



# REGULATORY IMPACT ANALYSIS FOR UKRAINE

Year 2006



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DAI Europe, a European firm based in London, provides international development and transition consulting services to bilateral and multilateral donors, governments, and enterprise, banking, and finance clients throughout the world. For more than 20 years, DAI Europe has been providing innovative solutions to complex development and transition problems in public sector governance and private sector development and finance.

# **RIA MANUAL FOR UKRAINE**

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# INTRODUCTION

## DESCRIPTION OF MANUAL AND AUDIENCE

This is a Manual designed for those involved with policy and decision-making to improve the quality of regulatory acts through the production of a Regulatory Impact Analysis.

This will help to assess the impacts and outcomes of regulatory acts on groups and individuals in society, especially those in the private sector.

By producing this analysis in a consistent method and scrutinizing their content all stakeholders can identify and contribute to developing better policies, making better decisions that will have better outcomes.

The Regulatory Impact Analysis is a key tool in enabling *Better Regulation* within Ukraine.

This Manual explains the requirements under Ukrainian Law for completing Regulatory Impact Analysis and details how to complete a Regulatory Impact Analysis. It also defines what regulatory acts are in accordance with the Law of Ukraine.

This Manual is for all those involved in and affected by regulatory acts.

This Manual contains the following three chapters:

### *Chapter One: Legal Requirements for Regulatory Impact Analysis in Ukraine*

This chapter explains the context for Regulatory Impact Analysis and the stipulations within Ukrainian Law for producing Regulatory Impact Analysis.

### *Chapter Two: Completing a Regulatory Impact Analysis*

This chapter explains what a standard Regulatory Impact Analysis is and the requirements for each section of a Regulatory Impact Analysis. It also gives guidance on how to complete the different sections of the Regulatory Impact Analysis.

### *Chapter Three: Recommendations for Regulatory Analysis in Ukraine*

This chapter gives recommendations for improving the Regulatory Impact Analysis process in Ukraine. It is included for discussion and is not intended for the recommendations to be adopted without amendment or in the immediate future.

# Chapter One – LEGAL REQUIREMENTS FOR REGULATORY IMPACT ANALYSIS IN UKRAINE

## LEGAL REQUIREMENTS IN UKRAINE

In the Law of Ukraine on the 'Principles of State Regulatory Policy in the Area of Economic Activity' the following policy is stated in Article 1. Definition of Terms:

**State Regulatory Policy in the Area of Economic Activity** (*hereinafter - State Regulatory Policy*) - state policy that aims to improve the legal regulation of economic relations as well as administrative relations between regulatory bodies and other bodies of state authority and business entities, to prevent the adoption of economically inexpedient and ineffective regulatory acts, to reduce the interference of the state in the activity of business entities, and remove obstacles for the development of business activity pursued within the purview, under the procedure and in a manner established by the Constitution ( 254k/96-VR ) and laws of Ukraine.

### Table 1.

This policy defines the reason and rationale for Regulatory Impact Analysis in Ukraine. The principles of the State

Regulatory Policy are described below. These principles are core values of the Regulatory Impact Analysis.

## ARTICLE 4. PRINCIPLES OF STATE REGULATORY POLICY

The principles of state regulatory policy shall be as follows:

- **Expediency** - justified need for state regulation of economic relations in order to deal with an existing problem;
- **Adequacy** - correspondence of the forms and level of state regulation of economic relations to the need for dealing with an existing problem and market requirements with allowance for all acceptable alternatives;
- **Effectiveness** - achievement through a regulatory act of the best possible result at the least required costs for business entities, citizens and the state;
- **Balanced approach** - maintenance in regulatory activity of a balance of interests of business entities, citizens and the state;
- **Predictability** - consistency of regulatory activity, its correspondence to the goals of state policy as well as to the plans for drafting regulatory acts to make it possible for the business entities to project their activity;
- **Transparency and allowance for public opinion** - openness for individuals, legal entities and their associations of the actions of regulatory bodies at all stages of their regulatory activity, binding consideration by regulatory bodies of the initiatives, remarks and proposals submitted under legally established procedure by individuals and legal entities and their associations, binding and timely notification of individuals, legal entities

and their associations about adopted regulatory acts, informing the public about regulatory activity.

**Table. 2.**

The principles of implementing the State Regulatory Policy are as follows.

**ARTICLE 5. SUSTAINMENT OF STATE REGULATORY POLICY IMPLEMENTATION**

The implementation of state regulatory policy shall be sustained by:

- Establishing a uniform approach to the preparation of an analysis of a regulatory effect and to the tracking of the effectuality of regulatory acts;
- Preparing an analysis of a regulatory effect;
- Planning activity for the design of draft regulatory acts;
- Promulgating the drafts of regulatory acts so as to receive remarks and proposals from individuals, legal entities and their associations, as well as holding open discussions with the participation of representatives of the public on issues related to regulatory activity;
- Tracking the effectuality of regulatory acts;
- Revising regulatory acts;
- Systematizing regulatory acts;
- Preventing the adoption of regulatory acts that are irrelevant or are not in accord with or duplicate Existing regulatory acts;
- Setting forth the provisions of a regulatory act in a manner that is accessible and unambiguous for the understanding of persons who must introduce or meet the requirements of this regulatory act;
- Promulgating information about implementation of regulatory activity.

**Table. 3.**

The Regulatory Impact Analysis is the methodology for implementing the State Regulatory Policy that has been approved by the Cabinet of Ministers of Ukraine on 11 March 2004 (Resolution #308).

**WHAT IS A REGULATORY IMPACT ANALYSIS?**

The Regulatory Impact Analysis fulfills the following legal requirement to produce an analysis of a regulatory act and is defined as follows:

**Analysis of a regulatory effect** - a document that substantiates the need of state regulation by means of adopting a regulatory act, that analyzes the effect a regulatory act produces on the market environment, ensures the rights and interests of business entities, citizens and the state, and also substantiates the conformity of the draft regulatory act with the principles of state regulatory policy;

**Table. 4.**

However the Regulatory Impact Analysis is key to implementing the overall State Regulatory Policy and it will fulfill most of the requirements in Article 5. as are highlighted above in Table 3. A Regulatory Impact Analysis is a structured and standardized format of completing the analysis of regulatory effect stated above. It assists those drafting regulatory acts with a systematic and logical framework to assess the issue or problem that they are trying to address. It also gives decision-makers clear evidence about the most effective option to implement based on a cost and benefits analysis that can measure whether the chosen option meets the Principles of State Regulatory Policy (Table 2 above on Article 4). And it allows stakeholders to understand the rationale



for government intervention and make suggestions on improving the proposal for

better delivery of the regulatory act.

