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REGULATORY IMPACT ANALYSIS (RIA) MANUAL



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CONTENTS

I. INTRODUCTION TO REGULATORY IMPACT ANALYSIS 5

1. What is RIA? 5
2. When RIA should be used? 5
3. The level of detail required in a RIA? 6
4. Who should carry out a RIA and who should control it?..... 7
5. RIA in the EU..... 8
6. The Main Benefits of RIA 9

II. HOW TO ORGANIZE A RIA PROCESS – THE RIA STEPS 10

1. STEP 1. - DEFINE THE PROBLEM, ITS CAUSES AND CONSEQUENCES 11
 - i. Problem Tree 13
 - ii. Example of the completed Problem Tree – business licensing 13
2. STEP 2. - DEFINE THE OBJECTIVES OF REFORM 14
 - i. From problem to goals and regulatory measures..... 14
3. STEP 3. - IDENTIFY THE OPTIONS FOR RESOLVING THE PROBLEM 16
 - i. Spectrum of options 17
 - ii. From relevant to feasible and preferred options..... 19
4. STEP 4. - ANALYSIS OF THE OPTIONS 21
 - i. Direct and indirect impacts 21
 - ii. Distributional impacts..... 22
 - iii. Costs 22
 - iv. Checklist for calculating the economic costs of regulatory change..... 23
 - v. Benefits 23
5. STEP 5. - COMPARING THE OPTIONS 24
 - i. Cost benefit analysis 24
 - ii. Cost effectiveness analysis 26
 - iii. Multi criteria analysis 27
 - iv. The standard cost model..... 29

6. STEP 6. - IMPLEMENTATION AND MONITORING	31
7. CROSS CUTTING RIA ACTIVITIES	32
i. Data gathering in RIA	32
ii. Consultation with interested parties during the IA.....	33
a. Main Benefits of Consultation.....	33
b. Impediments to Good Consultation.....	34
c. Minimum EU Standards for Consultation	34
d. Common consultation pitfalls.....	35
e. Phases of the Consultation Process	35
f. Consultation Techniques	35
g. Analysis and evaluation of consultation.....	38
8. PREPARATION OF THE RIA REPORT	39

I. INTRODUCTION TO REGULATORY IMPACT ANALYSIS

1. What is RIA?

Regulatory Impact Assessment (RIA) is a **process** of several steps which aims to analytically and systemically answer the question of **whether a regulatory intervention is needed**, and if so **which of the possible options is the best solution to the problem**.

RIA is based on:

- asking the right questions when considering the need for regulatory intervention, and during the development of regulation;
- gathering the necessary data;
- organizing the analysis so that it follows a set of logical steps, and applying adequate methods;
- exchanging information between the regulator and the stakeholders.

There is no best practice model of RIA used internationally. However any RIA needs to include the following:

- a clear identification of objectives;
- structured consultation with stakeholders;
- detailed examination of impacts; and
- consideration of the use of alternatives to regulation

KEY MESSAGES

- ➡ The best way to learn how to do RIA is through solving practical problems – not from a book or manual. The manual is only a tool to remind you about the process, possible techniques of analysis, and problems...

RIA IS NOT	RIA IS
Just a document attached to the draft legislation	A process in which different methods of analysis are used
Analysis solely from the perspective of the regulatory authority	Analysis from the perspective of society as a whole
A way to justify intervention “ex-post”	A way to analyze the costs and benefits of regulatory change “ex ante”
A replacement for political decisions	The basis for reaching political decisions

2. When RIA should be used?

RIA should always be initiated at the earliest possible stage as it is designed to help inform the decision makers of whether to regulate or not. Often the decision to regulate has already been made (e.g. in a Program or Strategy of the Government). In this scenario RIA focuses on options within the legislation rather than the option of whether to regulate or not.

Some possible exceptions when RIA should not be compulsory:

- the budget bill
- emergency legislation (e.g. to introduce measures after floods or earthquakes)
- security legislation
- legislation which transposes EU legislation, and so does not permit the consideration of options on how the legislation will be implemented.

3. The level of detail required in a RIA?

The level of detail required and the analytical approach to be taken, must be assessed on a case-by-case basis depending on the significance of the legislative proposal. The greater the importance or significance of the proposal, the more analysis will be required. The decision as to whether a basic (light) RIA is sufficient, or the RIA should be more detailed, can be based on two principles: proportionality and precaution.

The **proportionality principle** means that the effort to do a RIA should be commensurate with the level of expected impacts of the legislation. The more important the regulation the greater the impacts and the greater the need to justify in detail the analyzed alternatives, to be specific about recommended solutions, and to forecast and quantify the costs and benefits. Sensitive issues such as environment or health may require more detailed RIA treatment. Also, a more detailed RIA may be triggered under certain circumstances e.g. detailed analysis is performed when the implementation of the Standard Cost Model has determined that the initial compliance costs for businesses will exceed, for example, €100,000, or cumulative costs for five years are greater than €0.5 million.

The **precautionary principle** is applied where potentially unacceptable risks have been identified and these risks cannot be determined with sufficient certainty. In these circumstances, a decision to implement a more detailed RIA can be taken despite a lack of certainty. The use of the precautionary principle is often advocated for cases with irreversible impacts. In such cases, the possibility of irreversible losses may point towards caution and the application of the precautionary principle.

Key Messages

- ➔ A system of RIA should be implemented gradually, and in the initial stages of implementation when the capacities to perform RIA have not been developed sufficiently, a basic (light) RIA model can be applied.
- ➔ Considering the intensity of legislative activity in a country that is a candidate for EU accession, and that is in the process of harmonization with EU legislation, the role of the RIA Unit can be focused on “damage control” rather than aiming for sophisticated analysis.

Five minimum requirements for a functional RIA Light system*

- 1) Political commitment to establish and operate an effective and self-sustaining RIA process;
- 2) A unit or group of regulatory reformers — preferably based in a central area of government — which oversees, comments and reports on the quality of regulatory proposals, before decisions about regulation are made;
- 3) Consistent criteria and rules employed to screen regulatory proposals;
- 4) The regulatory policy development process is transparent and includes consultation with stakeholders; and
- 5) A capacity building program is in place, involving preparation of guidelines, training of officials preparing RIA, and establishing monitoring, evaluation and reporting systems.

* *Better Regulation for Growth Program - Making It Work: "RIA Light" for Transition and Developing Countries (Peter Ladegaard, Stephen Rimmer and Delia Rodrigo)*

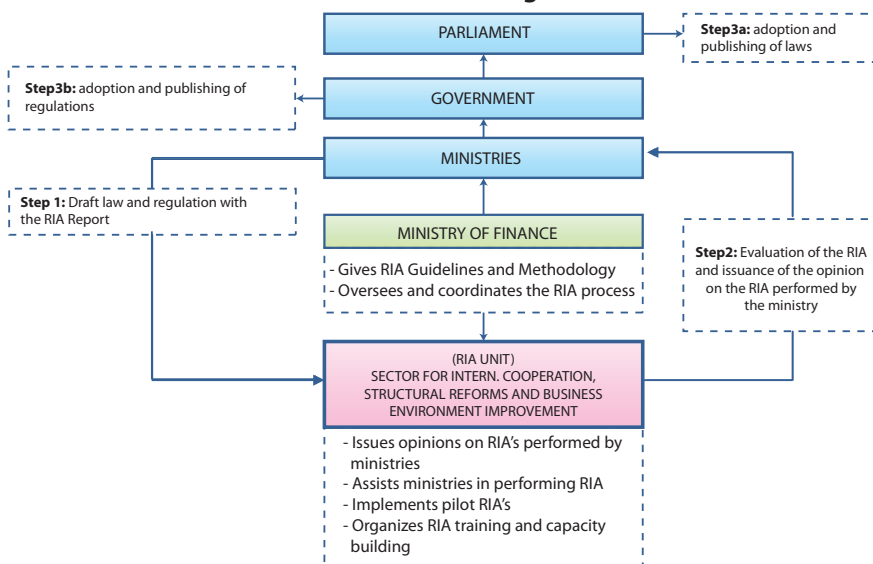
4. Who should carry out a RIA and who should control it?

