Collecting and Using Data for Regulatory Decision-Making, in Regulatory Impact Analysis: Best Practices in OECD Countries, OECD, 1997. Available on: <http://www.oecd.org/gov/regulatory-policy/35258828.pdf>

CANADA. Treasury Board of Canada Secretariat (2006), Regulatory Impact Analysis in Regulatory Process, Method and Co-operation - Lessons for Canada from International Trends. Working Paper Series n.026. Available on: [http://regulatoryreform.com/wp-content/uploads/2014/09/Regulatory\\_Impact\\_Analysis\\_In\\_Regulatory\\_Prodcess\\_Method\\_and\\_Co-operation\\_Lessons\\_for\\_Canada.pdf](http://regulatoryreform.com/wp-content/uploads/2014/09/Regulatory_Impact_Analysis_In_Regulatory_Prodcess_Method_and_Co-operation_Lessons_for_Canada.pdf)

CANADA. Treasury Board of Canada Secretariat (2007), Canadian Cost-Benefit Analysis Guide: Regulatory Proposals. Available on: <https://www.tbs-sct.gc.ca/rtrap-parfa/analys/analys-eng.pdf>

CENTRE FOR EUROPEAN POLICY STUDIES – CEPS (2013), Assessing the Costs and Benefits of Regulation, Study for the European Commission, Secretariat General, Brussels. Available



on: [http://ec.europa.eu/smart-regulation/impact/commission\\_guidelines/docs/131210\\_cba\\_study\\_sg\\_final.pdf](http://ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/131210_cba_study_sg_final.pdf)

EUROPEAN COMMISSION (2015). Better Regulation “Toolbox”, Chapters 3 and 8. Available on: [http://ec.europa.eu/smart-regulation/guidelines/docs/br\\_toolbox\\_en.pdf](http://ec.europa.eu/smart-regulation/guidelines/docs/br_toolbox_en.pdf)

MEXICO (2013). Regulatory impact evaluation guide, Vol. I - Methods and Methodologies. Available on: [http://www.cofemer.gob.mx/presentaciones/English\\_Guide\\_Vol%201\\_FINA.pdf](http://www.cofemer.gob.mx/presentaciones/English_Guide_Vol%201_FINA.pdf)

OECD (2008), Introductory Handbook for Undertaking Regulatory Impact Analysis – RIA, Version 1.0 October 2008. Available on: <https://www.oecd.org/gov/regulatory-policy/44789472.pdf>

OECD (2009), Methodological Frameworks for Regulatory Impact Analysis - Valuation, Risk and Benefit-Cost Analysis, in Regulatory Impact Analysis: A Tool for Policy Coherence, OCDE Reviews of Regulatory Reform, chapter 3. Available on: [https://read.oecd-ilibrary.org/governance/regulatory-impact-analysis\\_9789264067110-en#](https://read.oecd-ilibrary.org/governance/regulatory-impact-analysis_9789264067110-en#)

OECD (2009) Regulatory Impact Analysis: A Tool for Policy Coherence, Chapter 3, Available on: [http://www.keepeek.com/Digital-Asset-Management/oecd/governance/regulatory-impact-analysis\\_9789264067110-en#.WYoa24grKUk#page1](http://www.keepeek.com/Digital-Asset-Management/oecd/governance/regulatory-impact-analysis_9789264067110-en#.WYoa24grKUk#page1)

UNITED STATES. United States Office of Management and Budget (2003), Regulatory Analysis, Circular A-4. Available on: [http://ec.europa.eu/smart-regulation/impact/commission\\_guidelines/docs/131210\\_cba\\_study\\_sg\\_final.pdf](http://ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/131210_cba_study_sg_final.pdf)

UNITED STATES. United States Office of Management and Budget (2003), Regulatory Impact Analysis: Frequently Asked Questions. Available on: <https://www.regulationwriters.com/downloads/Circular-A-4-RIA-FAQ.pdf>

UNITED KINGDOM (2018). HM Treasury, Green Book: Central Government Guidance on Appraisal and Evaluation. Available on: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/685903/The\\_Green\\_Book.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/685903/The_Green_Book.pdf)

UNITED KINGDOM. Department for Business Innovation & Skills (2015), Better regulation framework manual: practical guidance for UK government officials. Available on: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/583871/bis-13-1038-Better-regulation-framework-manual.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/583871/bis-13-1038-Better-regulation-framework-manual.pdf)

UNITED KINGDOM. Department for Communities and Local Government (2009), Multi-criteria analysis: a manual. Available on: [http://eprints.lse.ac.uk/12761/1/Multi-criteria\\_Analysis.pdf](http://eprints.lse.ac.uk/12761/1/Multi-criteria_Analysis.pdf)

VISCUSI, W. Kip, Improving the Analytical Basis for Regulatory Decision-Making, in Regulatory Impact Analysis: Best Practices in OECD Countries, OECD, 1997. Available on: <http://www.oecd.org/gov/regulatory-policy/35258828.pdf>

### 3.8 Implementation, inspection and monitoring strategies

**This stage presents the implementation strategy of the most appropriate alternative identified in the previous stage.**

**In cases where the recommended alternative involves the creation of obligations for third parties, it shall be indicated whether it is necessary to provide for coercive mechanisms in case of non-compliance and how obligations will be monitored.**

**In this stage, it is necessary to indicate whether the implementation of the recommended alternative requires amendments to existing rules or its repeal.**

**This stage shall also present a strategy to monitor the results of the recommended alternative in case it is implemented, indicating how the regulatory entity shall monitor whether the planned targets are being met.**

**It is critical that this stage suggests indicators to assess the recommended alternative. If no specific alternative was recommended in the previous stage, it is necessary to suggest at least general indicators to monitor the targets achievement.**

If the previous stage has pointed out the need for intervention, it will be necessary to indicate how this alternative shall be implemented, if mechanisms to guarantee compliance are necessary and how the intervention effectiveness shall be monitored.

If the responsible areas for **implementation**, **inspection** and **monitoring** of the recommended alternative are not yet involved in the RIA preparation, it is imperative that they are consulted at this time, since they may bring important inputs to its success.

The implementation strategy for the recommended alternative shall be presented in the RIA Report. In other words, after indicating what to do (choosing one of the alternatives), one shall briefly describe how to implement the proposed solution, considering the following aspects:

- If it is necessary to prepare any sort of instrument: to draft a rule, to define records or licenses, to prepare informative or educational material, etc.;
- If penalties are required in the case of non-compliance and what sanctions are recommended;
- Recommended deadline for the intervention to come into force and if having a maximum deadline for its duration or review is desirable;
- If it is necessary to amend or revoke other rules in force;
- If it is necessary or recommended to coordinate with other bodies or institutions;
- What areas within the regulatory entity shall be involved in the implementation;

- If the implementation requires specific data or information, if this information is available, or if additional action is required to obtain them;
- If there is need for specific communications or publicity plan, internal or external to the regulatory entity; and
- If there is need for specific preparation or adjustments by the regulatory entity prior to implementing the recommended alternative, and how much time is required for it - for example, if there is need to create or adapt systems, train civil servants, change work processes, recruit or relocate staff, etc.

The implementation strategy can be presented as a list or table showing the various actions required and identifying key implementation challenges, for example, technical, institutional or time-related challenges, as exemplified below.

**Table 4** - Description of the implementation strategy

<b>Challenges (for implementation of the proposed alternative)</b>	<b>Actions (to overcome challenges and to implement the chosen alternative)</b>	<b>Areas in Charge</b>	<b>Timeframe</b>

Source: Prepared by the author/s

The implementation strategy shall always seek simplicity, clarity and impose the lowest possible costs, both for third parties and for the regulatory entity itself.

At this stage, it is not necessary to present the draft of the recommended alternative (law or infra-legal rule, incentive, guidance or information).

Its purpose is to merely indicate the relevant guidelines, factors or parameters to follow in its preparation, in case the decision-making authority/ies decides for its preparation.

If the recommended alternative requires any sort of inspection to ensure compliance, this stage shall present the key points in this respect, which are:

- Recommended type of inspection: preventive, advisory, routine, random or selective inspection, audit, technical visits, follow-up inspections, as result of complaints or reported problems, etc.;
- Which areas will be responsible for the inspection;

- Whether the regulatory entity has the infrastructure, resources or the necessary personnel for an effective inspection;
- Whether the inspection requires specific data or information, whether they are available, and whether additional action is required to obtain them;
- Whether specific preparation or internal adjustment is required for the inspection and how much time is required; and
- Whether the costs of supervision are compatible and proportionate to the objectives to be achieved.

Finally, this stage shall inform how the regulatory entity intends to monitor the performance of the recommended action.

The success of the implemented alternative shall be verified by comparing the results observed and the previously defined objectives. To do so, it is necessary to prepare **indicators** that can measure whether the defined targets are being achieved.

Different categories of indicators can be used: efficiency, effectiveness, impact, process indicators, delay indicators, and others. The definition shall be made on a case-by-case basis, depending on the type of action to be monitored, and on the objectives and targets defined. However, whenever possible, the indicators shall be expressed quantitatively (values, percentages, averages, rates, indices, etc.). Qualitative indicators, when used, shall be objectively verifiable.

The list of indicators does not have to be extensive; instead, it is necessary to focus on indicators that are relevant to verify the performance of the implemented alternative. The indicators shall be comprehensible, timely measurable and shall not impose disproportionate costs. It shall always be verified whether the data or information required to calculate the indicator is available or can be obtained without undermining its viability.

For the monitoring it is also crucial to register the information about the initial scenario, which is the information that reflects the scenario prior to the intervention. By doing so, it will be possible to measure and evaluate, in the future, how the implemented alternative changed the problem.

One shall also propose to monitor whether the positive and negative impacts of the intervention are close to those predicted in the RIA.

The RIA Report shall also include the strategy for monitoring the proposed indicators. One of the recommended ways is to present it as a table containing basic information for each indicator, as exemplified below.

**Table 5** - Description of monitoring indicators

<b>Item to be measured</b>	Inform what is to be measured.
<b>Indicator</b>	Inform the indicator to be used, including its metrics / formula.
<b>Initial scenario parameter</b>	Measurement of the initial scenario, which will be a reference for the comparison with the indicator.
<b>Area in charge</b>	Area in charge of monitoring the indicator.
<b>Data sources</b>	Indicate sources to obtain the data needed to calculate the indicator, or how they can be gathered. It is important to verify whether the indicated data sources matches the adequate frequency to measure the proposed indicator.
<b>Data collection frequency</b>	If it is necessary to collect primary data, it is important to indicate how often it shall be produced or collected. If secondary data is used, indicate the best frequency to request or consult the data.
<b>Frequency of indicator calculation</b>	Indicate how often the indicator shall be calculated for proper monitoring.
<b>Target</b>	Inform the defined target to the indicator.
<b>Deadline for target achievement</b>	Set the desired date to reach the target.

Source: Prepared by the author/s

In addition to informing whether the defined targets are being achieved, it is desirable that the monitoring can also bring information that can be used as input for eventual reviews of the implemented alternative.

If the targets are not being achieved, monitoring shall be able to indicate if it is due to failure in the problem definition, in the intervention design, in the implementation or inspection, due to unforeseen external factors, or due to legislative changes, etc. Once these factors have been identified, monitoring shall ideally provide guidance on possible remedies.