## WHAT REGULATORY ACTS REQUIRE A REGULATORY IMPACT ANALYSIS?

The State Regulatory Policy aims to ensure that all regulatory activity in Ukraine adheres to the following principles:

- **Expediency**
- **Adequacy**
- **Effectiveness**
- **Balanced Approach**
- **Predictability**
- **Transparency and allowance for public opinion**

(see Table. 2 above on Article 4)

**Regulatory Activity** - activity that aims to prepare, adopt and track the effectuality and revise regulatory acts of regulatory bodies, individuals, legal entities and their associations, and territorial communities within the purview, under the procedure and in a manner established by the Constitution ([254k/96-VR](#)) of Ukraine, the present Law and other statutory acts

Table. 5.

All regulatory acts require a Regulatory Impact Analysis. The Law gives the following definition for a regulatory act:

### Regulatory Act is:

- a statutory act (adopted by an authorized regulatory body), which or the individual provisions of which are aimed at legally governing economic relations as well as administrative relations between regulatory bodies and other bodies of state authority and business entities irrespective of this document being regarded as a statutory act in accordance with a law governing relations in a certain area.
- other official document adopted by a duly authorized regulatory body, which sets forth, amends or waives legal provisions. This act is applied repeatedly to unlimited number of persons. Such document or its specific provisions thereof are aimed at regulating economic and administrative relations among regulatory bodies or other State authorities and subjects of economic activity, irrespective of the fact whether such document is deemed a normative-legal act regulating relations in a specific area according to the law.

### Table. 6.

A Regulatory Impact Analysis must be prepared for each draft regulatory act and it must be prepared before the draft

regulatory act is promulgated for remarks and proposals. All draft regulatory acts must be promulgated.

## WHAT ARE THE UKRAINIAN PROCEDURES FOR THE REGULATORY IMPACT ANALYSIS PROCESS?

### 1. Who is responsible for completing a Regulatory Impact Analysis?

The designer of the draft regulatory act is responsible for also producing the Regulatory Impact Analysis.

### 2. What are the rights of Citizens, Business Entities and their

### Associations, Scientific Institutions, counseling and Advisory Bodies in State Regulatory Policy Implementation?

All of the above are entitled to:

- Submit to regulatory bodies proposals on the need to draft regulatory act as well as on the need of their revision;
- Take part in designing draft regulatory acts in cases provided for under legislation;
- Submit remarks and proposals on promulgating draft regulatory acts, take part in open discussions of issues related to regulatory activity;
- Be engaged by regulatory bodies for preparing analyses of regulatory effect, expert opinions about regulatory effect and performance of measures of tracking the effectuality of regulatory acts;
- Independently prepare analyses of regulatory effect of draft regulatory acts designed by regulatory bodies, track the effectuality of regulatory acts, submit thereupon remarks and proposals to a regulatory body or a body that under the present Law and on the basis of the analysis of reports on tracking the effectuality of regulatory acts adopted decisions on the need of their revision;
- Receive from regulatory bodies information about their regulatory activity in response to applications submitted under legally established procedure.

**Table. 7.**

**3. What happens if there is a disagreement about the Regulatory Impact Analysis?**

There is the opportunity for all stakeholders and members of the public to appeal against the assessment in the Regulatory Impact Analysis and the draft regulatory act.

The adoption of a regulatory act will be will not be approved in certain circumstances, as defined in Law.

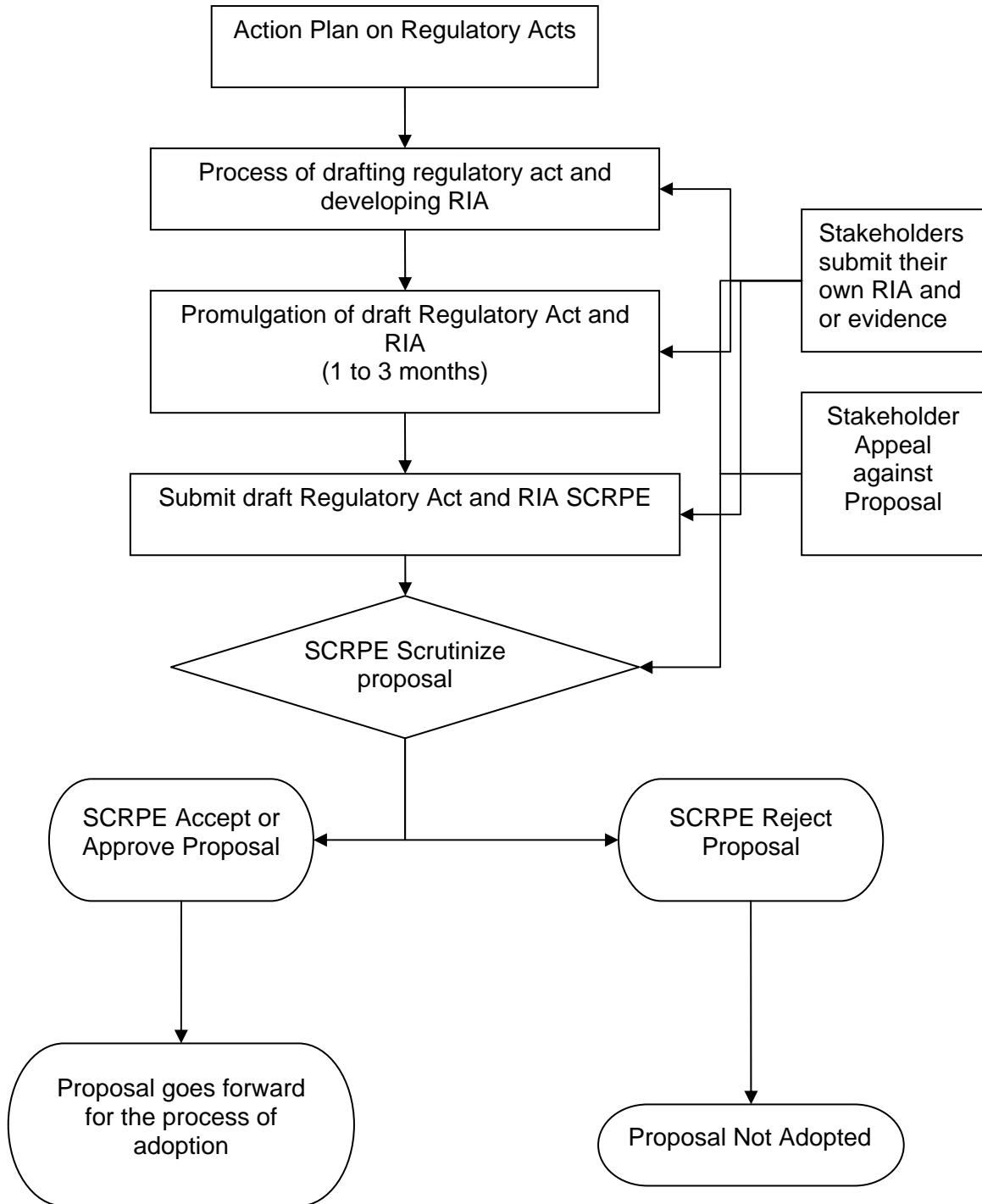
**4. What is the role of the State Committee on Regulatory Policy and Entrepreneurship (SCRPE)?**