RIAs are prepared by the ministries and regulatory authorities that propose new regulations. A ministry or regulatory authority not only has the best understanding of the area which is being regulated, but is also usually disposed of data relevant to the regulated area, and of contacts with all the stakeholders involved.

Given the possibility of regulatory capture by the regulated businesses (at the expense of consumers, competitiveness and society at large) as well as the possibility of vested interests of the regulator, the RIA process should be overseen by an independent unit based at the center of government. This unit, not being involved in regulating businesses can provide an impartial and professional opinion as to the quality of the RIA performed.

Key Messages

- ➡ Appoint the person in the working group in the ministry or regulatory authority who will be responsible for the preparation of the RIA report
- ➡ Prepare the RIA report in parallel with drafting the legislation.

Institutional Mechanism for RIA in Montenegro:**5. RIA in the EU¹**

At the level of the European Commission the Impact Assessment Board (IAB) was created in 2006, as a **central quality control** and support function working under the authority of the Commission President.

The Board examines and issues opinions on all the Commission's IA's. It is independent of the policy making departments. Its **members** are high-level officials from the Commission departments most directly linked with the three pillars of the impact assessment - economic, social and environmental impacts. The members have been appointed in a **personal capacity** and on the basis of their expert knowledge.

The Board **examines and issues opinions on the quality** of individual draft impact assessments prepared by the Commission departments. The Board can also draw on **external expertise**. The Board also provides advice to Commission departments on **methodology** at the early stages of preparation of the impact assessments.

The **opinions** of the Board are not binding. However, the opinion accompanies the draft initiative together with the impact assessment report throughout the Commission's political decision-making. The Commission impact assessment is an aid - not a substitute - for political judgment. Ultimately it is the Commission which decides whether or not to adopt an initiative, taking account of the impact assessment and the Board's opinion.

The work of the IAB is **transparent**. All impact assessments and all IAB opinions are published once the Commission has adopted the relevant proposal.

¹ http://ec.europa.eu/governance/impact/iab/iab_en.htm

EU IMPACT ASSESSMENT KEY PROCEDURAL STEPS:

- Plan impact assessment (IA): Roadmap, integration in the Commission's strategic planning and programming (SPP) cycle and timetable.
- Work closely with your IA support unit throughout all steps of the IA process.
- Set up an impact assessment steering group and involve it in all IA work phases.
- Consult interested parties, collect expertise and analyze the results.
- Carry out the IA analysis.
- Present the findings in the IA report.
- Present the draft IA report together with the executive summary to the Impact Assessment Board (IAB) and take into account the possible time needed to resubmit a revised version.
- Finalize the IA report in the light of the IAB's recommendations.
- IA report and IAB opinion(s) go into inter-service consultation alongside the proposal.
- Submission of IA report, executive summary, IAB opinion(s) and proposal to the College of Commissioners.
- Transmission of the IA report and the executive summary with the proposal to the other EU institutions.
- Final IA report and IAB opinion(s) published on dedicated Europa website.
- In the light of new information, or upon request of the EP or the Council, the Commission may decide to update the IA report

Source: EU Impact Assessment Guidelines (at http://ec.europa.eu/governance/impact/commission_guidelines/docs/iag_2009_en.pdf)

6. The Main Benefits of RIA

"... RIA's most important contribution to the quality of decisions is not the precision of the calculations used, but the action of analyzing and questioning, understanding real-world impacts, and exploring assumptions."²

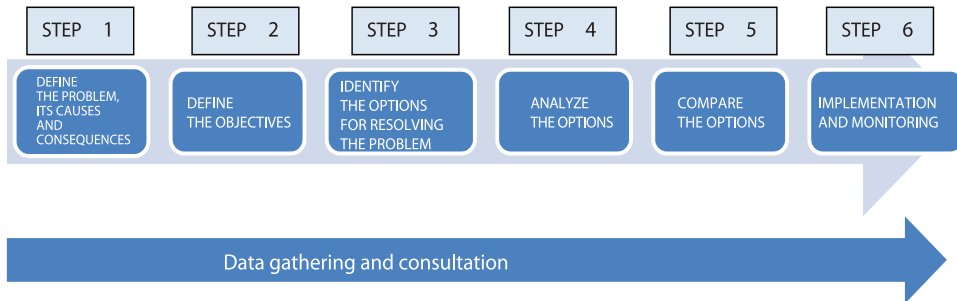
The main benefits of RIA can be summarized as follows:

- policy makers can better understand the consequences, i.e. the costs, benefits and distributional impacts, of the decision (who has the benefits and who bears the costs);
- better insight and understanding of the real impacts of regulations, considering that RIA helps assess and describe the costs and benefits;
- timely discovery of indirect and unintended impacts of regulations;
- simplification of the regulatory environment;
- transparency of the process: stakeholders can present their views and additional facts in consultation with the regulator and in public consultation;
- improving the work of the public administration by enhancing coordination of regulatory activities and increasing the accountability of regulators.

² Regulatory Policies in OECD Countries: From Interventionism to Regulatory Governance. OECD (2002), p 47

II. HOW TO ORGANIZE A RIA PROCESS – THE RIA STEPS

This section of the report gives an overview of the RIA process and analytical steps to follow



SUMMARY OF KEY STEPS

1. Identify the problem

- Determine the extent of the problem
- Determine the causes
- Determine the target population and distribution of impacts
- Determine whether the problem is lack of regulation
- Indicate why the problem has not been resolved by the existing regulatory framework

2. Define the objectives

- Formulate goals, results and regulatory measures so that they correspond to the problems, consequences and causes
- Limit the number of goals and clearly set priorities
- Goals should be in accordance with strategies and programs of the Government

3. Identify the options for resolving the problem

- Identify policy options to meet the objectives (relevant – feasible – preferred options)
- Consider regulatory and non-regulatory options
- Narrow the number of options through screening for constraints and measuring against predefined criteria

4. Analyze the options

- List the positive and negative direct and indirect impacts
- What are the likely economic, social and environmental impacts of each of the options?
- Include assessment of administrative burden
- Apply relevant analysis methods – try to provide quantitative and monetary impacts if possible
- Specify which social groups, economic sectors or particular regions are affected
- Consider implementation risks, uncertainties and obstacles to compliance

5. Compare the options

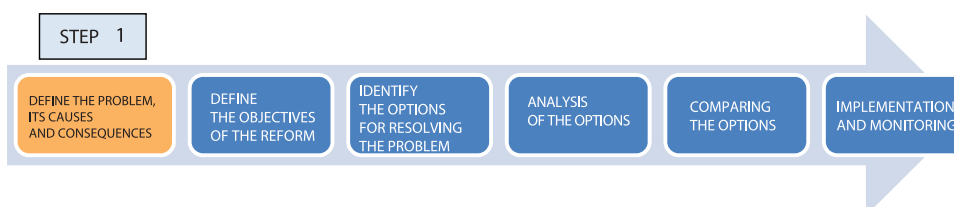
- Indicate how positive/negative impacts have been weighted for each short-listed option

- If possible, rank the options in terms of the various evaluation criteria
- If possible and appropriate, set out a preferred option

6. Implementation and monitoring

- How will the preferred option be implemented?
- Who is responsible for administering the option?
- How will it be enforced (reporting, audits, inspections, self-monitoring)?
- How and when will the preferred option be reviewed?