Whenever possible, the regulatory entity shall publish the monitoring indicators for the implemented alternative.

## RECOMMENDED READING

CANADA (2009). Treasury Board of Canada Secretariat, Handbook for Regulatory Proposals: Performance Measurement and Evaluation Plan Available on: [http://publications.gc.ca/collections/collection\\_2013/sct-tbs/BT22-134-2009-eng.pdf](http://publications.gc.ca/collections/collection_2013/sct-tbs/BT22-134-2009-eng.pdf)

OECD (2014), Regulatory Enforcement and Inspections, OECD Best Practice Principles for Regulatory Policy, OECD Publishing. Available on: <http://www.oecd.org/gov/regulatory-enforcement-and-inspections-9789264208117-en.htm>

MOSSE, Roberto and SONTHEIMER, Leigh Ellen (1996). Performance Monitoring Indicators Handbook. World Bank Technical Paper No. 334. Available on: [http://siteresources.worldbank.org/BRAZILINPOREXTN/Resources/3817166-1185895645304/4044168-1186409169154/24pub\\_br217.pdf](http://siteresources.worldbank.org/BRAZILINPOREXTN/Resources/3817166-1185895645304/4044168-1186409169154/24pub_br217.pdf)

SANDHU-ROJON, Ruby. Selecting Indicators for impact evaluation, United Nations Development Programme (UNDP). Available on: <http://www.i-three.org/wp-content/uploads/2015/03/Selecting-Indicators-for-Impact-Evaluation.pdf>

### 3.9 Considerations on contributions and comments received throughout the RIA preparation

**In order to provide transparency, this stage shall present a summary of the information, contributions and comments collected from stakeholders and how they were taken into consideration in the analysis.**

The RIA Report shall include a specific section containing the regulatory entity's considerations on relevant manifestations, contributions and comments received during consultation processes with external or internal actors along the RIA preparation.

Please note that the considerations included in the RIA Report shall not be confused with those that must be presented for Public Consultation or Hearing processes. The regulatory entity's positioning about comments or contributions received in these processes will be reported separately.

The objective of this section of the RIA Report is to provide transparency of information and opinions gathered from stakeholders **along the RIA process**, as well as to inform how these contributions were used in the analysis and demonstrate that there was no bias or favouritism. This section shall summarise:

- Stakeholders engaged;
- When and how the engagement process took place;

- The relevant data, contributions and manifestations gathered in these engagement processes and how they were used; and
- Entity's comments about relevant objections or questionings received in these processes.

Individual and detailed considerations of all contributions received are not necessary. It is recommended though special attention shall be paid to contributions regarding sensitive points of the analysis such as the methodology used or the distribution of the alternatives impacts among different groups.

If a manifestation requires a more detailed or complex response, it is recommended to summarise it in the RIA Report and that the full analysis is either attached to the report or forwarded directly to the contributor.

If a contribution or manifestation received at a more advanced stage of the RIA leads to a review and relevant changes on previous stages, we recommend it to be explained briefly in the Report.

If relevant stakeholders have not manifested their opinions, it is important to present this information in the RIA Report as well.

Finally, it is important to protect the confidentiality of sensitive information for stakeholders or for the regulatory entity itself.

#### RECOMMENDED READING

JORDAN (2010). A manual for stakeholder consultation: Jordan. USAID Jordan Economic Development Program. Available on: <http://regulatoryreform.com/wp-content/uploads/2015/02/Jordan-Stakeholder-Consultation-Manual-2009.pdf>

EUROPEAN COMMISSION (2002). Towards a reinforced culture of consultation and dialogue - General principles and minimum standards for consultation of interested parties by the Commission. Available on: [http://ec.europa.eu/governance/docs/comm\\_standards\\_en.pdf](http://ec.europa.eu/governance/docs/comm_standards_en.pdf)

### 3.10 Participant information and signature of the designated person in charge of the RIA preparation

In order to promote transparency, the RIA Report shall present the name and position of all the civil servants who took part in its preparation.

As an institutional document that will be part of the decision-making process, the RIA Report shall present the signature of at least one designated civil servant responsible for its preparation. This may be the head of the department responsible for the analysis, the coordinator of the working group created to conduct the RIA or another civil servant designated by the institution.

## RIA Level II

### 3.11 International experience

**The objective of this stage is to survey alternative approaches given by other countries to the regulatory problem under analysis in order to help identify solutions, effects or impacts not yet detected by the regulator.**

The objective of this stage is to investigate how the same regulatory problem – or a similar one – was treated in other countries, thereby bringing additional subsidies that may improve the RIA. International experiences mapping can also be based on the nature of the problem under analysis (market failure, institutional failure, regulatory failure, etc.).

Studying international experiences can contribute to the various RIA stages. For example:

- By bringing other perspectives of the regulatory problem;
- By pointing to approaches and alternatives of intervention not yet identified by the regulator;
- By indicating impacts of the problem or impacts of the alternatives not initially identified by the regulator;
- By bringing useful data to the analysis;
- By anticipating problems observed in alternatives that have already been tested;
- By anticipating unexpected reactions from stakeholders to alternatives that have already been tested;
- By assisting in the definition of monitoring indicators;
- By bringing performance benchmarks.

International experience can be an important benchmark, especially when considering that the tradition of independent regulation is quite recent in Brazil, compared to several other countries. However, it is evident that the experiences observed internationally shall be incorporated taking into account the domestic peculiarities. To investigate international experiences, the regulatory entity can consult international sectoral bodies, organisations and institutions, in addition to peer agencies, bodies or entities from other countries. For instance, OECD and the World Bank have tradition in publishing benchmarking studies and international best practices on specific regulatory issues.



### 3.12 Measuring the impacts of the alternatives on different stakeholders<sup>8</sup>

**When the regulatory problem or the impacts of the considered alternatives are more complex, the regulatory entity shall make greater efforts to measure impacts on affected stakeholders.**

**The impacts measurement shall be carefully planned, preferably with the help of the affected stakeholders.**

**The same impact can have opposite effects on different stakeholders (positive effects on some and negative on others). It is important to ensure that they are not double counted at the time of measurement.**

**Impacts can be measured in different ways, using qualitative or quantitative analysis, with or without monetisation.**

**The methodology choice depends on several factors and all of them offer advantages and disadvantages that the regulatory entity needs to evaluate before deciding which is best suited to the specific case.**

**The quality of the available data is also a relevant variable when choosing the methodology. Interacting and consulting with the affected stakeholders can be an important source to obtain and validate the necessary data.**

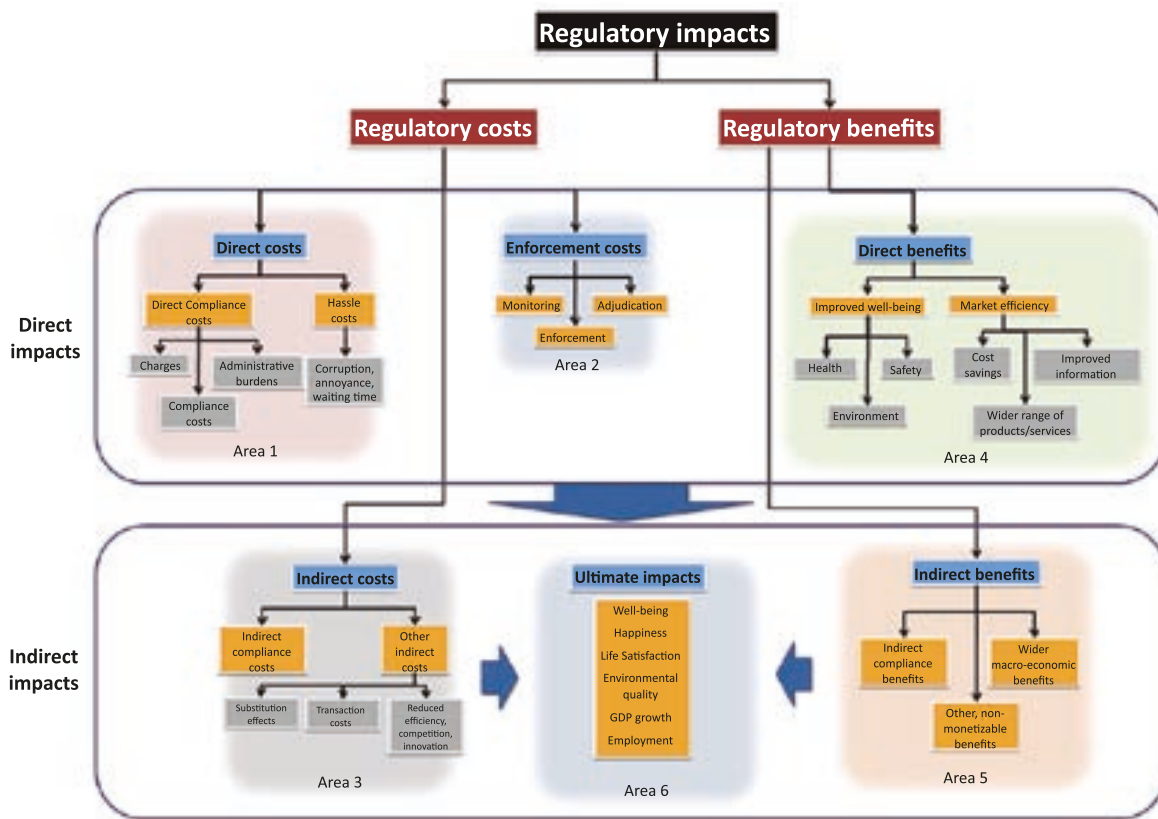
**Measurement of the impacts of each alternative shall always have the no-action option as reference. In other words, the impacts shall be measured as a net gain or cost in relation to the scenario of inaction by the regulatory entity.**

**Only one methodology shall be used to measure the impacts, otherwise it will not be possible to obtain a comparable final result that allows for a choice among the various alternatives.**

The impacts that the regulator can create with the intervention can be positive or negative. Several typologies used internationally organise these impacts into categories in order to assist in the preparation of the RIA. An example is the typology used in the European Union, which is recommended here because it is sufficiently complete. Further details on the definitions adopted for each type of impact and the methodological tools that can be used for the measurement can be found in the Centre for European Policy Studies - CEPS (2013) document.

<sup>8</sup> This Guide was developed with the support of UK Prosperity Fund, led by the UK Embassy in Brazil, for the hiring of Senior Regulatory Quality Specialist Delia Rodrigo.

**Figure 4 - Typology of negative and positive regulatory impacts**



Source: CEPS (2013).

The impacts of the alternatives can be measured in different ways. Qualitative or quantitative methods can be used, with or without monetisation. There are different methodologies for this, for example, multi-criteria analysis, cost analysis or cost-benefit analysis, some of which were already presented in section 3.7

The methodology choice depends on several factors, but they all have advantages and disadvantages that the regulator needs to evaluate before deciding how to compare the alternatives.

**Table 6 – Possibilities of measuring impacts and methodologies most commonly used in RIA<sup>9</sup>**

Qualification and quantification of impacts	Quantification of impacts		
	Quantification and monetisation of costs		Quantification and monetisation of costs and benefits
Multi-Criteria Analysis	Cost Analysis	Cost-effectiveness analysis	Cost-benefit analysis

Source: Prepared by the author/s

<sup>9</sup> Table 3 of section 3.7 also mentions the risk analysis and the risk-risk analysis methodologies.