All draft regulatory acts and their Regulatory Impact Analysis must be officially submitted to SCRPE before the process of adoption begins.

The assessment in the Regulatory Impact Analysis will demonstrate whether the regulatory act follows the principles of the State Regulatory Policy (see Table 2 on Article 4).

If SCRPE is satisfied with the assessment of the analysis then it will accept the draft regulatory act. However if it is not satisfied with the assessment then it will reject the draft regulatory act.

## UKRAINIAN REGULATORY IMPACT ANALYSIS (RIA) PROCESS



# Chapter Two – COMPLETING A REGULATORY IMPACT ANALYSIS

## BEFORE YOU START

It is stated in Law that all Regulatory Bodies must produce plans of their activity in designing draft regulatory acts for the next year not later than by December 15 of the current year and have them approved, unless stated otherwise in legislation. (*Principles of State Regulatory Policy in the Area of Economic Activity*, Article 7.)

The **Regulatory Impact Analysis (hereinafter – RIA)** can be used to

design the draft regulatory act and hence help Regulatory Bodies develop plans of their activity in designing draft regulatory act. The RIA template (see 2.1.2 below) can be used to map out the purpose of the draft regulatory acts, time of design, and those responsible for designing the draft regulatory act. This can also include who needs to be consulted and to whom the draft regulatory act should be promulgated to.

## THE RIA AS A PLANNING TOOL

The RIA is a document that evolves as the draft regulatory act develops. Therefore when the RIA is initially drafted it will be a skeleton plan that identifies what data and information is required and how this information will be found. It will

be developed later with further detail. Therefore it is a useful tool that will help in planning the development of the draft regulatory act and the analysis of regulatory effect.

**Regulatory Best Practice:**  
Start the RIA when beginning to design the draft regulatory act!

Here are some questions to consider and record in the RIA:

- What is the purpose of the draft regulatory act? What outcome are we trying to achieve?
- What is the problem that requires need for a regulatory action?
- Who are the stakeholders involved with this problem?
- What are the expectations of the stakeholders?
- What are the constraints in meeting the expectations of the stakeholders?
- What are we assuming?
- What evidence/information do we have?
- What evidence/information do we need? How will we find the evidence/information?
- Who must be involved in developing the draft regulatory act?
- What do we need from others in order to develop the draft regulatory act?
- How will we measure successful delivery of the draft regulatory act?
- What is our risk assessment of the factors that could affect the successful delivery of the draft regulatory act?

## SOME IMPORTANT CONSIDERATIONS WHEN COMPLETING THE RIA

A key component of the RIA process is having dialogue and consultation with stakeholders and those that will be affected by the draft regulatory act.

This helps to identify consequences of the draft regulatory act that were not intended and can easily fix a potential problem in the draft regulatory act before it is adopted and when it is difficult to amend. Informal consultations should start before the draft regulatory act is promulgated as this will assist in checking assumptions and identifying issues to be addressed at an early stage when there is greater opportunity to address these issues.

Early consultation with stakeholders can help when adopting the draft regulatory act as stakeholders will be aware from an early stage about the proposed outcome and intended effect. They will also be more receptive if they feel they have not been imposed upon and have had a part to play in developing the draft regulatory act.

These consultations can also help to identify areas of regulatory activity in other parts of government that could be used to achieve the same aim as the draft

regulatory act. This can avoid duplication of effort across Ministries and also prevent unnecessary regulations or burdens for business as stated in the State Regulatory Policy (see 1.1 above). The more complicated the regulatory environment the more difficult it is for stakeholders to comply with regulations, therefore a better regulatory environment is advantageous to regulators as well as those being regulated.

When planning the detail in the RIA and hence the time that will be needed to complete the RIA, it is important to be aware that the level of detail in the RIA should be proportionate to the effects of the draft regulatory act. Therefore if the effects of the draft regulatory act will not be large then the RIA will not require large amounts of detail. However the evidence for the effect should be documented in the RIA whether the effect will be large or small. This provides justification for the draft regulatory act when seeking approval from SCRPE. It also shows stakeholders that the effects have been calculated and anticipated through a legitimate process and this will assist stakeholders adopt and implement the draft regulatory act.

### Regulatory Best Practice:

- Consult stakeholders before promulgating the draft regulatory act and RIA to improve the quality of the regulatory act and RIA and obtain stakeholder buy in. The RIA provides the opportunity to consult early using the RIA template.
- Use early consultations with other Ministries to avoid duplication of effort and identify areas where state regulation can be simplified and reduced.
- The level of detail in the RIA should be proportionate to the effects of the draft regulatory act.