1. STEP 1. - DEFINE THE PROBLEM, ITS CAUSES AND CONSEQUENCES



How to define the problem

- ✓ Determine the extent of the problem
- ✓ Determine the causes
- ✓ Determine the target population and distribution of impacts
- ✓ Determine whether the problem is lack of regulation
- ✓ Indicate why the problem has not been resolved by the existing regulatory framework

After the problem has been defined and the regulatory change initiated, a preliminary workplan should be drafted. The preliminary workplan will be subject to change, but it is important to determine the timeframe and to indicate as precisely as possible all activities which will be undertaken during the Regulatory Impact Analysis.

The usual pitfalls in defining the problem:

- Too narrow a definition of the problem, which leads to the selection of a specific alternative not taking into account other possible alternatives
- Describing the solution instead of the problem
- Defining the problem as a lack of something
- Defining the problem as a strictly technical issue
- Lack of insight into the incentives of the regulated subjects
- Lack of information on the magnitude of the problem
- Relatively small problem inflated by the media (which creates political need for regulation)

Example: Defining the problem strictly from a technical aspect

The example that is often used to illustrate the consequences of wrong definition of the problem from a strictly technical aspect is the example of accidental drug poisoning of children in the USA, where:

- The regulator defined the problem as a technical problem – unsafe drug containers which could be easily opened by children
- The above led to the technical solution – introduction of safety caps for containers, so children could not open them easily. Also, the label “child proof” was introduced.
- After the introduction of the regulatory measure, the number of accidental drug poisonings of children increased.
- The regulator did not take into account behavior modification as a result of the regulatory changes:
 - Senior citizens with arthritis could not open the containers, they began to leave them open;
 - Because of the “child proof” labels parents did not take necessary precautions, and left drugs in places that were within reach of children.

Example: Narrow and wide definition of problem – business registration reform

- **NARROW DEFINITION: Registration process in courts is slow because of the insufficient number of judges and inappropriate equipment** (narrow definition points to the solution that the problem could be simply solved by increase in human and/or technical resources in commercial courts).
- **WIDER DEFINITION: Registration process in courts is slow because of insufficient capacities of courts, and expensive because of high establishment costs** (wider definition of problem, which in addition to the above-mentioned, takes into consideration the possibility of limiting fees in order to make the registration process cheaper).
- **THE WIDEST DEFINITION: Registration process in courts is slow, expensive, non-transparent and unreliable** (comprehensively defined problem, which is the basis for consideration of a number of alternatives, including transferring the registration competencies from the courts to an administrative body).

Example: Narrow and wide definition of problem – food products poisoning

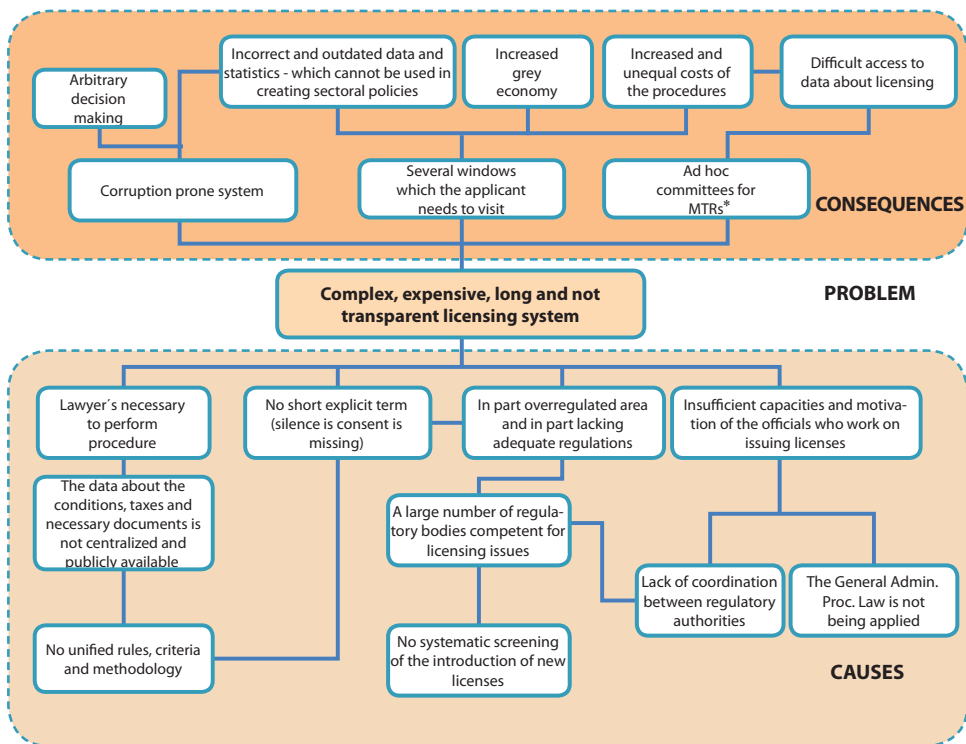
- **Some food products are transported inappropriately** (narrow definition which leads to a solution based only on costs and benefits of introduction of appropriate transport)
- **Some food products are transported at inappropriate temperatures** (wider definition of problem, so the different methods for maintenance of temperature are considered)
- **Some food products arrive to retail stores bacteriologically faulty** (even wider definition of problem which includes other reasons, in addition to inadequate temperature)
- **Large numbers of consumers are poisoned due to consumption of food products bought in retail stores** (the widest definition of problem which considers risks not only in transport, but in retail and consumer use of products also)

i. Problem Tree

The “Problem Tree” is an extremely useful instrument that enables the “branching” of the problem into causes and consequences. The steps in creating a problem tree are:

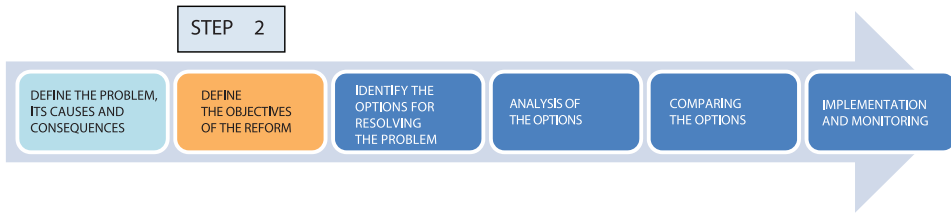
- list all possible problems related to the analyzed area, taking into account that only real/actual problems, and not possible or future ones, should be considered;
- determine the main problem;
- determine which problems are “causes” and which “consequences”;
- arrange the “causes” and “consequences” in a hierarchical order - determine whether they are connected and their mutual relationship.