A multi-criteria analysis can have the same technical rigor and complexity as a cost-benefit analysis. However, in some countries the cost-benefit analysis is mandatory because quantification and monetisation are considered essential elements of the evidence-based decision-making process.

The correct identification of impacts, their quantification and monetisation allow for an understanding of how the costs and benefits of possible interventions are distributed within the society, and also allowing the choice of the best option to ensure social well-being. However, the feasibility of monetisation depends, largely, on the data collected during the RIA process. Only with good quality data it is recommended to quantify and monetise costs and benefits of the alternatives.

In many circumstances, impacts cannot be presented in monetary terms. Goods that have no price and are not traded are called intangible goods, even though it may be possible to use some technique to attribute monetary value to it. For example, commuting time in a transportation system is intangible because it is not traded and does not have a price; however, it can be monetised.

The impacts that the government can cause with an intervention can be of different types. The possibility to quantify and monetise them will depend on the elements involved. The following examples show the types of goods that can be considered under RIA:

- Goods that have a market value and can be monetised, such as urban transport units or products offered at the supermarket;
- Goods that have no market value but can be quantified and monetised, such as the risks associated with health;
- Goods that have no market value and can be quantified but not monetised, such as the number of endangered species;
- Goods that have no market value and cannot be quantified, such as social justice.

The decision of what to measure and how to do it will depend on the subject to be analysed, the data available and the institutional capacity to develop advanced methodological approaches.

The impacts of each alternative shall always have the no-action option as reference, in other words, the impacts shall be measured as a net gain or cost in relation to the inaction scenario – where the government takes no action.

Impact measurement is a process that is generally conducted according to the following steps:

- a) Identification of the impacts of the alternatives on different stakeholders or groups;

- b) Selection of methodology to compare the alternatives;
- c) Comparison of the alternatives.

### 3.12.1 Identifying the impacts of the alternatives

The first step consists on identifying the positive and negative impacts that will be considered into the analysis in order to compare the alternatives. From the problem identification, the regulatory entity shall identify the problem causes and effects to be solved. These effects will be part of the impacts that the regulatory entity shall try to minimise, if they are negative, or maximize if they are positive. The regulatory entity shall also include the impacts that the possible intervention will have on the problem causes, because they are the ones that must be modified to change the current situation. The causes will be impacted differently depending on the choice of intervention. For example, if one of the alternatives is based on an information campaign and another consists in drafting a regulation, they will affect the problem causes differently.

The regulatory entity can use a typology of positive and negative impacts such as the one presented at the beginning of this section. However, it is important to remember that each problem will have its characteristics, and therefore the impacts will be specific to the case. The regulatory entity shall try to include as many as possible relevant impacts in the analysis. It is useful to prepare, for each alternative considered, a table presenting its impacts to each stakeholder or group.

**Table 7** – Identification of positive and negative impacts

ALTERNATIVE No. X		
Stakeholders	Negative impacts	Positive impacts
Stakeholder 1		
Stakeholder 2		

Source: Prepared by the author/s

The impacts shall be carefully identified with the help of affected stakeholders. It is important to avoid duplicating the impacts that will be considered in the analysis. A negative impact for some affected groups can be positive for others, for instance. It is also recommended to review the list of affected stakeholders, because it is possible that some of them may not have been identified in the previous stages.

For example, the introduction of a new technical standard would increase the direct costs of refrigerator manufacturers by \$50 million. Half of that amount would be passed on to consumers through price increases. To consider \$50 million in costs for producers and \$25

million in costs for consumers would be duplicating the impact of the new rule. The right thing to do would be to assign an \$25 million impact for each of these groups. However, the opportunity costs that consumers will have from deciding not to buy a refrigerator due to increased prices shall also be recorded as a net loss to society.

### **3.12.2 Selecting the adequate methodology to compare the alternatives**

The next step is to determine the most appropriate methodology to compare the alternatives. Several elements need to be considered in order to decide which methodology to use:

- Regulatory entity capabilities to apply the methodology;
- Data availability and quality;
- Proportionality in relation to the impacts, because the greater the impacts, the bigger shall be the methodological effort.

Only one methodology shall be used in the analysis, otherwise it will not be possible to obtain a comparable final result that allows for a choice among the various alternatives.

The most commonly methodologies used in the RIA to qualify, quantify and monetise can be grouped into four categories<sup>10</sup>:

- Multi-criteria analysis (qualification and even quantification of the impacts, but without the need for monetisation);
- Cost analysis, especially compliance costs (quantification and monetisation of costs only);
- Cost-effectiveness analysis (quantification and monetisation of costs and possible quantification, but no monetisation of benefits); and
- Cost-benefit analysis (quantification and monetisation of costs and benefits).

Each of them requires the use of other methodological tools. The quality of the data available or that can be obtained is essential to advance from quantification to monetisation.

Each methodology requires the definition of a data collection strategy. An interaction with affected stakeholders will probably be necessary to obtain the required information and its validation. Data collection is a process that shall be started with the definition of the problem, but the alternatives analysis stage will surely require additional efforts to obtain specific data, if the regulatory entity wishes to use advanced quantitative methodologies.

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<sup>10</sup> The presentation order does not represent a preference of the choice of methodology.

### 3.12.2.1 Multi-Criteria Analysis

Multi-criteria analysis covers several methodological techniques that contribute to the decision-making process, without the need to monetise the impacts of the alternatives.

The basic principle of multi-criteria analysis consists in the comparison of alternatives taking into consideration their performance against various criteria that are relevant to decision-making. The elected criteria shall make it possible to capture and compare the positive and negative impacts presented by each alternative, but without the need for quantification and monetisation. The criteria shall also have a direct relationship with the defined objectives.

Criteria are the performance measures whereby the alternatives are going to be compared. A way to select them is to ask: “What would be the difference between a good and a bad decision-making having in mind the problem we are trying to solve?” The criteria must guarantee that the alternatives can be differentiated and they will generally be linked to the objectives. Aspects relevant to the problem solution shall be thoroughly covered by the criteria, which shall be independent one from another and selected with the participation of the affected stakeholders or groups, since they will have different perspectives on problem. The number of criteria shall not be too large, but enough to enable a well-substantiated decision-making process.

The use of a performance matrix makes it possible to determine the best choice of action considering the criteria defined. Performance matrices can be qualitative, with no weight and no value, and can be very complex in the allocation of values and weights.

**Table 8** – Example of a simple performance matrix for multi-criteria analysis

Criteria	Weight*	Alternative 1		Alternative 2		Alternative 3	
		V**	We***	V**	We***	V**	We***
Criterion 1							
Criterion 2							
Criterion 3							
Result ****							

Source: Created by the author/s

\* Weight - The weights assigned to the criteria reflect their importance in decision-making

\*\* Value - Values indicate how the alternatives of action reaches each criteria

\*\*\*Weighting - Product of the multiplication of weight by value, allows a score for each criterion of each alternative

\*\*\*\*Result – Sum of the weighted values of each alternative

Each criterion is given a score and a weight according to its expected contribution to achieve the defined objectives. Additionally, the results can be subjected to a sensitivity analysis to verify if, modifying some variables such as weights or values, the alternatives point to the same results.

The most common error in multi-criteria analysis is to assign weights to criteria arbitrarily, without a predefined methodology. Methodology validation is relevant, considering that the views of different stakeholders shall be considered in the analysis to define the best choice of action.

### **3.12.2.2 Compliance cost analysis**

Several countries quantify the costs of possible interventions, that is, how much it would cost to comply with regulation. Compliance relates mainly to those who have to comply with the obligations imposed by the regulator. However, it can also be measured in relation to the regulatory entity, taking into account what it takes to implement, inspect and monitor the intervention.

The basic monetisation of compliance costs consists of converting into monetary values the time invested in the process to guarantee compliance, as well as taking into consideration other costs in tariffs, fees and charges due to the intervention.

Various methodologies have been developed to monetise some of those costs. The Standard Cost Model, for example, was created in the Netherlands to measure the administrative costs resulting from the obligation to provide information and data for institutions in the process of complying with the regulation.

#### **3.12.2.2.1 Standard Cost Model**

The Standard Cost Model (SCM) enables the measurement of the administrative barriers that arises from the obligations related to the generation, custody and transmission of information. It is a methodology that starts from estimates of the time businesses and citizens need to allocate for administrative activities (AA) in order to obtain something from the State: a permit, a license, a document, etc.

The methodology can be used to analyse an existing regulation (*ex-post* analysis) or to assess the possible costs imposed in case there is a regulatory intervention (*ex-ante* analysis). The regulation is disaggregated in units called “information obligations” (IO). The methodology enables a standardisation of AA required to comply with the obligations. To obtain information about activities, time and costs necessary to fulfill obligations, it is possible to arrange focal groups of 6 to 8 companies or citizens, for example.

The SCM has a common formula to express administrative costs in monetary terms:

$$\text{Administrative Cost}_{IO} = \sum AA (\text{Time} \times \text{Price}) \times (\text{Population} \times \text{Frequency})$$

Where:

- TIME = Time required to complete each AA and therefore fulfil a certain IO;
- PRICE = Costs associated with execution of each AA (calculated from basic salary, tariffs, etc.);
- POPULATION = Work force involved in the fulfilment of a specific IO; and
- FREQUENCY = Frequency at which each IO must be fulfilled.

The phases and key steps to estimate the administrative costs of an intervention are:

**Table 9** – Administrative Costs Estimates

Phase 1 Preparation	Phase 2 Data survey and characterisation	Phase 3 Quantification of times and costs	Phase 4 Calculation and reporting
	<p><b>Step 1</b> – Process mapping</p> <p><b>Step 2</b> – Identification of information obligations</p> <p><b>Step 3</b> – Segments definition</p> <p><b>Step 4</b> - Population and frequency identification</p> <p><b>Step 5</b> – Transfer</p> <p><b>Step 6</b> –Relevant cost parameters identification</p> <p><b>Step 7</b> – Campaigns definition and interviews preparation</p>	<p><b>Step 8</b> – Selection of sample companies for interview</p> <p><b>Step 9</b> – Interviews</p> <p><b>Step 10</b> – Standardisation</p>	<p><b>Step 11</b> – Extrapolate data on national level</p> <p><b>Step 12</b> – Comparative assessment/ evaluation</p> <p><b>Step 13</b> – Final report</p>

Source: Agency for Administrative Modernisation



The values obtained from using SCM will be monetised. They will reflect how much it costs to perform administrative activities to comply with information obligations imposed by regulation.

### 3.12.2.3 Cost-effectiveness analysis

The cost-effectiveness analysis is an alternative to the cost-benefit analysis. It was originally developed at the time of World War II to help decision making in situations where there were limited resources. It was later used in public policy areas where benefits are intangible and, therefore, difficult to monetise, such as health or environment. In the United States, for example, a cost-effectiveness analysis is accepted if the regulator can prove that the benefits cannot be monetised.

The cost-effectiveness analysis allows comparing the costs of alternatives and their effectiveness, the latter understood as the ability of the alternative to meet the objectives defined at the beginning of the RIA. Effectiveness also reflects the positive outcome of the intervention, that is, its main benefit.