## REGULATORY IMPACT ANALYSIS TEMPLATE

<b>Regulatory Impact Analysis Template</b>		
	<b>Section of RIA</b>	<b>Content of section</b>
<b>1</b>	<b>Title of RIA</b>	Insert name of draft regulatory act.
<b>2</b>	<b>Identify the Goal</b>	State the intended outcome of the regulation. State the purpose of the intervention.
<b>3</b>	<b>Define the Problem</b>	Identify and analyze the problem. Evaluate the importance of the problem. Substantiate why the defined problem cannot be dealt with via economic mechanisms and requires state regulation. Substantiate why the defined problem cannot be dealt with via existing regulatory acts or amendments to them.
<b>4</b>	<b>Identify Alternative Options</b>	Identify all acceptable alternative methods of achieving the set goals, including those that do not foresee direct state regulation.
<b>5</b>	<b>Assessing the Options – Impact Analysis</b>	Evaluate all acceptable alternative methods of achieving the set goals, including those that do not foresee direct state regulation.  Determine the expected results from the adoption of the proposed regulatory act, including estimates of expected expenses and advantages for business entities, citizens, and the state in consequence of the operation of the regulatory act.
<b>6</b>	<b>Engaging with Stakeholders</b>	State the consultation and promulgation methods used in developing the draft regulatory act and RIA. Document the responses, both in favor and against, the adoption of the proposed regulatory act and any relevant evidence presented or uncovered. State how the feedback from stakeholders has been addressed in the draft regulatory act and RIA.
<b>7</b>	<b>Implementation and Compliance</b>	Substantiate the proposed validity period of the regulatory act. Evaluate the possibility of introducing and meeting the requirements of the regulatory act depending on the resources at the disposal of bodies of state authority, bodies of local self-government, individuals and legal entities that must introduce or meet these requirements. Evaluate the risk of the effect of external factors on the operation of the proposed regulatory act.
<b>8</b>	<b>Monitoring and Evaluation</b>	Determine the indicators of the regulatory act's effectuality. Determine the actions that will have to be taken to track the effectuality of a regulatory act in case it is adopted.

<b>9</b>	<b>Summary and Recommendation</b>	<p>Present arguments in favor of the advantages of the chosen method of achieving the set goals.</p> <p>Describe mechanisms and actions that will ensure dealing with the identified problem by adopting the proposed regulatory act.</p> <p>Substantiate the possibility of achieving the set goals in case the proposed regulatory act is adopted.</p> <p>Prove substantially that the achievement of the set goals via the proposed regulatory act is possible at the least costs for business entities, citizens and the state.</p> <p>Prove substantially that the advantages gained by operation of the proposed regulatory act justify the respective costs in case if the costs and/or advantages cannot be determined quantitatively.</p>
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## COMPLETING A REGULATORY IMPACT ANALYSIS

### Title of RIA

1	INSERT NAME OF DRAFT REGULATORY ACT.
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The RIA should state clearly the name of the draft regulatory act. It is important to be consistent in the name of the draft regulatory act as often it can have

different names used, for instance in the media or by the public. The Title should clearly identify what the proposed draft regulatory act is about.

### Identify the Goal

2	STATE THE INTENDED OUTCOME OF THE REGULATION. STATE THE PURPOSE OF THE INTERVENTION.
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Be clear about the aim of the intervention being proposed and its purpose. Ultimately explain what the end goal is – what is the outcome that is trying to be achieved? If possible define a target for the proposed regulation that can be measured so that the actual outcome can be measured.

Avoid using long descriptive aims that are too broad as this can make the actual outcome difficult to realize or measure. However you should also not have a goal that is too narrow as this will limit the options that can be considered. The aim

should also not presuppose the course of action as this will not allow for fair consideration and assessment of all possible options. And the aim should not include benefits of the goal or any course of action as it again presupposes that action is required and that the desired option without having fully assessed its impacts or the impacts of alternative options. **This is the most important part of the RIA and if the goal is wrong then there will be difficulties in completing the RIA and ultimately developing the draft regulatory act.** Here are some examples of good and bad aims:

Good Aim	Bad Aim
<p>Reduce heart disease in adults by 10% within the next 5 years.</p> <p>Increase the production of Agriculture in Ukraine by 10% by year 2020.</p> <p>Prevent accidents in manufacturing, specifically in the mining sector, caused by certain prescribed dangerous metals.</p> <p>Amend the State Compensation Scheme in order to:</p> <ol style="list-style-type: none"> <li>1) Target the funds in the Scheme to those who most need protection and cannot afford private insurance cover.</li> <li>2) Clearly define the boundaries for State Compensation and Private Cover, so that financial markets may develop services to cater for those not covered by the State Compensation Scheme.</li> </ol>	<p>Improve public health.</p> <p>Provide State Subsidies for Agricultural production in order to achieve a 10% increase in production by 2020.</p> <p>Ban the use of any dangerous metals in the mining sector.</p> <p>Harmonize a number of legal acts to improve state compensation schemes that will provide a clear definition of cases for compensation for use of the state and the insurance sector so that government can target its compensation better and insurance markets can clearly provide services not covered by the state. This will strengthen the insurance market while protecting those that need state compensation.</p>

**Defining the problem**

3	<p>IDENTIFY AND ANALYZE THE PROBLEM.          EVALUATE THE IMPORTANCE OF THE PROBLEM.          SUBSTANTIATE WHY THE DEFINED PROBLEM CANNOT BE DEALT WITH VIA ECONOMIC MECHANISMS AND REQUIRES STATE REGULATION.          SUBSTANTIATE WHY THE DEFINED PROBLEM CANNOT BE DEALT WITH VIA EXISTING REGULATORY ACTS OR AMENDMENTS TO THEM.</p>
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Identifying the problem can be quite difficult. This is because it can be easy to identify symptoms of a problem but not the actual problem itself. Be clear about the root problem that you are addressing in the regulation. You should include any relevant background information about this problem and wider issues that should be made known when dealing with the problem.

The problem definition should be based upon evidence and any assumptions should be stated. Without evidence of the problem you cannot be sure that you are actually tackling the issue you want to and therefore cannot be sure if you will have the intended outcome that you desire.