ii. Example of the completed Problem Tree – business licensing



* Minimum technical requirements

2. STEP 2 - DEFINE THE OBJECTIVES OF REFORM

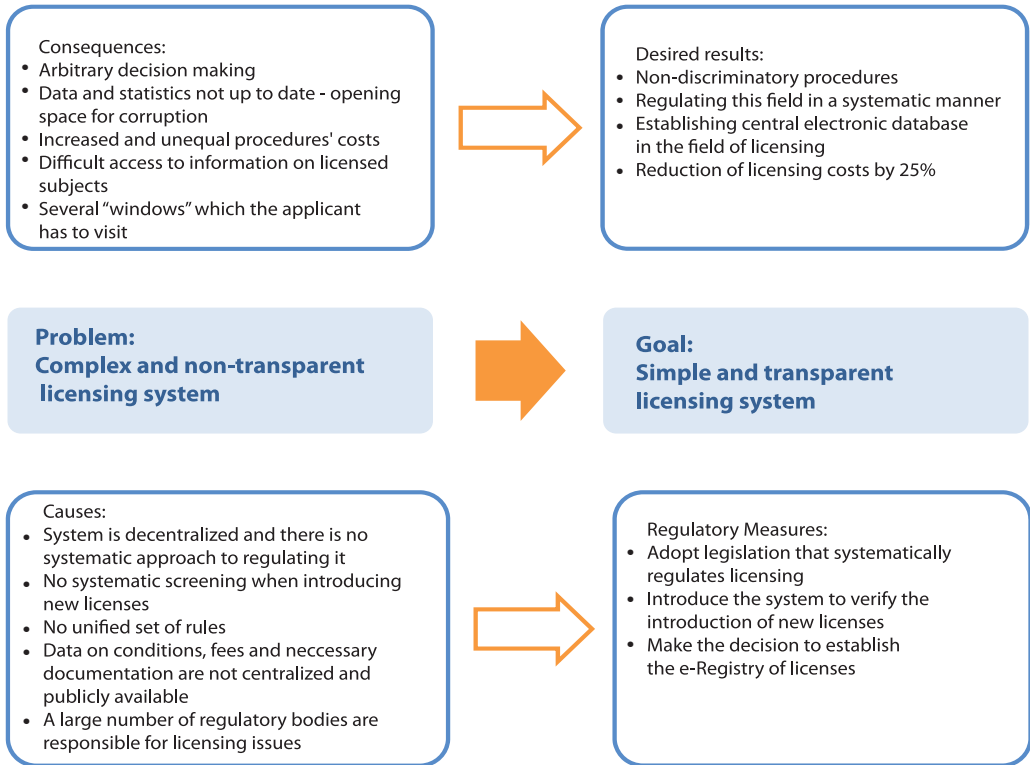


The second step in the Regulatory Impact Analysis is the clear defining of objectives that the proposed measures would address. A clear presentation of objectives enables better oversight over the implementation and evaluation by using clearly defined indicators.

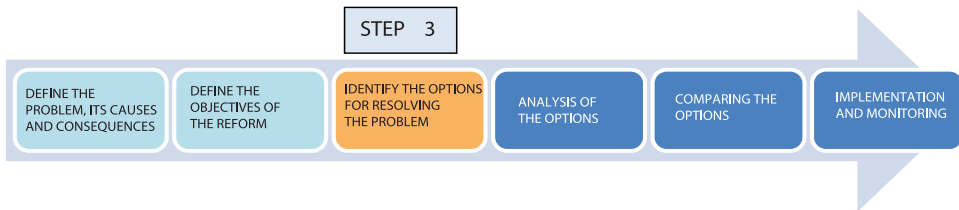
How to define the goals of the reform
✓ Formulate goals, results and regulatory measures so that they correspond to the problems, consequences and causes
✓ Limit the number of goals, and clearly set priorities
✓ Ensure goals are in accordance with strategies and programs of the Government
SMART- objectives ³ should be:
✓ Specific: objectives should be precise and concrete enough not to be open to varying interpretations. They must be understood similarly by all.
✓ Measurable: objectives should define a desired future state in measurable terms, so that it is possible to verify whether the objective has been achieved or not. Such objectives are either quantified, or based on a combination of description and scoring scales.
✓ Achievable: if objectives and target levels are to influence behavior, those who are responsible for them must be able to achieve them
✓ Realistic: objectives and target levels should be ambitious – setting an objective that only reflects the current level of achievement is not useful – but they should also be realistic so that those responsible see them as meaningful.
✓ Time-dependent: objectives and target levels remain vague if they are not related to a fixed date or time period.

i. From problem to goals and regulatory measures

After creating the Problem Tree, the problem, consequences and causes are easily transformed into goal, results and regulatory measures.

Example: Defining the goal and regulatory measures – licensing reform in Montenegro:

3. STEP 3. IDENTIFY THE OPTIONS FOR RESOLVING THE PROBLEM



Although the existence of the problem was identified this does not mean that the introduction of regulation is needed. It is necessary to determine whether the introduction of regulation is essential. Often it is possible to use alternatives to regulation, e.g. informational and educational campaigns, or different market measures which impact the incentives of target groups.

Identifying Options
✓ Identify policy options to meet the objectives (relevant – feasible – preferred options)
✓ Consider regulatory and non-regulatory options
✓ Narrow the number of options through screening for constraints, and measuring against pre-defined criteria

Before identifying preferred options the whole spectrum of possible options should be taken into account. The so called Spectrum of Options is a useful approach. The usual reaction of regulators to a problem is the application of the so-called traditional or prescriptive approach, i.e. the introduction of regulation that explicitly imposes or prohibits certain actions or activities, that is monitored by the authorities, and where sanctions are prescribed in the case of breach of the regulation. However, alternative regulatory instruments can also achieve the objective with significantly lower costs than the traditional approach. It is also often possible to use alternatives to regulation. The following figure represents the so-called spectrum of regulatory and non/regulatory options that can be considered during the RIA process.

i. Spectrum of options

Traditional approach	<ul style="list-style-type: none"> Regulations followed by implementation and monitoring of implementation, as well as the application of appropriate sanctions by Government authorities Obligatory instructions and standards
Co-regulation	<ul style="list-style-type: none"> Transfer of authority to representative associations Codes and standards supported by regulatory body
Self-regulation	<ul style="list-style-type: none"> Voluntary codices and standards
Economic instruments	<ul style="list-style-type: none"> Fiscal and financial instruments (taxes, subsidies, fees for usage of resources, and other incentives) "Transferable" rights
Informational approach	<ul style="list-style-type: none"> Informational and educational campaigns
No regulation	<ul style="list-style-type: none"> Market solution - no need for any intervention

Every option within the spectrum has its advantages and disadvantages.

REGULATORY AND NON-REGULATORY OPTIONS	ADVANTAGES	DISADVANTAGES
TRADITIONAL APPROACH	<ul style="list-style-type: none"> quick imposing of rules which prescribes some activities as illegal; sending a message that an issue is considered very important for a regulator; relatively precise control over how regulated activities are conducted; in situations when sanctions are necessary 	<ul style="list-style-type: none"> requires additional legislation and new bureaucratic procedures incentives for interest groups to influence regulatory bodies; imposes inflexible solutions, which can be problematic when the regulated field is characterized by quick changes that lead to accelerated obsolescence, non-enforcement, or in the worst case, obstacles to the development of the sector. Encourages the search for "creative" solutions or interventions; High implementation costs (supervision).