The effectiveness and as a consequence, the benefit, is represented as a “measure of effectiveness” that does not need to be monetised but must be quantified. Examples of effectiveness measures are: lives saved, jobs created, species protected, etc. For example, the regulator does not need to reach a monetary value for “jobs created”, but must establish a number of jobs created so that the alternative will be considered effective.

Cost-effectiveness analysis is a good methodology when available resources are fixed and the regulator tries to find the option that will bring the best results with the available resources. However, if the availability of resources is not known, cost-effectiveness analysis may present a distortion to the best option choice, because the lowest cost-effective alternative will not always be the best. In this regard, the regulator will always need to review the analysis results to guarantee that the benefits are being properly assessed.

In addition to quantifying costs and selecting a measure of effectiveness, the cost-effectiveness analysis needs to compute the relationship between them, as follows:

$$\begin{aligned} \text{Cost-effectiveness ratio} &= C_1/E_1 \\ \text{Effectiveness-cost ratio} &= E_1/C_1 \end{aligned}$$

$C_1$  = cost of alternative 1, in monetary terms

$E_1$  = effectiveness for alternative 1, in units.

The first equation represents the cost per unit of effectiveness (for example, monetary units spent for a life saved) and, in this case, the alternatives have to be ranked from lowest to highest. The most cost-effective (CE) option would be the one that has the lowest CE ratio. The second equation represents the effectiveness per cost unit (e.g. lives saved per monetary unit spent). In this case, the alternatives are ranked from the highest to lowest cost-effectiveness ratio (EC).

For example, if the Ministry of Health does not have a defined budget and is only searching for the best way to rescue 30,000 children from malnutrition, then it will seek the best cost-effectiveness ratio. However, if the Ministry has an annual budget of \$ 800,000.00 for an intervention to reduce child malnutrition, it will need to determine how many children will be rescued from malnutrition with these resources, and it will seek the intervention that offers the best cost-effectiveness ratio.

#### **3.12.2.4 Cost-Benefit Analysis**

According to the practices of more advanced countries in RIA, the analysis that provides more objective information and data for decision-making is the cost-benefit analysis. The methodology requires the quantification and monetisation of all the costs and benefits of each alternative under analysis.

In most cases, the great challenge of quantifying and monetising benefits is the fact that they are not traded on the market. If the benefits have no market value, then the cost-benefit analysis demands the use of other methodological approaches to assign monetary values and calculate the cost-benefit ratio.

The techniques to attribute values to non-tradable goods may be classified into two major categories, according to the behaviour of consumers: revealed preferences and declared preferences. In revealed preferences techniques, individuals reveal their preferences in observed real situations, while in declared preferences, individuals are going to be presented to hypothetical situations that could come close to reality. The main idea of these approaches is to capture people's willingness to pay (or the willingness of people to be compensated) to achieve, maintain, or change their behaviour in relation to intangible assets. For example, how much a person is willing to pay for a medical treatment can be used to assign a monetary value to suffering (the willingness to pay to eliminate suffering). The use of this methodological approach involves a lot of interaction with potentially affected stakeholders, especially with the preparation of surveys and studies with well-defined groups, statistical and probability analyses to understand trends in answers, and development of models that can create information, in case there is no adequate information already available. These approaches require time, resources and organisation.

In addition to categorizing, quantifying and monetising the costs and benefits that will be integrated into the analysis, this methodology requires attention to the following aspects:

- The costs and benefits must be presented as a cash flow for a reference period, and the values need to be discounted at present value. Several countries recommend adopting a 10-year period as parameter. However, this period shall be defined on a case-by-case basis;
- The regulator must depreciate the monetary values obtained by using a discount rate to compare values at different points of time. The discount rate used in RIA cost-benefit analyses worldwide tend to reflect the opportunity cost of the economy as a whole and are unique for the entire Administration. The values of future costs and benefits must be brought to net present value, because the value of money in the present is not the same as it will be in the future;
- It is important to take into account the distributional effects. Cost-benefit analysis allows finding the best choice for economic efficiency, but the regulator shall also understand the effects of the alternatives on various social groups. That is, it is important to consider the gains and losses of different stakeholders affected by the alternatives;
- Once the cost-benefit analysis has been concluded, it is important to conduct a sensitivity analysis to confirm if the results remain after a few modifications in the variables values.

The cost-benefit analysis will show the best alternative in economic terms. The result must be analysed based on the Net Present Value (NPV). The alternatives can be classified according to the NPV obtained. The one that has the best NPV (positive and higher) will be the most suitable alternative.

#### RECOMMENDED READING

AGÊNCIA PARA MODERNIZAÇÃO ADMINISTRATIVA. Guia Prático para a Quantificação dos Encargos Administrativos de Acordo com a Metodologia Standard Cost Model – Manual PT SCM, Lisboa. Available on: <https://www.ama.gov.pt/documents/24077/178841/manualSCM.%20pdf/22919800-c3f1-4dce-b2e9-22752f004110>

CEPS (2013) – CENTRE FOR EUROPEAN POLICY STUDIES. Assessing the Costs and Benefits of Regulation, Study for the European Commission, Secretariat General, Brussels. Available on: [http://ec.europa.eu/smart-regulation/impact/commission\\_guidelines/docs/131210\\_cba\\_study\\_sg\\_final.pdf](http://ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/131210_cba_study_sg_final.pdf)

DEPARTMENT FOR COMMUNITIES AND LOCAL GOVERNMENT (2009). Multi-Criteria Analysis: A Manual, London. Available on: [http://eprints.lse.ac.uk/12761/1/Multi-criteria\\_Analysis.pdf](http://eprints.lse.ac.uk/12761/1/Multi-criteria_Analysis.pdf)

OECD (2007). Methodological Frameworks for Regulatory Impact Analysis: Valuation, Risk and Cost-Benefit Analysis, SG/GRP(2007)6, Paris. Available on: <https://www.oecd-ilibrary.org/docserver/9789264067110-3-en.pdf?expires=1539883883&id=id&accname=ocid75017727&checksum=7899CC39739704FC46726EA27C98688C>

OECD (2014). OECD Regulatory Compliance Cost Assessment Guidance, Paris, OECD Publishing. Available on: <http://www.oecd.org/gov/regulatory-policy/compliance-costs.htm>

OFFICE OF BEST PRACTICE REGULATION (2016). Cost-benefit Analysis Guidance Note, Canberra. Available on: <https://www.pmc.gov.au/sites/default/files/publications/006-Cost-benefit-analysis.pdf>

UNITED STATES GOVERNMENT (1992). Guidelines and discount rates for benefit-cost analysis of Federal programs, Circular A-94, Office of Management and Budget, Washington, D.C. Available on: <https://www.wbdg.org/FFC/FED/OMB/OMB-Circular-A94.pdf>

WORLD HEALTH ORGANISATION (2003). WHO Guide to Cost-Effectiveness Analysis, Geneva. Available on: [http://www.who.int/choice/publications/p\\_2003\\_generalised\\_cea.pdf](http://www.who.int/choice/publications/p_2003_generalised_cea.pdf)

### 3.13 Risk Assessment<sup>11</sup>

**In cases of greater complexity, the regulatory entity shall seek to incorporate the risk assessment in the preparation of the AIR.**

**The severity and probability of risks occurrence shall be identified from the definition of the regulatory problem. Subsequently, an appropriate strategy of analysis, treatment, management and supervision of risks shall be developed along the other stages of the RIA.**

**The relationship of the regulatory entity with the risks identified will define the strategy to be adopted in the treatment of those risks: acceptance, impediment or mitigation.**

**The regulatory entity cannot ignore the risks associated with their regulatory activities, but shall pursue a balance in their interventions, seeking not to cause additional risks or unjustified costs for its treatment.**

**In its decisions, the regulatory entity shall balance the benefits of the intervention, the cost of the risks treatment and the losses associated to the risks.**

In both public and private activities, there are risks that might affect what has value to businesses, institutions, and society in general. The identification, prevention and treatment of these risks are important to the analysis because they are relevant in the decision-making process.

<sup>11</sup> This Guide was developed with the support of UK Prosperity Fund, led by the UK Embassy in Brazil, for the hiring of Senior Regulatory Quality Specialist Delia Rodrigo.

In some countries, the risk assessment is made by specialized areas, which have the necessary capabilities for this task. However, all regulators shall know how to integrate the risk to the RIA. The main role of the regulatory entity in this respect is to try to identify, evaluate and adopt measures to compare the possible risk effects. In this sense, establishing the risk probability and severity when defining the regulatory problem and then developing adequate strategies for risk assessment, treatment, management and supervision are important steps to be included in the preparation of the RIA.

Risk is a factor that can be present in all regulatory entity activities. Therefore, it is necessary to strengthen the abilities for its management and to guarantee more intelligent interventions that can reduce its probability and negative effects.

### Important concepts

#### Several concepts are relevant in risk treatment:

- **Risk** is an uncertain future event with a negative effect<sup>12</sup>. It is also considered as “an effect of uncertainty on objectives” (ISO 31000). It can also be defined as the possibility of someone being harmed or something being damaged or experiencing any adverse effect from being exposed to a danger.
- **Danger or source of risk** is an object, an action or an activity that, either individually or combined, has the inherent potential to create a risk.

The difference between risk and danger is relevant because the regulator shall correctly define the risk and the source that produces such risk. Some examples may help to better understand the differences between these concepts:

Regarding smoking problem, the source of risk are the cigarettes, which expose citizens to the possibility of developing cancer. The risk refers to the development of lung cancer, which is 15 times more likely to occur among people who smoke.

The 15-knot wind that blows directly into an airfield is a danger. The aircraft loss of control during landing or takeoff is one of the possible consequences of the danger. The possible consequence of aircraft loss of control is the risk, expressed in terms of probability and severity.

- **Probability** refers to the possibility, the frequency of the risk materialized.

For example, the probability of a child born with cleft lip in Brazil is one per 550 births per year. In this case, the probability that the baby will have a cleft lip is 1/550, equal to 0.0018.

<sup>12</sup> As pointed out by the Office of the Chief of Staff/Ipea (2018), “it should be pointed out that there might be risks with positive results, also called opportunities, in addition to those with negative impacts, known as threats. In this guide, for the purposes of a public policy implementation strategy, only the negative risk will be considered, and the responsible body or entity is authorized to include or not positive ones in the management of risks related to the implementation of the public policy proposed”.

- **Severity or seriousness** of the risk describes the damage to the affected stakeholders or society jointly, resulting from the risk, in case it happens. For example, shoplifting at supermarkets in a Brazilian city had been estimated as 80 occurrences per year. The value of the stolen goods is estimated at \$ 1,500.00 on average per occurrence. The economic damage caused is, therefore, of \$ 120,000.00 annually in the city concerned. Therefore, we can measure the severity of the shoplifting-related risk in this city.
- **Effect, expected damage or risk level** is the risk magnitude calculated by multiplying the risk probability by the severity of the consequences. The result reflects the risk social cost, considering the probability that it might happen.

For example, intoxication effects produced by the ingestion of seafood are estimated at \$ 8,500.00 (treatment and medications per patient) and the probability that the intoxication might happen is of 1 per 50 (0.02) at each meal with seafood. The damage expected for the risk of intoxication is  $\$ 8,500.00 \times 0.02 = \$ 170.00$

The subject of risk is frequently present in the activities of the regulatory entity. There are no interventions without risk; however, the risk management capacity varies greatly between areas of regulatory/public policy. The incorporation of this element into the regulatory process is relatively recent. Most countries are still experiencing theoretical approaches that can assist in the proper risk management and their externalities in the regulatory process.