Here are examples of problem definitions:



Good Problem Definition	Bad Problem Definition
<p>Evidence shows that 90% of adults do less exercise than the recommended daily exercise for their age group. However sales of fruit and healthy food products have increased by over 25% over the past 2 years.</p> <p><i>This recognizes the scale of the problem for better option design and solution identification</i></p>	<p>The public are eating too many foods that contain high levels of salt, fat and sugar which is leading to poor public health.</p> <p><i>This gives little information that is based on evidence</i></p>
<p>There has been an increase danger of accidents caused by speeding on newly built roads due to a lack of knowledge about the new speed restrictions.</p> <p><i>This definition recognizes the reason for speeding and hence may lead to better signage or an education campaign</i></p>	<p>There has been an increase danger of accidents caused by speeding on newly built roads.</p> <p><i>This is the symptom of the problem and hence this definition may lead to heavier enforcement and sanctions such as imprisonment or large fines for those speeding</i></p>

In this section of the RIA you must evaluate the magnitude of the problem and how important the problem is. This should be based on evidence that you can use to prove the need for intervention or regulatory action. This is usually called a *Risk Assessment*.

You should also include an explanation of why state regulation is required to address this problem. Sometimes there

are other mechanisms that may address the problem better than state regulation.

Finally you should describe the regulatory environment that the proposed regulation is being introduced into and explain why existing regulations, or amendments to them, cannot address the problem. Here are examples of Problem Definitions and Risk Assessment:

<p align="center"><b>Good Problem Definition/ Risk Assessment</b></p>	<p align="center"><b>Bad Problem Definition/ Risk Assessment</b></p>
<p>The Insurance Industry Association has calculated that over \$10m was claimed to be spent on stolen credit cards last year. This amount has been increasing every year by 25%. The impact of this has been that banks are making it compulsory for credit card holders to have insurance against theft and fraud. The cost of credit card insurance was \$0.25 per day 2 years ago. It is now \$1.00 per day. This is an increase of 300% in 2 years.</p> <p>The amount that banks can charge for insurance is not regulated by Law and there are limited restrictions on who can hold a credit card, such as credit card holders must be over 16. However there is no requirement for businesses to check that a credit card belongs to the person using it, under state law. However the Society of Banks that regulates Banking procedures is currently reviewing the credit card authorization process in banks and also the processes for retailers to be able to access credit card payment.</p> <p>As a result of this occurrence, many people are cancelling their existing credit cards and there is a 20% reduction in new applications for credit cards. This will have an impact on public spending and it is estimated that it could reduce consumer spending by 5% this year.</p> <p><i>This problem definition and risk assessment shows the impact of the problem and the scale of the problem. It also recognizes the current regulation and an opportunity to influence voluntary regulation through the Society of Banks' review.</i></p>	<p>There is an increase in credit card fraud in retail outlets. Therefore Banks are increasing insurance for credit card holders.</p> <p>There is no regulation on the insurance of credit cards.</p> <p>The result of this problem is that sales in retail outlets has decreased last month by a small amount.</p> <p><i>This problem definition and risk assessment has little detail or evidence. Based on this the obvious course of action may be to regulate the insurance of credit cards.</i></p>

## Identifying options

4	IDENTIFY ALL ACCEPTABLE ALTERNATIVE METHODS OF ACHIEVING THE SET GOALS, INCLUDING THOSE THAT DO NOT FORESEE DIRECT STATE REGULATION.
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It has been stated above about the importance of having a clearly defined goal and a problem based on evidence that is being addressed.

This is key to being able to design credible alternatives to be considered.

Often legislation is considered to be the main option however it may not be the most effective way of addressing a problem and therefore there are many other options that must be thought about.

Below are some options that should be considered. These are just some alternatives and can be used during brainstorming of solutions to come up with possible options.

However the 'Do Nothing' option must be considered and documented in all RIAs as the baseline for judging the alternatives.

### 1) Do Nothing

This is the baseline case when no action is taken. It shows the impacts from the continuation of the current defined problem and will help to measure the impacts of other options.

Sometimes not taking action can have less impacts than taking action, which is why this must be considered in every RIA. Here are some questions that the 'Do Nothing' option will help to answer:

- Should government intervene or is some other body or mechanism better placed to address the problem e.g. market forces?
- Will intervention make things worse?
- Is the problem temporary and could it go away naturally?
- Will intervention transfer the problem somewhere else?

### 2) Review Existing Interventions

When considering options, the existing regulations should be known. An option can include amending existing regulations that are may be not as effective as they should be, and an amendment may make them effective enough to obtain the desired outcome.

This assessment can also help to judge whether existing regulations should be simplified or abolished in favor of new regulations. Here are some questions that will help consider such options:

- Is the problem due to existing interventions?
- If so what has gone wrong with the existing intervention e.g. scope of legislation or implementation of policy?
- Consider if this can be resolved by the below:
  - Simplifying the intervention.
  - Targeting the intervention to certain areas.
  - Improving enforcement procedures.
  - Improving the awareness of the intervention amongst stakeholders.
  - If the current intervention should be abolished.

### 3) Self-Regulation

The State may not always be the most efficient or effective body to regulate an activity. It may be too costly for the State to do this or simply the State can save costs by allowing another body to regulate for the desired outcome instead.

An example is in tackling client abuse within professions which often professional associations regulate themselves through codes of conduct. Consider these questions when considering such options:

- Would a group be best placed to agree a set of standards or criteria to self-regulate an area or sector?
- If a group doesn't already exist, are stakeholders willing to take this on as an alternative to government regulation?
- What are the other benefits of self-regulating in this area e.g. raising standards in a profession or industry?

#### **4) Voluntary Guidelines and Codes of Practice**

An option to consider is whether there are mutual interests between the desired outcome of the State and stakeholders. If there are then it may be possible to balance these mutual interests voluntarily.

This could save the State costs, ensure there are no unnecessary burdens on stakeholders and still have the benefits of regulation without legislation. Consider these questions:

- Are there mutual private and public interests that could help encourage voluntary action? If so are stakeholders willing to buy-into a voluntary scheme?
- Are all key stakeholders represented in the voluntary scheme?
- Will the voluntary scheme be easily accessible to all stakeholders e.g. small business?

#### **5) Information and Education schemes**

When defining the problem sometimes the issue that needs to be addressed is a lack of awareness or knowledge about an existing or new regulation. Also should government be regulating in certain

areas, such as the use of contraception in tackling sexual health diseases. Simply by educating citizens or stakeholders could have the desired outcome and behavioral change in people. You may consider these questions when assessing information or educational campaigns:

- Should government intervention occur to address this problem?
- Or should the public be allowed to exercise its own judgment?
- *Therefore* is government's role to assist the public in making an informed decision?