REGULATORY AND NON-REGULATORY OPTIONS	ADVANTAGES	DISADVANTAGES
CO-REGULATION AND SELF-REGULATION	<ul style="list-style-type: none"> • Lower implementation costs for the state – costs are transferred to regulated subjects in the form of their representative associations; • Rules adjusted to the specific needs of a particular sector; • Possibility for the application of innovative and flexible solutions; • Thorough adoption where there is a common interest in the control of regulated subjects; • Better understanding of technological developments and specialized practices 	<ul style="list-style-type: none"> • Risk that interest groups take over the legislative process through creation of obstacles for the entry of new participants to the market, by imposing unnecessarily high standards; • Inexpedient and inefficient sanctions in cases of non-obedience; • Insufficient resources for adequate implementation of regulation; • Inadequate representation of bodies which implement self-regulation or carry out co-regulation
ECONOMIC INSTRUMENTS	<ul style="list-style-type: none"> • Less discretion on the part of state authorities because incentives (both positive and negative) function automatically; • Freedom of regulated subjects to choose whether they want to use the incentives; • Lower administrative burden and costs of supervision; • Greater level of flexibility and possibility to adjust to current circumstances 	<ul style="list-style-type: none"> • Often mean very complex rights assignment systems; • Supervision systems must often be complex if tax evasion and other abuses are to be avoided; • Effects of incentives are not certain, and their forecasting requires lengthy analysis and significant resources • Could send the wrong signal that certain levels of undesired behavior are acceptable
INFORMATIONAL AND EDUCATIONAL CAMPAIGNS	<ul style="list-style-type: none"> • Good for situations where the implementation of regulations is very costly or very complex; • Provides superior information to the regulated subjects; • Does not impose single solutions for all subjects; • Simple application. 	<ul style="list-style-type: none"> • Potentially high campaign expenses; • It is difficult to establish the relation between campaigns and changed behavior of regulated subjects

It should not be forgotten that the basic RIA question is whether a certain field needs to be regulated. In situations where a certain field was not previously regulated, it should be taken into account that regulatory instruments might not be needed, and that the market itself could provide an efficient solution. In other words, regulatory intervention might even worsen the situation, such that the *status quo* could be the preferred option. In situations where the field had already been regulated, it is possible that the problem occurred as a consequence of the previous intervention, and the problem could be eliminated by abrogating or reversing changes to the existing regulation, that is, with the “market solution”.

ii. From relevant to feasible and preferred options

After the definition of problems and objectives, analysts should always consider a range of options that is as broad as possible (relevant options). During the “identification of relevant options” phase, the process of informal consultations with the stakeholders is very useful.



Range of relevant options
✓ the “do nothing option” – status quo (the status quo option is desirable when the expected benefits of the regulatory change are lower than the costs. This means that there is no need to regulate or amend the regulation in a certain area, but that the problem is an implementation problem)
✓ the administrative procedures simplification option
✓ the self-regulation and market measures option
✓ the minimum investments option (if resources are limited, it is necessary to consider the option that would enable the partial realization of the goals with minimum investment);
A combination of different options: These options do not have to be set as alternatives. A combination of different options is often the most effective solution. In practice, the implementation of a single option is very rare; usually a combination of options is used.

After forming the list of relevant options, it is necessary to limit the initial selection to those that are feasible (feasible options).

How to get from relevant to feasible options - key factors in identifying feasible options
✓ motivation of target population, regulatory authorities and implementing agencies
✓ length and cost of implementation
✓ available data and experiences up to date

If the number of options is still large, it is necessary to perform a preliminary (informal) selection to reduce the number of options to three or four options, not including the *status quo* option. All options must be realistic.

The main pitfall in the selection process is to consider only three options – *status quo*, the already pre-selected option and an unrealistic option, leading to the selection of the regulator’s preferred option as the final choice without adequate analysis being conducted.

The preferred option(s) – most often a combination - is identified after analyzing the feasible options.

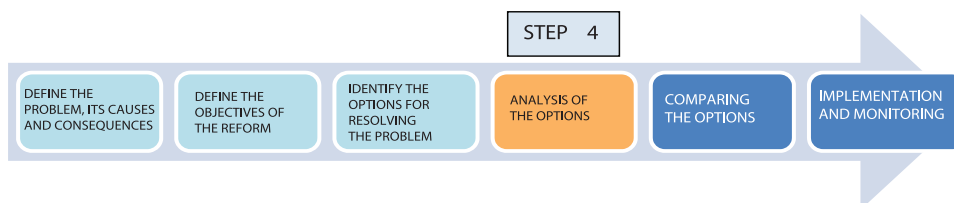
Example – Relevant options in the business registry reform in Montenegro

- **Option 1: Status quo.** Registration remains a court procedure; and tax and other registrations carried out at the Tax Administration remain detached from the company registration process.
- **Option 2: Registration remains a court procedure** but a unified application procedure is set up with other registration procedures located at the Tax Administration; data exchange between the Central Registry and Tax Administration is established (minimum investment option).
- **Option 3: Registration is transformed into an administrative procedure** by transferring it to the competence of the Tax Administration, and one window for the receipt of a unified registration form is established (Single window option)
- **Option 4: Establishment of a new administrative institution for registration of companies that also takes over other public registries.** Establishment of a single window that integrates all relevant business start up registrations and procedures in the registration process, and which issues a unique registration number used for all state authority needs (the option of a new institution as a single window for a number of registries).

Example – Feasible options in business licensing reform in Montenegro

- **Option 1. Establishment of an E-Registry for business Licensing**
- **Option 2. Establishment of an E-Registry for licensing, alongside measures to simplify and rationalize licenses.**
- **Option 3. Business Licensing Center as an independent institution (including E-Registry)**
- **Option 4. Business Licensing Center within an existing institution (including E-Registry)**

4. STEP 4. ANALYSIS OF THE OPTIONS



How to analyze the options

- ✓ List the positive and negative direct and indirect impacts
- ✓ What are the likely economic, social and environmental impacts of each of the options?
- ✓ Include assessment of administrative burden
- ✓ Apply relevant analytical methods – try to provide quantitative and monetary impacts if possible
- ✓ Specify which social groups, economic sectors or particular regions are affected
- ✓ Consider implementation risks, uncertainties and obstacles to compliance



i. Direct and indirect impacts

Direct impacts occur as the direct consequence of the regulatory change. These are actual impacts on the target population (companies, consumers...), and include the costs that they shall incur due to the change, or to the temporary interruption of the production process, operational costs, and administrative costs. There are also the direct costs that the State and the regulatory authorities shall incur in the implementation of the regulatory change (enforcement, supervision, inspections costs, etc.).

Indirect impacts are those that affect other subjects not directly targeted by the regulations, as well as those that indirectly affect the target population. These are primarily impacts on productivity, competitiveness, change in market structure, innovation, and so on. Some impacts that do not affect the regulated target population should also be taken into consideration (e.g. impacts on the environment).

ii. **Distributional impacts**

In addition to the determination of who is going to be affected by the regulatory change, the consequences of regulatory change on different groups should be analyzed (e.g. specific sectors of the economy, consumers, regions...).