The first step is to determine the regulatory entity's tolerance to risk regarding the theme under analysis. This tolerance will determine the type of treatment that will be adopted. There are three main strategies for the regulator, and each has advantages and disadvantages, as follows:

- **Accept the risk.** This strategy consists in identifying the risks and not taking proactive measures to reduce its probability of occurrence or its severity. It is appropriate when the risk is too small and when the cost of avoiding or minimizing it can be greater than the expected damage. Accepting the risk can be linked to a crisis management strategy if this risk eventually materializes;
- **Avoid the risk.** This strategy seeks to avoid the risk completely, prohibiting activities that might cause it. This type of strategy can be interesting when the probability of the risk happening is high, the damage can be very significant and/or the activity that generates the risk does not bring great benefit to society. The problem associated with this strategy consists of creating additional consequences that can bring even higher costs;
- **Mitigate the risk.** Risk mitigation consists of trying to reduce the probability of its materialization or the severity of its effects. The risk mitigation requires adequate resources for its

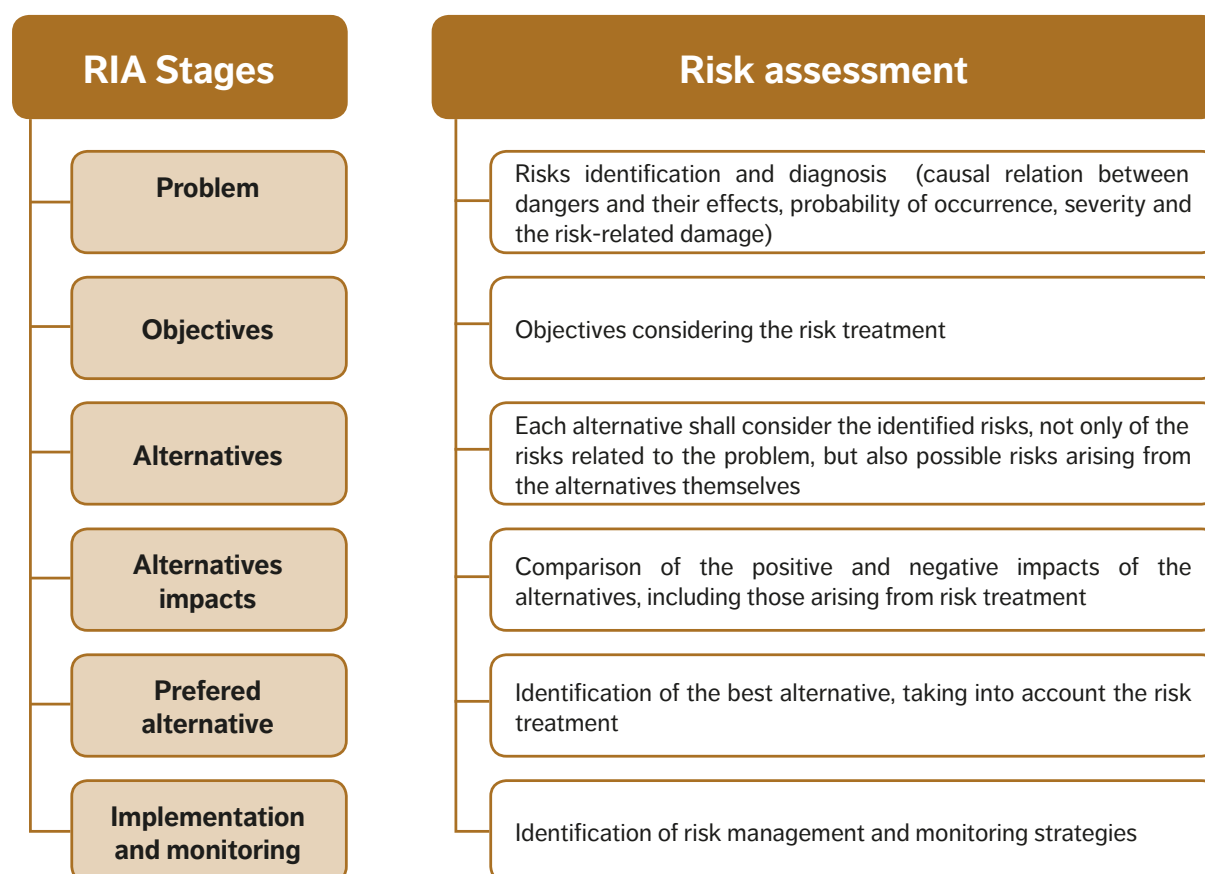
management and it is necessary to establish a mechanism of supervision and inspection that can guarantee the total or partial risk transfer (usually with the risk management being transferred from the regulator to a third party) and a successful control.

Risk mitigation is the strategy most used internationally, and regulators seek to improve it to guarantee, ultimately, the social welfare. The regulatory entity cannot ignore the risks associated with its activities; however, it shall pursue a balance in regulatory interventions, seeking not to cause additional risks or unjustified costs for its treatment.

If the problem the regulatory entity investigates refers to some kind of risk, the risk assessment shall be included in all RIA stages. The risk can be treated in a purely descriptive manner, but an advanced RIA shall present more elements to measure the effects that the risk can bring for the relevant stakeholders and to society.

As the following illustration shows, the risk treatment can be integrated into each of the RIA stages, aiming to guarantee the social welfare without imposing unnecessary costs or reducing the opportunities for the affected stakeholders.

**Figure 5** - Including Risk Assessment into the RIA



Source: Prepared by the authors

A more detailed explanation on including risk assessment in RIA is presented below:

- 1 - In the problem definition, the regulatory entity is expected to be able to identify and diagnose the associated risks<sup>13</sup>: the causal relation between the hazards and the effects they might cause to stakeholders and society as a whole; the probability of occurrence (researching historical data on the phenomenon or international experiences), and the risk characterization, describing its severity and the damage it can bring if it actually happens.

While elaborating the RIA, the regulatory entity shall try to find the best balance between the benefit of any intervention, the degree of risk that can be accepted and the risk management costs. Risk assessment shall start from the problem identification (at this stage, the risks have already been identified and there is a clear understanding of their causes, as well as their possible effects). The correlation between causes and effects is fundamental to the design of an appropriate strategy for risk management.

- 2 - Once the risk is integrated to the problem definition, the regulatory entity shall establish the objectives of its possible intervention. Most likely, the objectives will be related to the risk management, seeking a balance between the costs and damages that they impose on society, as well as the benefits of a possible intervention. Whatever the strategy used (accept, avoid or mitigate the risk), the regulatory entity shall have well-defined objectives.
- 3 - The selection of alternatives will be linked to the defined objectives and to the problem. Regulatory and non-regulatory alternatives can be used for the risk treatment. Any kind of proposed intervention shall bring strategies for risk management, allowing for the comparison between possible alternatives.

Aside the risks related to the problem, the alternatives might have associated risks as well, which shall also be considered into the analysis. Each alternative may have different types of associated risks: operational, reputational, legal, financial or budgetary<sup>14</sup>.

- 4 - When analyzing the impacts of the alternatives, regardless of the chosen methodology, it is also necessary to incorporate the risk assessment. If the defined objective is to mitigate the risk, a multi-criteria analysis shall capture how each of the alternatives is effective on the risk mitigation. The multi-criteria analysis can help in understanding how the alternatives are perceived by the different stakeholders and how they perform considering the criteria adopted for the analysis and comparison. The multi-criteria analysis allows qualifying and quantifying risk-related elements, but the monetization is not necessary. If the cost-benefit methodology is chosen, it will be necessary to estimate monetary values for the different alternatives.

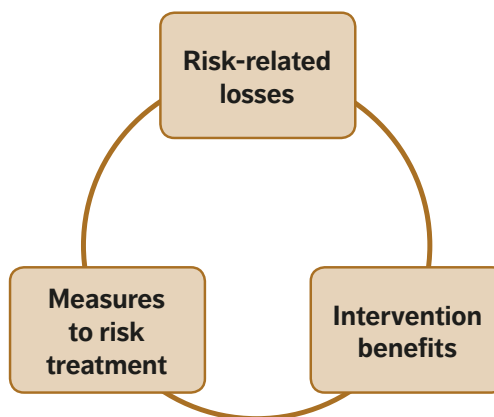
<sup>13</sup> The Office of the Chief of Staff/Ipea publication (2018), presented in the Bibliography at the end of this section, offers a list of the most used techniques for the identification of the risks, such as: brainstorming, interviews, checklists, and the Delphi Technique.

<sup>14</sup> Office of the Chief of Staff/Ipea (2018), page 145.



Risk quantification is generally composed of three main elements, shown in the following illustration. They will be combined with other costs and benefits identified and must be monetized:

**Figure 6** - Main Elements in the Risk Quantification



Source: Adapted from UNECE (2012)

- Measures to risk treatment refer to the cost of the interventions that the regulatory entity can use to treat risk. If the strategy selected is the mitigation one, then it shall include the mitigation measures as well as control and monitoring measures. Measures to risk treatment also refer to the measures that regulated stakeholders need to implement to minimize risk probability and severity;
- Risk-related losses refer to those costs that would result if the risk were materialized, as well as the opportunity costs that arise from their treatment. They shall be associated to the various stakeholders affected by the possibility of the risk happening;
- The intervention benefits refer to the benefits that will be obtained, in terms of social welfare, if the risk treatment is successful and the objectives of the alternatives are achieved.

Any action that the regulatory entity intends to take, may impact the relation between these three elements: costs of the measures to risk treatment, benefits of the intervention, and risk-related losses. The regulatory entity shall analyze several situations:

- If the regulatory entity intends to reduce the costs of risk mitigation measures, the losses associated with such risk may increase and the benefits of intervention may decrease;
- If the regulatory entity intends to minimize the losses associated with the risk, and increase the intervention benefits, it will have to extend the mitigation measures, which will be followed by an increase to their costs;

- In case the regulatory entity chooses to increase the intervention benefits, it will have to extend the mitigation measures, which in turn will increase the intervention costs.
- 5 - The RIA conclusion shall indicate the best alternative; the one that reaches the intended results while bringing more positive than negative impacts for the society. It will also be the one that offers the adequate risk management, considering the problem definition, the objectives defined, and the management of specific uncertainties for its implementation.
  - 6 - In the final stage of RIA, it shall be proposed a strategy for implementing, inspecting and monitoring the preferred alternative, considering the risk aspects. A good implementation and monitoring planning is critical for the adequate risk management and a successful intervention.

### **Example of risk assessment in the RIA: Surgical Gloves Case**

Inmetro and Anvisa have identified that there was a problem related to the size and resistance of surgical latex gloves sold in Brazil. Most of these products were imported from China, where size standard is different from the Brazilianian standard. In addition, they would tear easily, bringing risks to patients and professionals. Trying to minimize these problems, Inmetro defined requirements relating to the size and resistance of latex gloves.

At a certain point, the two regulators considered that there should also be requirements defined for latex-free surgical gloves, which are those used in cases of allergy to the material. Thus, the regulatory alternative established for latex gloves (mandatory certification) was extended to latex-free gloves.