#### **6) Economic Incentives**

Economic incentives can be very useful when trying to change behavior of organizations or individuals. However given resource implications these incentives must be carefully devised in areas where it is actually feasible to offer such incentives. Consider these questions:

- Can economic incentives be used to address the problem and change behavior?
- Economic incentives include; price mechanisms, tax incentives and disincentives.
- Will this have added benefits e.g. encourage innovation and reduce enforcement costs?

#### **7) Risk-Based Insurance or Risk Pricing**

Sometimes the State can use markets, such as the insurance market, to change the behavior of organizations and individuals. This may not be possible in most instances but in some cases this type of option can work for instance mandatory car insurance for all car drivers.

- Can insurance markets be used to change behavior by making

stakeholders insure themselves against risks?

### 8) Sun-setting

Sun-setting can be used to set an automatic end date for a regulation this can be useful in a number of areas where measures may be required due to a crisis or emergency, or where there are rapid changes such as in technology. This provides a mandatory date when the regulation will be abolished and hence must be reviewed and a new updated regulation be designed for adoption. Consider these questions:

- Is the proposal in response to a short-term issue?
- Is the proposal necessary for emergency action?
- Are there significant uncertainties within the proposal e.g. scientific unknowns?
- Is the problem likely to change e.g. due to technological advancement?
- *Therefore* can the proposal have an 'expiry date'?

### Assessing the options – analysis of impacts

5	<p>EVALUATE ALL ACCEPTABLE ALTERNATIVE METHODS OF ACHIEVING THE SET GOALS, INCLUDING THOSE THAT DO NOT FORESEE DIRECT STATE REGULATION.</p> <p>DETERMINE THE EXPECTED RESULTS FROM THE ADOPTION OF THE PROPOSED REGULATORY ACT, INCLUDING ESTIMATES OF EXPECTED EXPENSES AND ADVANTAGES FOR BUSINESS ENTITIES, CITIZENS, AND THE STATE IN CONSEQUENCE OF THE OPERATION OF THE REGULATORY ACT.</p>
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The approved *Methodology for the Regulatory Impact Analysis and Regulatory Impact Evaluation* states that no less than two possible methods for problem solution must be documented and assessed in the RIA (Paragraph 4). It also states that there should be an evaluation of each method and reasons for rejection of the use of alternative methods for solving the problem with the arguments for the benefits of the method selected. This section should document this assessment of the options.

The impacts of each option should be recorded here. There should be a quantitative analysis of each option that in particular costs the impact, both negative and positive, for each of the following stakeholders:

- The State
- The Citizen
- Business Entities

It should also identify any distributional impacts in each of the stakeholders above. For instance if a particular business sector will be impacted on more than another or if there is a disproportionate impact to a part of society. This will assist the decision-making process by showing where the impacts of each option will be. Then the net impact on each group should be calculated.

The use of experts such as economists and statisticians should be planned in order to calculate the costs and benefits of each option and the impacts on each group. If exact figures are not known then ranges of possible costs and benefits and or estimates can be used. This will provide a cost-benefit analysis of each option.

In some cases quantitative information may be not available and in these cases qualitative analysis should be used.

However quantitative cost-benefit analysis should be sought wherever possible.

The cost-benefit analysis should be proportionate to the impacts of the regulation. Therefore a regulation with small impacts will require a simple cost-benefit analysis that lists the positive and

negative impacts of each option. If the regulation has large impacts then a more complex cost-benefit analysis will be required with economic models.

Here are some questions that will assist the options analysis and help guide the assessment of impacts of each option:

<b>Assessing the Options – Impact Analysis</b>	<i>Use these questions for each option</i>
Assess the impacts of the ‘Do Nothing’ Option.	What will happen if government does not intervene? What are the consequences and impacts and for whom?
State the groups that will be directly affected by the proposed action in each option.	Have the stakeholders that will be directly impacted on been identified? What is the size of these groups? What is the scale of impact on these groups? Both positive and negative. Will there be any disproportionate impacts on any particular group or any vulnerable group?
State any indirect consequences in each option.	What are the wider consequences, positive or negative, of the options? Does the option contribute to a cumulative impact on a group? Are there any unintended consequences that stakeholders have identified?
Examine the potential risks of each option to success and include an explanation of the mitigating measures to address these risks and those risks of any unfair or disproportionate impacts on particular groups.	What are the risks of failure? What contingency plans are there to combat these risks of failure? What are the risks of the proposed action for particular groups, especially vulnerable groups, which could impact on the successful delivery of the proposal? What measures are there to minimize these risks? What are the resource implications of these measures? And if necessary have these resources been agreed?
State the organizations such as public bodies that will be affected by the proposals.	Which institutions will be affected? How will they be affected? For instance, will coordination and consultation be required with local/regional government?

<p>For each option include a cost benefit analysis of the impacts. This should be quantitative but can have some qualitative assessment too.</p>	<p>What are the benefits and costs of each option on the following:                  The State                  The Citizen                  Business Entities</p> <p><i>(Note: consideration should be given to the economic, social and environmental costs and benefits. Quantitative estimates are preferred to qualitative estimates, and these should be consulted on to verify the impacts.)</i></p>
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### Engaging with Stakeholders

<p>6</p>	<p>STATE THE CONSULTATION AND PROMULGATION METHODS USED IN DEVELOPING THE DRAFT REGULATORY ACT AND RIA. DOCUMENT THE RESPONSES, BOTH IN FAVOR AND AGAINST, THE ADOPTION OF THE PROPOSED REGULATORY ACT AND ANY RELEVANT EVIDENCE PRESENTED OR UNCOVERED. STATE HOW THE FEEDBACK FROM STAKEHOLDERS HAS BEEN ADDRESSED IN THE DRAFT REGULATORY ACT AND RIA.</p>
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The importance of consultation has already been mentioned in 2.1.1. The RIA provides the opportunity for the consultation and promulgation process and results to be recorded.

This helps to show how the draft regulatory act has been developed and informed with stakeholders' input.

This is an opportunity to show the transparency of the development of the regulation which is one of the key

principles of the State Regulatory Policy (Table 2 on Article 4 above).

This section also provides the opportunity to document responses to the consultation and promulgation and explain the proposed course of action following promulgation of the draft regulatory act.