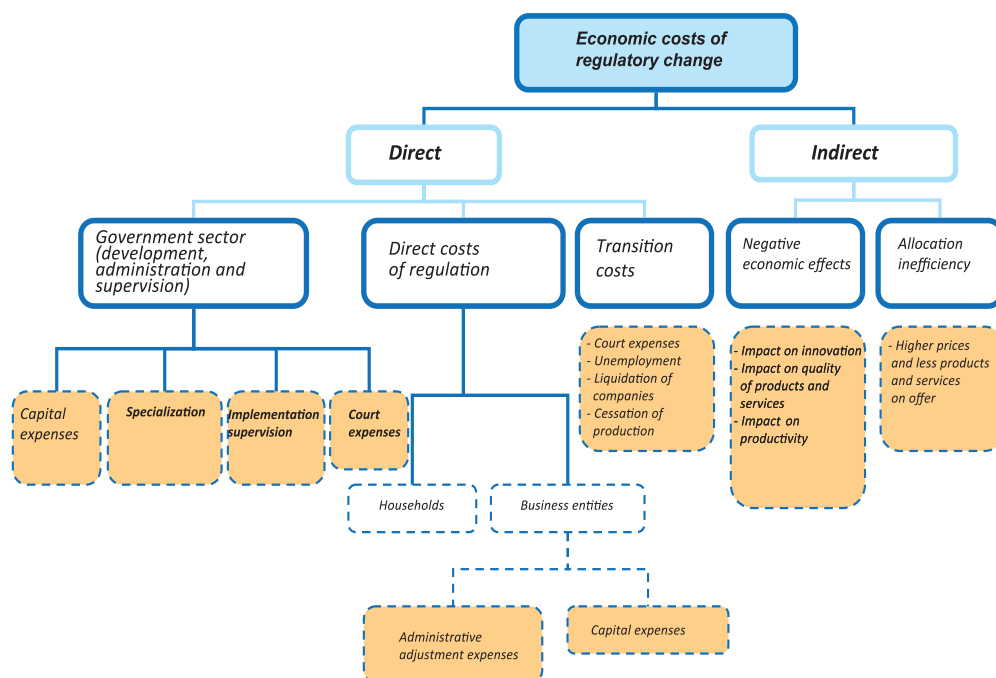
Analyzing distributional impacts means determining who “wins” and who “loses” under the analyzed option. For example, what will be the impact on existing inequalities (e.g. gender or ethnic issues), on SMEs vs. large companies, on newly established companies vs. long-time operating companies, and so on.

Distributional and allocation impacts are linked. Considering that resources are limited, allocation costs always exist since a specific regulatory change means that the same resources cannot be used in another way.

iii. **Costs**

Types of Costs	
RIA requires the determination of costs that are the consequence of the regulatory change. It is important to stress that RIA should not focus only on the costs imposed on the target population but also on the costs and impacts on society as a whole.	
The costs of implementation of an option	Occur when the target population has to engage additional resources in order to comply with the requirements of the regulatory change. These are for example the costs of new administrative requirements (e.g. opportunity costs – working hours needed to comply with the administrative requirements) as well as all other costs imposed by regulatory change (e.g. purchase and installation of new equipment, production costs such as the use of new raw materials, or changes in the production process).
The costs of enforcement of an option	Are borne by the state's administration - national and local. These costs include administration costs, capacity building of civil servants, supervision and reporting, inspections, and so on. They can be expressed in monetary terms or in working hours.
Transition costs	Depend on the period of implementation that was considered in the analysis. In the short term, the annual costs of compliance are often greater than in the long term, because in the long term the target population - consumers or companies - can adjust to the new circumstances. Also, transition impacts can include not only disruption of regular activities (such as possible closure of production facilities and related unemployment), but also the reallocation of resources to other activities.

iv. Checklist for calculating the economic costs of regulatory change

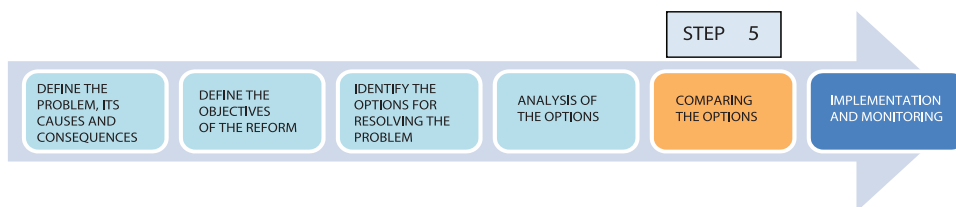


v. Benefits

A RIA must include an analysis of both the costs and benefits of regulatory change. Other potential types of benefits exist alongside purely economic benefits. Examples include:

- Safety, health and environmental protection: e.g. decreases in injuries or deaths, or a reduction in disease and mortality caused by environmental pollution;
- Benefits in the form of decreased costs of implementation or enforcement of regulations;
- Benefits in the form of increased investments, greater use of innovation in production, enhanced productivity and competitiveness, and so on.

5. STEP 5. COMPARING THE OPTIONS



How to compare options

- ✓ Indicate how positive/negative impacts have been weighted for each short-listed option
- ✓ Present results of the weighting
- ✓ Present the aggregated and disaggregated results
- ✓ Highlight the trade-offs and synergies associated with each option
- ✓ If possible, rank the options in terms of the various evaluation criteria

In comparing options the following criteria are used, and it should be explained how they have been applied:

- effectiveness of the option in relation to the objectives,
- efficiency of the option in achieving the objectives,
- coherence of the option with regard to overarching Government strategies and priorities.

The three most relevant methods of impact analysis and comparing options are cost-benefit analysis, cost-effectiveness analysis, and multi-criteria analysis.

i. Cost benefit analysis

Cost-benefit analysis (CBA) is a method of quantitative economic analysis used in the evaluation and ranking of alternative projects, policy measures, or, in our case, alternative regulatory changes. CBA provides answers to the following questions:

- Will regulatory change provide net social benefits?
- Should the proposed option be adopted?
- Which of the different options should be adopted?
- Should the introduction of the regulatory change continue?

The basic characteristic of the CBA is that costs and benefits are observed from the perspective of society as a whole, taking into account a wide spectrum of impacts. It expresses benefits and costs in monetary equivalents (i.e. monetizes costs and benefits), and does so for both costs and benefits that do not have market prices or where market prices do not fully reflect social benefits and costs.

The crux of the CBA methodology is how to monetize costs and benefits given that market prices may or may not be relevant or available.

- When market prices exist and when they are relevant, they represent the most accurate measure of the value of goods and services in society, so it is easy to calculate costs and benefits.
- When market prices exist, but are not relevant due to state intervention or some market deficiency, it is necessary to calculate “shadow prices”, i.e. prices which account for real social costs and benefits.
- Finally, when regulatory changes affect some other parameters that do not have market prices, or have impacts that are otherwise difficult to capture (e.g. number of deaths or injuries, or environmental impact) there are various techniques for indirectly monetizing costs and benefits.

Cost Benefit Analysis (CBA) can be full or partial.

- **Full cost-benefit analysis** should be used when the most significant part of both costs and benefits can be quantified and monetized, and when there is a certain degree of choice as regards the extent to which objectives should be met (as a function of the costs associated with the proposed measures). It entails identifying and evaluating expected economic, environmental and social benefits, and costs of proposed public initiatives. A measure is considered to be justified where net benefits can be expected from the intervention.
- A **partial cost-benefit analysis** can be done if only a part of the costs and benefits can be quantified and monetized. The resulting net benefits should be considered alongside the qualitative assessment of the other costs and benefits.

The time value of money should always be taken into account, i.e. all future monetized costs and benefits should be expressed in present value. Standard textbooks explain discounting in greater detail and good RIAs will have clear examples of cost benefit analysis.