Latex-free gloves were basically imported and accounted for about 1% of the glove market, the remainder being filled by latex gloves. With the new rule, importers have come to the conclusion that it would not be worth to sell these products, because the certification costs would make the sale price unsustainable. Hence, there was a latex-free gloves shortage in the Brazilian market. Hospitals like Albert Einstein and Hospital das Clínicas of São Paulo contacted Inmetro and Anvisa informing that many surgeries had to be cancelled and rescheduled because they could not buy latex-free gloves.

In this case, there are at least two risks to consider: the first one related to the problem that was intended to be solved or minimized with the mandatory certification of surgical gloves, that is, the risks for professionals and patients resulting from the poor quality of surgical gloves, which would easily tear. The second is the risk of surgical gloves shortages in the Brazilian market due to the increase of costs to manufacturers and importers, caused by the alternative chosen to solve the problem (mandatory certification).

## RECOMMENDED READING

AUSTRALIAN GOVERNMENT (2007). Best Practice Regulation Handbook, Canberra. Available on: [https://www.pmc.gov.au/sites/default/files/publications/COAG\\_best\\_practice\\_guide\\_2007.pdf](https://www.pmc.gov.au/sites/default/files/publications/COAG_best_practice_guide_2007.pdf)

CASA CIVIL DA PRESIDÊNCIA E INSTITUTO DE PESQUISA ECONÔMICA APLICADA (2018). Avaliação de políticas públicas: guia prático de análise ex ante, Vol. 1, Brasília, IPEA. Available on: <http://www.cgu.gov.br/Publicacoes/auditoria-e-fiscalizacao/arquivos/guia-analise-ex-ante.pdf>

COFEMER (2013). Guía para Evaluar el Impacto de la Regulación, Vol. 1 Métodos y Metodologías, México. Available on: [http://www.cofemer.gob.mx/presentaciones/Espa%F1ol\\_Vol%20I.%20Metodos%20y%20Metodologias\\_FINAL.pdf](http://www.cofemer.gob.mx/presentaciones/Espa%F1ol_Vol%20I.%20Metodos%20y%20Metodologias_FINAL.pdf)

EUROPEAN COMMISSION (2009). Impact Assessment Guidelines, Brussels. Available on: [http://ec.europa.eu/smart-regulation/impact/commission\\_guidelines/docs/iag\\_2009\\_en.pdf](http://ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/iag_2009_en.pdf)

EUROPEAN COMMISSION (2016). Better Regulation Toolbox. Toolbox 15: Risk Assessment and Management, Brussels. Available on: [https://ec.europa.eu/info/files/better-regulation-toolbox-15\\_en](https://ec.europa.eu/info/files/better-regulation-toolbox-15_en)

ISO 31000: 2018 “Risk management – Guidelines”, International Organization for Standardization. Available on: <https://www.iso.org/standard/65694.html>

MOR, Guy (2018). A Guide to Risk Management in Regulation and Public Policy, Prime Minister’s Office, Tel Aviv. Available on: [http://www.pmo.gov.il/policyplanning/mimshal/Documents/O-16944%20roham\\_risk\\_man%20EN%20forWeb.pdf](http://www.pmo.gov.il/policyplanning/mimshal/Documents/O-16944%20roham_risk_man%20EN%20forWeb.pdf)

OECD (2010). Risk and Regulatory Policy. Improving the Governance of Risk, OECD Publishing, Paris. Available on: [http://www.pmo.gov.il/policyplanning/mimshal/Documents/O-16944%20roham\\_risk\\_man%20EN%20forWeb.pdf](http://www.pmo.gov.il/policyplanning/mimshal/Documents/O-16944%20roham_risk_man%20EN%20forWeb.pdf)

UNECE (2012). Risk Management in Regulatory Frameworks: Towards a Better Management of Risks, New York and Geneva. Available on: [http://www.unece.org/fileadmin/DAM/trade/Publications/WP6\\_ECE\\_TRADE\\_390.pdf](http://www.unece.org/fileadmin/DAM/trade/Publications/WP6_ECE_TRADE_390.pdf)



# 4. REGULATORY OUTCOME EVALUATION - ROE

Regulatory Outcome Evaluation - ROE is the systematic evaluation process of an intervention to determine whether its objectives have been achieved (OECD, 2015). It shall not be mistaken with the inspection or monitoring processes, that aims to verify compliance with obligations and the defined target achievement. The ROE goal is to verify what actually occurred after implementation of the chosen alternative by the regulatory entity.

Although not widely disseminated, the ROE is considered an important stage in the regulatory cycle because, in addition to providing a return on the intervention performance, it brings important inputs to the evolution of regulation over time. As highlighted by the Australian authority (2011), even if all regulations are subject to strict regulatory impact analysis processes (ex-ante), unpredictable factors or context changes might occur, as well as technological changes or unavoidable adjustments in the agents' behavior after the intervention. In addition, the effects of a regulation may be altered by other rules, regulations or laws created or modified after the regulation comes into force. Therefore, in the medium and long run, a regulation that was initially effective and efficient can become outdated or inadequate.

The lack of any kind of ex-post evaluation may result in:

- The continuity of ineffective regulations, which generate unnecessary costs to regulated entities and to the government;
- The unawareness of unwanted impacts generated by the intervention;
- The unawareness about the necessity or opportunity for improvement of existing regulations;
- Lack of technical foundation to evidence the benefits promoted by the intervention and to demonstrate the decision suitability taken by the regulatory entity.

In its Recommendation on Regulatory Policy and Governance (2012), the OECD recommends:

“Conduct systematic programme reviews of the **regulatory stock** against clearly defined policy goals, including consideration of costs and benefits, to ensure that regulations remain up to date, cost justified, cost effective and consistent, and deliver the intended policy objectives.”

**It is recommended that the ROE be prepared at least for the cases of more complex rules, submitted to RIA level II, or to regulations that have been exempted from RIA due to urgency.**

The ROE type and complexity will depend on the type of intervention being evaluated. According to the United Kingdom Authority (2011), there are three main perspectives that can be adopted in an ROE:

- Process evaluation: seeks to evaluate how the intervention was implemented, focusing on the means and processes used and how they contributed to the success or failure in achieving the expected objectives;
- Impact evaluation: seeks to evaluate whether the intervention implemented really acted on the identified problem, what positive or negative impacts it generated, how they were distributed among the different stakeholders or groups, and if there were unexpected impacts;
- Economic evaluation: seeks to evaluate whether the benefits generated by the intervention outweighed its costs. When conducting a ROE, one shall try to identify other factors that may have contributed to the observed results, trying to isolate, as much as possible, the effects that directly resulted from the intervention. While assessing the intervention efficiency, efficacy and effectiveness, a good ROE shall also take into consideration what would have happened in the period under examination if no action had been taken.

The processes of inspection and monitoring of the intervention can bring important data and information to the ROE. Therefore, it is recommended that basic questions and considerations that will be addressed in the ROE, be analyzed during the RIA elaboration, when formulating the inspection and monitoring strategy.

From the achieved conclusions, the ROE shall provide guidance on the relevance of maintaining, amending or revoking the evaluated regulation.

In order to bring other perspectives to the evaluation, the ROE may be conducted by a different team other than the one that conducted the RIA, by a group specially organized for this task, by an external consulting, etc.

**RECOMMENDED READING**

GERMANY (2013). Expert report on the implementation of ex-post evaluations: Good practice and experience in other countries, National Regulatory Control Council. Available on: [https://www.normenkontrollrat.bund.de/Webs/NKR/Content/EN/Publikationen/2014\\_02\\_24\\_evaluation\\_report.pdf?\\_\\_blob=publicationFile&v=2](https://www.normenkontrollrat.bund.de/Webs/NKR/Content/EN/Publikationen/2014_02_24_evaluation_report.pdf?__blob=publicationFile&v=2)

OECD (2015). Regulatory Policy Outlook 2015, Chapter 5, OECD Publishing, Paris. Available on: [http://www.keepeek.com/Digital-Asset-Management/oecd/governance/oecd-regulatory-policy-outlook-2015\\_9789264238770-en#page120](http://www.keepeek.com/Digital-Asset-Management/oecd/governance/oecd-regulatory-policy-outlook-2015_9789264238770-en#page120)

OECD (2016). Supporting Evidence-based Policy: The Importance of Ex-post Evaluation, Public Governance and Territorial Development Directorate.

UNITED KINGDOM (2011). HM Treasury, The Magenta Book: Guidance for Evaluation. Available on: <https://www.gov.uk/government/publications/the-magenta-book>





# 5. GLOSSARY

**Administrative costs:** costs (financial, time-related, learning, adaptation or implementation) incurred for complying with the obligations created by the State related to the generation, storage and submission of information, obtaining permits, licenses, forms, inspections preparation, etc.

**Administrative rules:** rule oriented to discipline subjects related to the management, administration or operation of the regulatory entity or to discipline the activities and behavior of its agents, without creating obligations or effects to external agents.

**Decisions intended to regulate specific situations:** rules directed to determined and specific person or company, creating individual legal situations, such as authorizations, concessions, and permissions. Changes in rates, tariffs or prices with revision rules predetermined contracts can be included in this category.

**Effectiveness:** performance related to the achievement of the intended objectives or impacts. An effective action is the one capable of achieving the desired objectives or impacts, regardless of the costs involved or the targets achieved.

**Efficacy:** performance related to the results achievement. An effective action is the one capable of achieving the planned targets, regardless of the costs involved or the objectives or impacts achieved.

**Efficiency:** performance considering the relationship between the achieved results and the resources employed. An efficient action is one that is able to achieve the desired results at the lowest possible cost, regardless of the achievement of the desired impacts.

**Evaluation:** activity that seeks to analyze whether the expected impacts and the objectives originally defined were achieved, using indicators specifically prepared for such analysis and having the initial scenario prior to the intervention as the parameter.

**Indicator:** variable used to describe, classify, sort, compare, qualify or quantify aspects of an object (policy, program, project, action, etc.), in a systematic manner. The main purpose of

an indicator is to translate, in a measurable way, certain aspect of a given reality (situation) or built reality (action) so that it allows its observation, monitoring and evaluation.

**Inspection:** activity that seeks to observe the agents’ practices in relation to the obligations to do or not to do defined in regulations, in order to verify whether they are being met.

**Monitoring:** activity that seeks to keep track of the impacts of the implemented alternative, using quantifying or qualifying methodologies, in order to check whether the defined targets are being met.

**Non-regulatory alternatives:** intervention options that seek to solve regulatory problems using incentive mechanisms that do not involve the Government editing rules of the “command and control” type. In general, they are based on economic incentives, self-regulation, co-regulation, and information and education campaigns.

**Objective:** statement of something to be achieved, defined in terms of a context, an object, and a preferred direction (such as reducing [direction] costs [object] related to the inspection of aircraft operators [context])

**Regulatory Outcome Evaluation (ROE):** instrument for evaluating the performance of the adopted or amended rule, considering the achievement of the objectives originally defined and the intended results, as well as other impacts observed on the market and on the society, as a result of the intervention.

**Regulatory alternatives:** intervention options that seek to solve regulatory problems changing the behavior of economic agents by means of “command and control”. Traditionally, they consist of rules edition, by the Government, that imposes a set of conducts or standards to be observed by individuals, under penalty of punishment.