The Law states the following in terms of the promulgation of the draft regulatory act and RIA:

#### ARTICLE 9. PROMULGATING DRAFT REGULATION ACTS IN ORDER TO RECEIVE REMARKS AND PROPOSALS

Every draft regulatory act shall be promulgated in order to receive remarks and proposals from individuals, legal entities and their associations.

When promulgating the draft regulatory act in order to receive remarks and proposals, the designer of this draft shall inform about it in a manner stipulated in Article 13 of the present Law.

In cases established by the present Law the draft regulatory act may be promulgated repeatedly.

The draft regulatory act, along with a respective analysis of regulatory effect, shall be promulgated in a manner stipulated in Article 13 of the present Law not later than within five working days after the date of the public announcement that the draft regulatory act shall be promulgated.

The public announcement that the draft regulatory act shall be promulgated shall contain the following:

- brief description of the draft;
- postal address and e-mail address (if available) of the draft's designer and of other bodies, to which under the present Law or by initiative of the designer the remarks and proposals are forwarded;
- information about the method of promulgating the draft regulatory act and respective analysis of regulatory effect (name of the print media and/or Internet web site where the draft regulatory act and analysis of regulatory effect will be promulgated or placed, or information about any other method of promulgation stipulated in paragraph 5, Article 13 of the present Law);
- information about the time, throughout which the remarks and proposals from individuals, legal entities and their associations will be accepted;
- information about the ways individuals, legal entities and their associations should submit their remarks and proposals;

The designer of the draft regulatory act shall establish the time, throughout which the remarks and proposals from individuals, legal entities and their associations will be accepted, and the time may not be less than one month and not more than three months after the date the draft regulatory act and the respective analysis of regulatory effect were promulgated.

All remarks and proposals concerning the draft regulatory act and the respective analysis of regulatory effect received throughout the established time shall be subject to binding consideration by the designer of this draft. Relying on the results of this consideration, the designer of the draft regulatory act shall completely or partially take into consideration the received remarks and proposals or reject them for convincing reasons.

Promulgating a regulatory act in order to receive remarks and proposals may not serve as an obstacle to hold public hearings or any other forms of open discussions of this draft regulatory act.

**Table 8.**

**Implementation and Compliance**

7	<p>SUBSTANTIATE THE PROPOSED VALIDITY PERIOD OF THE REGULATORY ACT.</p> <p>EVALUATE THE POSSIBILITY OF INTRODUCING AND MEETING THE REQUIREMENTS OF THE REGULATORY ACT DEPENDING ON THE RESOURCES AT THE DISPOSAL OF BODIES OF STATE AUTHORITY, BODIES OF LOCAL SELF-GOVERNMENT, INDIVIDUALS AND LEGAL ENTITIES THAT MUST INTRODUCE OR MEET THESE REQUIREMENTS.</p> <p>EVALUATE THE RISK OF THE EFFECT OF EXTERNAL FACTORS ON THE OPERATION OF THE PROPOSED REGULATORY ACT.</p>
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It is important to detail in the RIA how the regulation will be implemented. An explanation of the implementation plan should be documented in the RIA which should include the following:

- The process for implementing the regulation

- The body or bodies responsible for implementing the regulation
- The costs of implementation

There are also various incentives for those being regulated to comply with the proposed regulation. This should be carefully selected so as to not be onerous



on regulators or over-burdensome on those being regulated. Therefore penalties or heavy fines may not be appropriate in some cases if it is disproportionate to the effect of violating or not complying with the regulation. They may also not be appropriate if they will cost too much to enforce.

When designing the compliance mechanism for the regulation the following should be considered:

- The level of compliance being aimed for
- Any enforcement mechanisms
- The body or bodies responsible for enforcement
- The cost of enforcement and capacity/resources to enforce

- Other enforcement procedures that are already in existence and relevant to this issue
- Whether enforcement procedures can be simplified to reduce the amount of enforcement required
- The sanctions for non-compliance
- Consider how realistic the sanctions are and whether they are for deterrent or to be enforced
- Consider a 'period of grace' before the sanctions will be enforced

This will assist in determining what instruments for compliance should be used.

### Monitoring and evaluating

8	<p>DETERMINE THE INDICATORS OF THE REGULATORY ACT'S EFFECTUALITY.                  DETERMINE THE ACTIONS THAT WILL HAVE TO BE TAKEN TO TRACK THE EFFECTUALITY OF A REGULATORY ACT IN CASE IT IS ADOPTED.</p>
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The Law on the *'Principles of State Regulatory Policy in the Area of Economic Activity, Article 10'* and the adopted *Methodology for the Regulatory Impact Analysis and Regulatory Impact Evaluation* describe in detail how the effectuality of regulatory acts should be tracked. The following explains the mandatory elements that must be considered when developing the RIA:

10. The forecasted values of the regulation's effectiveness indicators shall be determined within different periods of time after the regulation is put into force. The mandatory indicators shall be the following:
- the amount of revenues to the state and local budgets and state funds-in-trust related to the impact of the regulation;
  - number of subjects of business activity and/or individuals the regulation applies to;
  - the range of spending made and the time consumed by the subjects of business activity and individuals involved in meeting the regulation's requirements;
  - the level of awareness of the basic provisions of the regulation among the subjects of business activity and/ or individuals .
11. The forecasted values of the regulation's effectiveness may have a quantitative form. In case it is impossible to calculate the value of one benefit or cost, a textual description of the regulation's effectiveness shall be given.

12. Upon the determining actions for regulatory impact evaluation the following shall be stated: time frames for both baseline and follow-up evaluations; types of data (statistical, scientific and research studies, or surveys) used in such evaluation; a target group to participate in the relevant survey; and scientific institutions to be involved in the evaluation.

**Table 9.**

Table 10 below gives a clear and detailed indication of what is expected in the Regulatory Impact Evaluation and the processes should be captured in this section of the RIA.

Furthermore the Regulatory Impact Evaluation states:

**METHODOLOGY FOR THE REGULATORY IMPACT EVALUATION**

1. This *Methodology* sets up requirements for evaluating the impact of regulations adopted (hereinafter referred to as the “evaluation”). This *Methodology* requirements do not apply to regulations adopted by the National Bank.

2. Baseline, follow-up, and periodical evaluations shall be conducted for the regulation within the period set up by the Article 10 of the Law of Ukraine “On the General Principles of State Regulatory Policy in the Sphere of Economic Activity”.