Advantages	Disadvantages
<ul style="list-style-type: none"> • accounts for all (negative and positive) effects of policy measures • allows side-by-side comparison of costs and benefits of the proposal over time • can also be used to rank alternative (including non-regulatory) proposals in terms of their net social gains (or losses) 	<ul style="list-style-type: none"> • cannot include impacts for which there exist no quantitative or monetary data • needs to be supplemented by additional analysis to cover distributional issues • has problems including some effects (social and environmental effects) • requires dealing with various technical issues such as periodic and social discount rates, and so on. • can be very time-consuming and costly

Main steps
✓ establish assumptions and the extent of the analysis
✓ decide the relevant period over which the new or changed regulation will have effect
✓ identify and list costs and benefits, and whether they can be monetized
✓ monetize costs and benefits where possible
✓ select discount rate
✓ discount costs and benefits
✓ assess risk and uncertainty
✓ consider costs and benefits that cannot be reliably monetized
✓ consider additional criteria
✓ recommend (select) the best alternative

Example: Performance Matrix for Relevant Options for Business Licensing Reform in Montenegro

Options \ Criteria	Net benefits	Private sector savings (recurring benefits)	Set-up Costs/Recurring Costs
Option 1. Licensing E- Registry	Positive	In a range from 37,500 to 75,000 Euros	78,800/16,000 Euros
Option 2. Licensing E- Registry + implementation of other measures to improve business licensing framework in Montenegro	Positive	In a range from 37,500 to 75,000 Euros Benefits from other measures not included	78,800/16,000 Euros Cost of other measures not applicable
Option 3. Licensing center as an independent institution (Licensing E-Registry included)	negative or barely positive	In a range from 93,000 to 188,000 Euros	272,700/168,000 Euros Regional offices not included
Option 4. Licensing center as a part of existing institution + E-Registry	probably positive	In a range from 93,000 to 188,000 Euros	181,900/118,000 Regional offices not included

ii. Cost effectiveness analysis

Cost effectiveness analysis (CEA) is a method of comparing the costs of different regulatory options. It is applied primarily when considering regulatory options in areas such as health, safety, transportation or education where benefits cannot be expressed in

monetary terms: i.e. when certain impacts can be expressed in physical units, like fewer deaths, or a better education system.

CEA establishes the costs for reaching specific physical volume units (e.g. avoided accidents, increased production, decreases in pollution, number of households treated, etc.), **and enables the ranking of options according to the costs per observed efficiency units** (or the opposite – efficiency units per certain amount of costs).

CEA does not answer the question of whether the regulatory activity should be undertaken. CEA is primarily applied when:

- It is difficult to express benefits brought by regulatory options in monetary terms;
- The budget is established (or the assumption on the amount of funds available), and the key question is which of the considered options brings the most benefit for a certain amount of costs, i.e. which is the most effective;
- Budget redistribution is considered: i.e. having a fixed level of resource availability;
- When prices do not fully reflect all costs and benefits of the regulatory options considered.

Advantages	Disadvantages
<ul style="list-style-type: none"> • relatively simple approach to measure costs compared to CBA (i.e. does not require exact benefit measurement or estimation) • can be used to compare alternatives that are expected to have more or less the same outcome 	<ul style="list-style-type: none"> • does not answer the question of whether to undertake the regulatory activity • concentrates on a single type of benefit (the intended effect of the measure), but would lead to an incomplete result if possible side-effects were not assessed

iii. Multi criteria analysis

The term multi-criteria analysis covers a wide range of techniques having the aim of capturing a range of positive and negative impacts into a single framework to allow easier comparison of scenarios. Essentially, it applies cost-benefit thinking to cases where there is a need to present impacts that are a mixture of qualitative, quantitative and monetary data, and where there are varying degrees of certainty.

Multi criteria analysis results are very often represented through a so-called Performance Matrix, which uses both quantitative and qualitative criteria to assess impacts, and compare options.

Example of a Performance Matrix:

Options	Criteria				
	Criteria 1 Safety (quantitative)	Criteria 2 Fairness (qualitative)	Criteria 3 Implementation time (quantitative)	Criteria 4 Transparency (qualitative)	Criteria 5 Monetary Savings
1	200 less death cases	✓✓	3 months to full implementation	✓✓	€3 million
2	100 less death cases	✓	1 year to full implementation	✓✓✓	€5 million
3	50 less death cases	✓✓✓	2 years to full implementation	✓✓✓	€2 million

Advantages	Disadvantages
<ul style="list-style-type: none"> • Enables simple comparison and analysis of different types of data (monetary, quantitative, qualitative) with different levels of certainty in the same framework • provides a transparent presentation of the key issues at stake and allows trade-offs to be outlined clearly; • easily understandable for decision makers and interested parties 	<ul style="list-style-type: none"> • includes elements of subjectivity, especially in the weighting stage where the analyst needs to assign relative importance to the criteria • cannot always show whether benefits outweigh costs • time preferences may not always be reflected. • Different interested parties value the importance of the criteria differently

Main steps

- ✓ identifying the objective
- ✓ identifying options to achieve the objective
- ✓ establishing criteria to be used to compare the options (these criteria must be measurable, at least in qualitative terms)
- ✓ assigning weights to each criterion to reflect its relative importance in the decision. These may be arrived at using participatory techniques, ethical principles, technical grounds, or an interactive procedure with the policy-makers
- ✓ scoring how well each option meets the criteria; the scoring needs to be relative to the baseline scenario
- ✓ ranking the options by combining their respective weights and scores
- ✓ performing a sensitivity analysis (i.e. seeing how variations in each criterion would affect the final recommendation) so as to test the robustness of the ranking.

iv. The Standard Cost Model

The Standard Cost Model (SCM) is a simple method for measuring administrative burdens imposed by regulations, primarily for businesses. The SCM considers the informational requirements imposed on businesses in the form of procedures and activities that must be undertaken, and calculates “administrative costs” based on both the time and cost required to comply. The SCM has been a very successful method for preventing new administrative burdens, and removing existing ones.

It is possible to apply the SCM both to existing as well as proposed new regulation. By applying this method the total administrative costs created by the regulation can be clearly expressed, and possibilities for simplifying or eliminating administrative requirements can be identified.

The SCM can be simply expressed as the product of “the price of the procedure – informational requirement” – **P** and the total annual number of procedures (informational requirements) – **Q**. The total number of procedures (**Q**) is obtained by taking the total number of entities which have to comply with the requirement imposed by the regulation – **N** and the frequency of the obligation to comply with a specific requirement – **F**.

In order to calculate the cost of the procedure, we should calculate the following components:

- The regulated entities (employees or externally hired persons) must spend a certain amount of time in order to comply with the imposed requirements. The time they need in order to comply with the administrative requirement (procedure) – **H**, i.e. costs to gather and submit the necessary information.
- For the calculation of the costs imposed on the regulated entities, in the form of time spent for compliance with the administrative requirement, the usual compensation (per hour or day) that the regulated entity pays to the persons engaged for the performance of administrative jobs is applied – **T**. Other costs, such as office supplies, travel costs etc. are taken into consideration.
- Certain administrative requirements also require the purchase of special equipment – **A**.
- Another category of costs is those incurred due to the necessity to hire a lawyer, bookkeeper or other professional – **E**.