**Regulatory problem:** one that results in distortions in the market functioning or limits the range of a specific public policy, which requires the regulatory authority to take a decision.

**Regulatory Stock:** collection of regulations published by the regulatory entity.

**RIA and ROE implementation in the context of regulatory entities:** it is the definition of the organizational units involved in RIA and ROE elaboration and their respective competences.

**Rule of Manifest low impact:** for the RIA purpose, noticeable low-impact rule must be understood as those that fit in the following cases:

- (a) do not cause significant impacts on health, safety, environment, economy or society; or
- (b) do not generate a significant cost increase for the regulated entities and users, nor significant budgetary expenses for the regulatory entity.”

**Rule of general interest:** rule that can potentiality influence the rights or obligations of economic agents, consumers or users of services provided by the regulated companies.

**Rule aimed at regulating rights or obligations defined in a superior legal instrument that does not allow the possibility of different regulatory alternatives:** rule drawn up in obedience of a superior legal instrument that requires the edition of a regulatory rule, but that already defines in its text the intervention to be taken, not allowing the analysis of alternatives by the regulatory entity.

**Regulatory stock management:** periodic examination of regulations published by the regulatory entity, in order to determine whether they shall be maintained or changed, updated or revoked, taking into account if it is still up-to-date, its effectiveness, coherence, consistency, etc.

**Stakeholder engagement:** for the purposes of this Guide, stakeholder engagement is considered in a broad sense, that is, any process that allows the receipt of information, comments, suggestions and contributions from agents directly concerned and the general public about regulatory problems under consideration by the regulatory entity, using different means and channels considered appropriate.

**Sensitivity analysis:** analysis of the variations on the results of an alternative in response to changes in the assumptions or parameters used. In a decision-making context, it can be used to: (a) test the alternative's robustness (how insensitive it is to parameters change); (b) check in which direction results will change depending on the parameters changes; (c) determine the limit that such parameters can vary without affecting the results.

**Target:** it is the specific result, tangible or measurable, of the objective to be achieved. It refers to the quantitative specification of the objective and shall preferably be accompanied by a time reference, that indicates the intended period for its achievement. (For example, reducing 5% of vehicle carbon-monoxide emission in two years).

**Urgency:** need for immediate or rapid response due the existence of imminent risk or serious damage to health, safety, environment, economy or society, or the need for prompt intervention due to a term defined in superior legal instrument.



# REFERENCES

AUSTRALIA (2003). Department of the Treasury, Practice Guide for Preparing Regulatory Impact Statements. Available on [http://www.treasury.act.gov.au/documents/regulatory\\_impact\\_statement\\_guide.pdf](http://www.treasury.act.gov.au/documents/regulatory_impact_statement_guide.pdf)

AUSTRALIA. Australian Government (2007), Best Practice Regulation Handbook, Canberra. Available on: [http://regulationbodyofknowledge.org/wp-content/uploads/2013/03/AustralianGovernment\\_Best\\_Practice\\_Regulation.pdf](http://regulationbodyofknowledge.org/wp-content/uploads/2013/03/AustralianGovernment_Best_Practice_Regulation.pdf)

WORLD BANK. Global Database for Regulatory Impact Assessment (RIA). Available on: <https://rulemaking.worldbank.org/en/ria-documents>

BRAZIL (2014). Agência Nacional de Saúde Suplementar, Guia Técnico de Boas Práticas Regulatórias: Orientações técnicas para o aprimoramento do processo regulatório, Rio de Janeiro. Available on: [http://www.ans.gov.br/images/stories/Materiais\\_para\\_pesquisa/Materiais\\_por\\_assunto/guia\\_tecnico\\_boas\\_praticas.pdf](http://www.ans.gov.br/images/stories/Materiais_para_pesquisa/Materiais_por_assunto/guia_tecnico_boas_praticas.pdf)

BRAZIL (2016). Agência Nacional de Transportes Terrestres, Manual de Análise de Impacto Regulatório, 2ª. Edição. Available on: [http://agendaregulatoria.antt.gov.br/html/objects/\\_downloadblob.php?cod\\_blob=1038](http://agendaregulatoria.antt.gov.br/html/objects/_downloadblob.php?cod_blob=1038)

CANADA (2009). Treasury Board of Canada Secretariat, RIAs Write's Guide. Available on: <https://www.tbs-sct.gc.ca/rtrap-parfa/riaswg-grrier/riaswg-grrier-eng.pdf>

EUROPEAN COMMISSION (2009). European Commission, Impact Assessment Guidelines. Available on: [http://ec.europa.eu/smart-regulation/impact/commission\\_guidelines/docs/iag\\_2009\\_en.pdf](http://ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/iag_2009_en.pdf)

EUROPEAN COMMISSION (2015). Better Regulation “Toolbox”, Capítulo 3. Available on: [http://ec.europa.eu/smart-regulation/guidelines/docs/br\\_toolbox\\_en.pdf](http://ec.europa.eu/smart-regulation/guidelines/docs/br_toolbox_en.pdf)

GUEDES, Felipe Machado (2015), “A Atuação do Estado na Economia como Acionista Minoritário: Possibilidades e Limites, Editora Almedina Brasil.

LADEGAARD, Peter Farup; RIMMER, Stephen; RODRIGO ENRIQUEZ, Delia (2009). Making it work: 'Ria light' for developing countries. Washington, D.C. : World Bank Group. Available on: <http://documents.worldbank.org/curated/en/184141468167049021/Making-it-work-Ria-light-for-developing-countries>

OECD (1995). Recommendation of the Council on Improving the Quality of Government Regulation. Available on: [https://www.oecd-ilibrary.org/governance/regulatory-policies-in-oecd-countries\\_9789264177437-en](https://www.oecd-ilibrary.org/governance/regulatory-policies-in-oecd-countries_9789264177437-en)

OECD (2002). Regulatory Policies in OECD Countries: from interventionism to regulatory governance, OECD Reviews of Regulatory Reform. Available on: [https://www.oecd-ilibrary.org/governance/regulatory-policies-in-oecd-countries\\_9789264177437-en](https://www.oecd-ilibrary.org/governance/regulatory-policies-in-oecd-countries_9789264177437-en)

OECD (2004), Regulatory Impact Assessment (RIA) Inventory: Note by the Secretariat, GOV/PGC/RD(2004)1. Available on: <http://www.oecd.org/gov/regulatory-policy/35258430.pdf>

OECD (2008), Introductory Handbook for Undertaking Regulatory Impact Analysis – RIA, Versão 1.0 Outubro 2008. Available on: <https://www.oecd.org/gov/regulatory-policy/44789472.pdf>

OECD (2009). Determinants of Quality in Regulatory Impact Analysis, Regulatory Division Public Governance and Territorial Development Department. Available on: <https://www.oecd.org/gov/regulatory-policy/42047618.pdf>

OECD (2009) Regulatory Impact Analysis: A Tool for Policy Coherence. Available on: [http://www.keepeek.com/Digital-Asset-Management/oecd/governance/regulatory-impact-analysis\\_9789264067110-en#.WYoa24grKUK#page1](http://www.keepeek.com/Digital-Asset-Management/oecd/governance/regulatory-impact-analysis_9789264067110-en#.WYoa24grKUK#page1)

OECD (2012). Recommendation of the Council on Regulatory Policy and Governance. OCDE Publishing, Paris. Available on: <http://www.oecd.org/governance/regulatory-policy/49990817.pdf>

POLAND. Ministry of Economy (2007), Guidelines for the Regulation Impact Assessment. Available on: <http://regulatoryreform.com/wp-content/uploads/2015/02/Poland-Guidelines-Regulation-Impact-Assessment-2007.pdf>

UNITED KINGDOM (2003). Department for Business Innovation & Skills, Better regulation framework manual: practical guidance for UK government officials. Available on: <https://www.gov.uk/government/publications/better-regulation-framework-manual>

UNITED KINGDOM (2003). HM Treasury, Green Book: Appraisal and evaluation in central government. Available on: <https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-government>

UNITED STATES (2003). United States Office of Management and Budget, Regulatory Analysis, Circular A-4. Available on: <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>





# ANNEX I

## ROADMAP TO CONDUCT A RIA

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### 3.1 Executive Summary

- Brief summary of the analysis and the conclusions achieved, in plain language, accessible to the general public, to be prepared after the RIA completion.

### 3.2 Problem identification

- What is the context in which the problem is inserted?
- What is the nature of the problem and its consequences?
- What are the problem causes or inducers?
- What is the extent or magnitude of the problem, that is, where does it occur (locally, regionally, nationally), how often, what is the size of the groups affected?
- What is the expected problem evolution in the future if nothing is done?

### 3.3 Identification of stakeholders or groups affected by the regulatory problem

- Which stakeholders or groups are being affected by the regulatory problem?
- How does the problem directly or indirectly affect each of the stakeholders or groups?
- How relevant are the effects observed to each stakeholder or groups?
- Do affected stakeholder or groups contribute for the problem continuity or deterioration? Is there any change in behavior or measure these stakeholder or groups could take in order to avoid or minimize the problem effects?
- How are the problem's effects evolving for each stakeholder or groups? What are the prospects for these effects if nothing is done?

### 3.4 Identification of the legal basis

- What is the legal basis that establishes the regulatory entity powers to act on the identified problem?
- Are there other institutions (from the government, at different state levels, international bodies) that can act on the problem with competing or complementary powers?
- Can the regulatory entity actions in relation to the problem create conflicts with the legal powers of other institutions?

- Are there relevant recommendations or determinations of other governmental institutions, such as audit or control courts, regarding the identified problem?

### **3.5 Definition of objectives to be achieved**

- Are the objectives directly related and proportional to the regulatory problem?
- Are the objectives aligned with the strategic objectives of the regulatory entity?
- Were the objectives defined in different hierarchical levels? Were general objectives transformed into specific objectives and, when necessary, into operational objectives?
- What are the expected results and effects of the intervention?

### **3.6 Description of the possible alternatives**

- What are the alternatives to tackle the problem and achieve the defined objectives? Discard non-viable, ineffective or difficult to implement alternatives.
- Are there non-regulatory alternatives available to tackle the identified problem?
- Do the alternatives chosen, including the no action alternative, take into consideration the activity scope of the regulatory entity, the implementation feasibility, as well as the proportionality to deal with the problem?

### **3.7 Possible impacts and comparison of the considered alternatives**

- What are the main impacts (economic, social, environmental) expected (positive and negative, desirable and undesirable, direct and indirect) of the considered alternatives?
- Are there specific impacts that shall be examined (for example, on competition, small and medium-sized companies, competitiveness, international agreements, etc.)?
- What are the likely benefits of the considered alternatives? Which stakeholders or groups will benefit (society, companies, government)? How will the benefits be distributed among them?
- What are the likely costs of the considered alternatives? Which stakeholders or groups will incur in these costs (society, companies, government)? How will the costs be distributed among the them?
- In what way the alternatives can be compared considering their effectiveness, efficiency and consistency in solving the problem?
- Do the considered alternatives result in benefits greater than the alternative of doing nothing (keeping the status quo)?
- What is the recommended alternative?