A baseline evaluation shall be conducted before the regulation or most of its provisions come into effect for the purpose of evaluating the status of economic relations to be regulated by the regulation before the act comes into effect.

A follow-up evaluation shall be conducted within one year after the regulation or most of its provisions come into effect, but no later than two years, if the regulatory authority that adopted this regulation does not set an earlier period for the purpose of evaluating goals achieved by this regulation. Values of quantitative and qualitative indicators of the regulatory impact shall be compared with similar indicators used in the baseline evaluation.

A periodical evaluation shall be conducted once every three years starting from the implementation of the follow-up evaluation, including cases when a regulation is adopted for a specific period of time is extended for the purpose of evaluating goals achieved by the regulation. Values of quantitative and qualitative indicators of the regulatory impact shall be compared with similar indicators used in the follow-up evaluation.

3. The evaluation shall measure the quantitative and qualitative value for each indicator determined by the regulatory impact analysis.

4. The baseline, follow-up, and periodical evaluations shall be conducted based on indicators and data determined by the regulatory impact analysis.

5. Data types used for evaluation shall be determined by the regulatory agency that adopted the regulation.

6. In case when indicators determined in the regulatory impact analysis cannot be measured by the available statistical and research data, a survey of the target group of subjects influenced by the regulation shall be conducted. The survey can be conducted either in verbal or written form (hereinafter referred to as the “survey”).

7. For measuring the quantitative and qualitative regulatory impact indicators, one may use statistical data for the relevant period preceding the evaluations commencement date; for the baseline evaluations one may use data for the period preceding the effective date of the regulation or most of its provisions.

8. The survey during the evaluation shall include the determination of subjects that would fulfill the requirements of the regulation (hereinafter referred to as the “target group”); designing a questionnaire, collecting information; and making a database of respondents, data processing, and analysis.

9. For identifying the target group, one may use open registers maintained by regulatory authorities and other state authorities.

10. The number of members of the target group determined for the follow-up evaluation through the survey should be equal to the number of the target group members that was determined for the baseline evaluation.

11. During the follow-up and periodical evaluations, the same approaches as those for determining the target group and a sample design (part of the target group that is selected for participation in the survey with the help of special methods for a reliable reflection of the structure and main characteristics of this group) shall be applied as for the baseline evaluation.

In the event that the total number of the target group does not exceed 150 persons, all respondents of the target group shall be surveyed without defining the sample.

12. The basis for designing a questionnaire during the baseline, follow-up and periodical evaluations is the quantitative and qualitative indicators of the regulatory impact that were set up in the regulatory impact analysis.

Reports shall be made separately for baseline, follow-up and periodical evaluations after implementation of the said activities. These reports shall be made public.

13. The report on the evaluations results shall indicate:

- the type and title of the regulation evaluated, the date of its adoption and number (for a baseline evaluation, the date of adoption and number are not indicated);
- the evaluation executor’s name/title;
- the regulation’s goals;
- the time frame for the evaluation’s implementation;
- the evaluation type (baseline, follow-up or periodical);
- the methods for obtaining evaluation results;
- the data and assumptions upon which the impact was evaluated, as well as methods of data collection to measure the indicators;
- the quantitative and qualitative indicators of the regulatory impact;
- the evaluation of the regulation’s results and goals achieved.

14. The evaluation report shall be signed by the head of the regulatory authority that adopted the regulation.

**Table 10.**

# SUMMARY AND RECOMMENDATIONS

9	<p>PRESENT ARGUMENTS IN FAVOR OF THE ADVANTAGES OF THE CHOSEN METHOD OF ACHIEVING THE SET GOALS.          DESCRIBE MECHANISMS AND ACTIONS THAT WILL ENSURE DEALING WITH THE IDENTIFIED PROBLEM BY ADOPTING THE PROPOSED REGULATORY ACT.          SUBSTANTIATE THE POSSIBILITY OF ACHIEVING THE SET GOALS IN CASE THE PROPOSED REGULATORY ACT IS ADOPTED.          PROVE SUBSTANTIALLY THAT THE ACHIEVEMENT OF THE SET GOALS VIA THE PROPOSED REGULATORY ACT IS POSSIBLE AT THE LEAST COSTS FOR BUSINESS ENTITIES, CITIZENS AND THE STATE.          PROVE SUBSTANTIALLY THAT THE ADVANTAGES GAINED BY OPERATION OF THE PROPOSED REGULATORY ACT JUSTIFY THE RESPECTIVE COSTS IN CASE IF THE COSTS AND/OR ADVANTAGES CANNOT BE DETERMINED QUANTITATIVELY.</p>
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This section of the RIA should give a clear explanation of why the chosen option is being put forward for adoption. There should be a clear concise summary of the reasons for the recommended regulation with the impacts of the chosen recommendation. It should state that the proposed regulation will meet the goal identified and address the problem identified.

There should be a summary table that gives a clear comparison of the impacts of each of the options and hence shows why the recommended regulation is the most effective and appropriate way forward.

Here is an example of a summary table:

Option	Costs	Benefits	Distribution of Impact	Overall Impact
Option 1 – Do Nothing	\$6m to State through reduction in taxes from business. \$12m to Business in lost sales and closures. Reduction in services to Citizens	No further costs to State.	Disproportionate impact on Businesses and Citizens in Rural areas.	Total cost of \$18m with \$12m to business.  Disproportionate impact on Rural areas.

Option 2 –	\$0.5 – 1m to State through simplification of laws and procedures. \$5m to Business through registration scheme. Reduction of services to Citizens.	\$2-3.5m in taxes from business. \$2m to Business through continued business.	Disproportionate impact on Business and Citizens in Rural areas and SMEs estimated at \$5m.	Total cost of between \$0.5 – 1.5m.  However cost to Rural areas and SMEs of \$5m.
Option 3 –	\$0.4m to State of education campaign. Estimated \$2m to Business through familiarization with education campaign.	Up to \$6m for State through taxes. Between \$10-12m for Business through continued business. Availability of services to Citizens.	Disproportionate impact on SMEs of familiarization estimated at \$0.5m in total.	Total benefit of \$13.6m – 15.6m.  However cost of \$0.5m on SMEs.

Finally each RIA must be signed by the Head of the Ministry or Regulatory Body that is drafting the regulatory act before

the RIA is finally submitted and published publicly as a final document.