### **3.8 Implementation, monitoring and inspection strategies**

- How will the recommended alternative be implemented?
- Do the stakeholders or groups affected need a transition or adjustment period (*vacatio legis*)?
- Does the recommended alternative require inspection? How will it be?
- How shall the proposed alternative be monitored? Define indicators to monitor if the targets are being achieved;
- Will the regulatory entity need adjustments to implement the inspection and monitoring strategy? Does the monitoring and evaluation structure already exist? Are the required data available or will it be necessary to collect new information?
- Is it necessary to develop or adapt any IT or information system?
- Shall the proposed rule be reviewed? Define a deadline for its revision.

### **3.9 Considerations on manifestations or comments received in stakeholder engagement processes**

- Which stakeholders or groups were consulted? When and how?
- What contributions and relevant information were received and how were they used in the analysis?

### **3.10 Full name, position and signature of those responsible for the RIA**

- Full name and position of the civil servants that took part in the RIA and signature of at least one civil servant responsible for the RIA Report.

### **3.11 International Experience**

- Are there international experiences related to the identified problem?
- How was the identified problem treated in the international scenario?
- Is it possible to replicate in Brazil the best international practices identified to solve the problem?

### **3.12. Measurement of the alternatives impacts on different stakeholders or groups**

- Does the relevance of the impacts identified in section 3.7 require the use of greater efforts for their measurement?

- What are the nature of the elements involved in measuring the impacts? Can they be quantified and/or monetized?
- What is the best methodology to measure the impacts?
- Are the available data adequate in terms of quality and quantity or is it possible to obtain them?
- Does the regulatory entity have the technical capacity to apply the chosen methodology?
- Do the identified impacts affect different stakeholders or groups in opposite directions? How shall they be calculated to avoid double-counting?

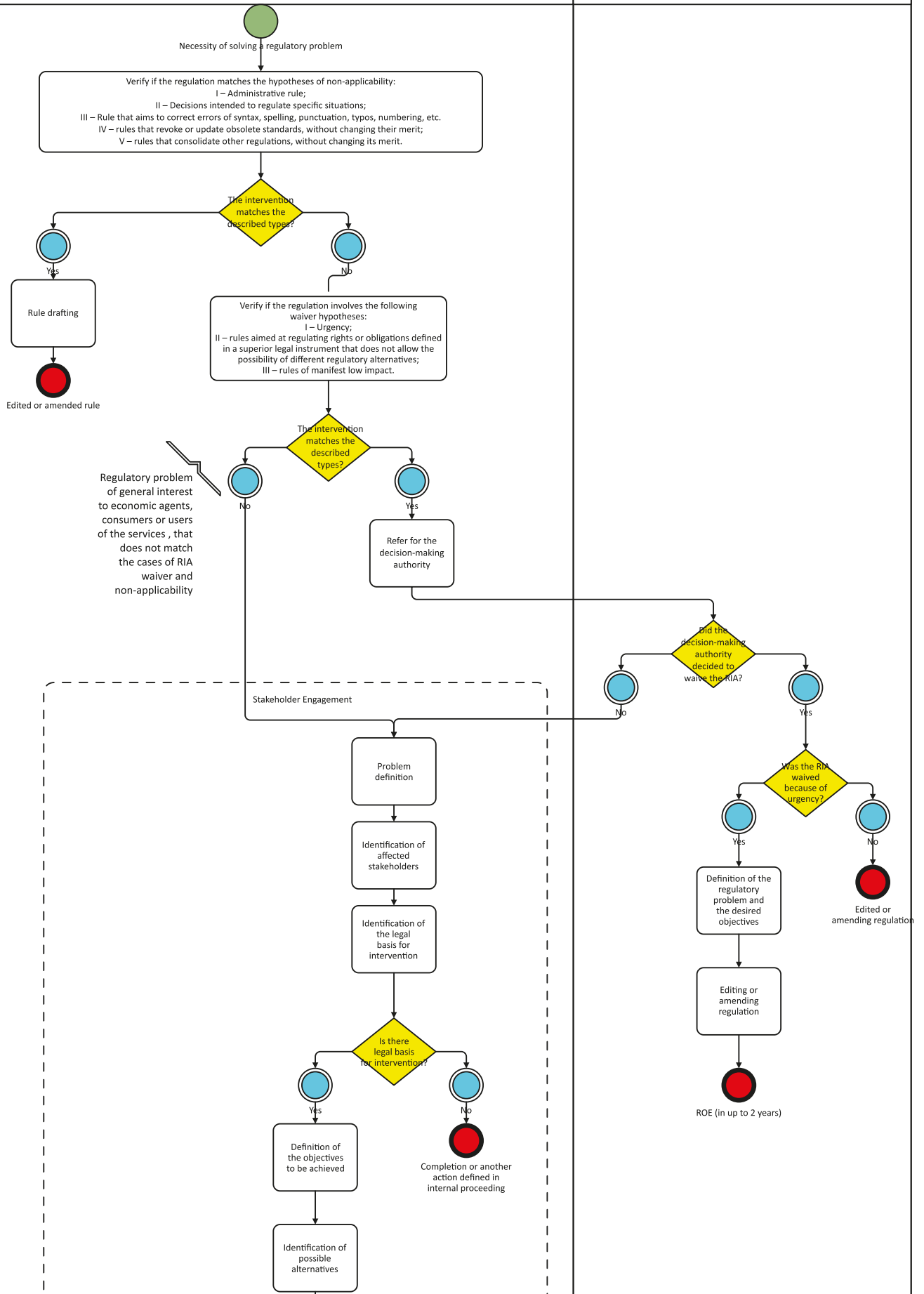
### **3.13. Risk Assessment**

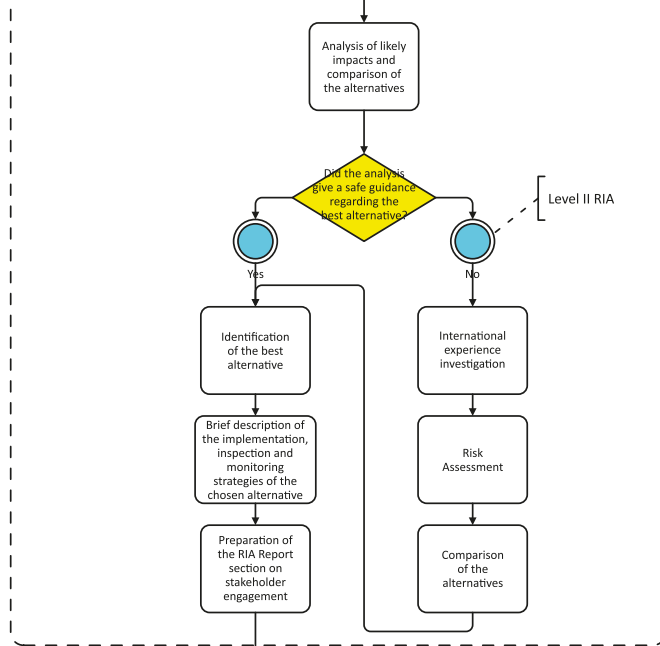
- What are the risks associated with the regulatory problem under analysis?
- What are the sources, probability of occurrence, and severity of the identified risks?
- Shall the identified risks be accepted, avoided or mitigated?
- How the alternatives consider the risks treatment? Do these alternatives bring new risks?
- How to implement and inspect for the risk treatment measures?
- How will the treatment costs and losses related to risks be incorporated into the measurement and comparison of the alternatives?

RIA FLOWCHART

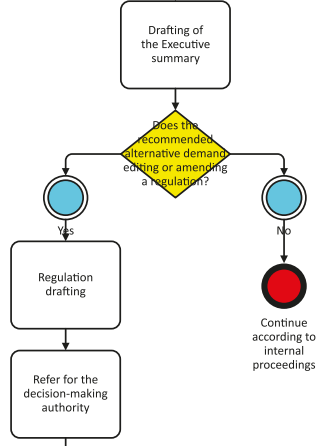
Technical team

Decision-making Authority

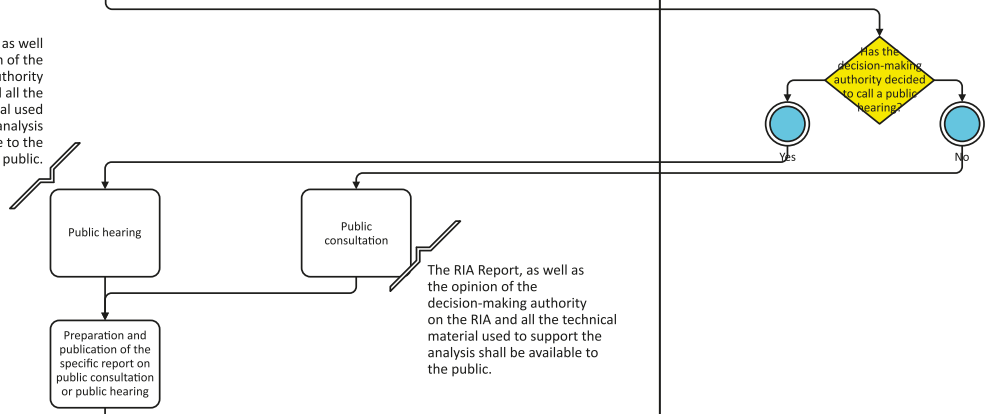




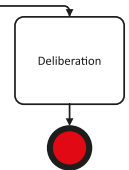
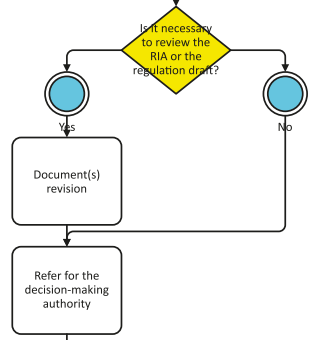
Level II RIA



The RIA Report, as well as the opinion of the decision-making authority on the RIA and all the technical material used to support the analysis shall be available to the public.



The RIA Report, as well as the opinion of the decision-making authority on the RIA and all the technical material used to support the analysis shall be available to the public.



Publication of the regulation or other recommended actions

## **ANNEX III**

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### SUMMARY OF THE INTERMINISTERIAL GOVERNANCE COMMITTEE'S DECISION

On June 11, 2018, the members of Interministerial Governance Committee, created by the Decree nº 9.203, from November 22, 2017, decided to<sup>15</sup>:

1. Approve the Guidelines and Suggested Analytical Roadmap for Regulatory Impact Analysis - RIA Guidelines and the Guidebook for the Preparation of Regulatory Impact Analysis - RIA Guidebook and recommend both documents as best practice to be adopted by all the Federal Public Administration, as well as to approve the undertaking of RIA pilot projects in the Federal Public Administration bodies along 2018.

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<sup>15</sup> The complete III Interministerial Governance Committee Meeting Register is available, in Portuguese, on: <http://www.casacivil.gov.br/orgaos-vinculados/comite-interministerial-de-governanca/3a-reuniao-ordinaria-do-comite-interministerial-de-governanca-11-de-junho-de-2018>

The background is a dark blue field filled with numerous semi-transparent, light blue cubes of various sizes and orientations. Some cubes are in sharp focus, while others are blurred, creating a sense of depth. Faint, vertical lines of white and light blue, resembling data or code, are scattered throughout the scene, particularly in the upper and right portions. The overall aesthetic is clean, modern, and technological.

**RIA**

**OFFICE OF THE  
CHIEF OF STAFF**

**BRAZILIAN  
GOVERNMENT**