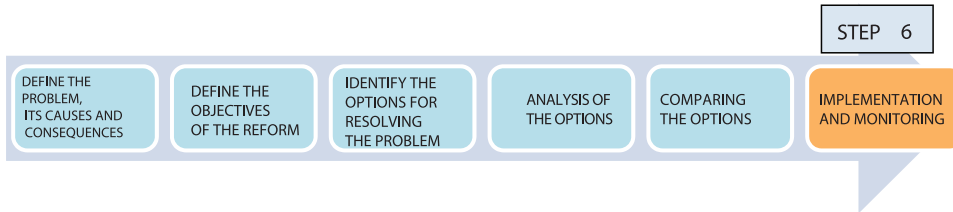
P (price of procedure) x Q (total number of procedures) = (H•T+A+E) • (N•F)	
H (Time)	The time necessary to comply with the administrative requirement, i.e. activity of gathering and submitting information.
T (Tariff - fee)	Compensation (per hour or day) which the regulated entity pays to the engaged persons for performing administrative activities. The compensation rate (or tariff) must correspond to the characteristics of the employees who perform administrative jobs in practice. The compensation rate (or tariff) for the employees in the regulated entity is determined in accordance with statistical data. Other costs, such as office supplies, travel costs etc. are taken into consideration.

A (special equipment and similar)	Costs of purchase of special equipment, when such equipment is necessary in order to comply with the specific administrative requirement.
E (external costs)	Compensation which the regulated entity must pay to e.g. a lawyer, bookkeeper or other professional in order to comply with the administrative requirement Fees and other compensations paid by the regulated entity due to the existence of the administrative requirement.
N (number of regulated entities)	The number and types of regulated subjects is determined by using data from public registers, statistical data or relevant reports.
F (frequency of obligation)	The frequency of gathering and submission of information during a specific period (usually one year) is determined based on the regulation, or on other sources.

Let us consider a simple example of the administrative procedure to obtain the approval issued by a regulatory body. The assumption is that the hourly rate in Montenegro is €3, and that the employee involved in the preparation of material, filling in the forms, copying and other activities related to this activity, spends a total of two hours and thirty minutes. Based on this, the cost of the procedure is €7.5. Other costs such as copying, mailing or eventual engagement of third parties needs to be added. In our example, those costs are €15 per procedure, giving a total cost of €22.5 per individual procedure. Based on data on annual frequency, the total administrative cost at the level of economy is calculated. When we do not know the total number of annual procedures, the frequency might be calculated on the basis of the number of regulated entities, and the annual frequency of administrative obligation (e.g. 6,000 regulated entities have the obligation to obtain the approval twice a year).

Example: Administrative procedure – obtaining approval							
	Tariff	Time	Individual procedure cost	Additional costs (copying, mailing etc.)	Total cost for individual procedure	Frequency (annually)	Total costs at the level of economy
Companies	€3	2h 30m	€7.5	€15	€22.5	10,000	€225,000

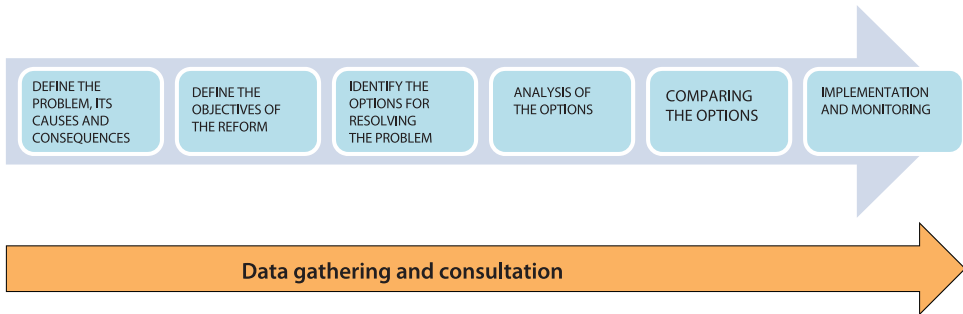
6. STEP 6. IMPLEMENTATION AND MONITORING



Once the regulation is adopted, the regulatory authorities responsible for the regulation as well as other policy makers need to verify whether the regulation is producing the impacts that were foreseen during RIA process, and whether the objectives are being achieved. If not, they need to know whether this is a result of the regulatory options selected, poor implementation, or maybe insufficient administrative capacities. Therefore, during the RIA process it is important to establish how monitoring and evaluation will take place, and to define the basic indicators that will measure whether the main goals are being achieved during implementation.

Main implementation and monitoring issues	
✓	How will the preferred option be implemented?
✓	Who is responsible for implementation of the option?
✓	Will there be transitional arrangements?
✓	Will there be fees and charges?
✓	How and when will the preferred option be monitored?
✓	Who will undertake enforcement - regulators or third parties?
✓	What is the expected compliance rate (10%, 40%, 95%)?
✓	Are penalties appropriate and proportionate to the problem and risk (warnings, financial penalties, license suspension or withdrawal, prohibition, etc.)?
✓	How and when will the preferred option be reviewed?

7. CROSS CUTTING RIA ACTIVITES



i. Data gathering in RIA

Data gathering is one of the most important activities in the RIA process. The quality of the RIA is dependent on the quality of available data. Therefore, particular attention should be given to this activity in terms of how to determine the necessary data, and which data gathering techniques to apply. Moreover, regulatory change is usually linked to a specific technical area, and so a RIA usually requires specific data.

Before you start gathering data you should:

- ✓ Identify the required and available data
- ✓ Define the techniques of data gathering for the missing data
- ✓ Determine the acceptable level data quality, taking into consideration the reliability and objectivity of the gathered data
- ✓ In the case of missing data, clearly indicate the assumptions made

Preliminary questions:

- ✓ Who shall gather and evaluate the data? Is there an existing system in place that enables supervision of implementation and evaluation?
- ✓ From whom shall the data be gathered?
- ✓ How shall the gathered data be used?

Considering that data gathering is a time-consuming process it is necessary to start the data gathering process as soon as possible, and utilize existing sources of data to the extent possible. Often, the required data can be found in the proposing ministry/regulatory authority, but it is important to keep in mind that the missing data might be obtained from the target population as well (representative associations, companies, individuals...) during consultations. The consultation process can help resolve the problem of missing data, especially since the target population may well be keen to participate in the development of regulatory change, and to provide as much data as possible to the regulator. Thus, part of the data gathering costs could effectively be borne by the target population that will be affected by the regulatory change.

Examples of data gathering techniques:
✓ Search of literature and existing databases
✓ Consultation with experts in the relevant technical area
✓ Publications and business reports
✓ Data gathering questionnaires for institutions, experts, individuals
✓ Focus groups
✓ Modeling

Although data gathering can be divided into phases (identification of required data, listing the available data and identification of missing data, determination of the way in which missing data will be gathered) these phases are not mechanical or sequential. This is because the data gathering process is a cross-cutting activity, and although it should be more intensive in the initial stage of RIA, refining and validation should be done throughout the RIA process.

Data gathering is performed throughout RIA implementation	
Preliminary data gathering in the phase of defining the problem.	The data confirms or rejects the existence of the problem, i.e. consequences of the problem.
Data gathering continues in the phase of identifying the options	Consideration of the status quo option requires data that permits analysis of current trends. Consideration of other options requires data and other information that can impact changes in the status quo. The more options considered, the bigger the need for data.
Data gathering in the analysis of options i.e. the quantification of costs and benefits	Different techniques are used depending on the analytical method applied. The main focus of data gathering in this phase is selecting the indicators that enable comparison of the options and finally identification of the preferred option/s.
Data gathering in the evaluation and monitoring of the enacted regulation	Careful choice of indicators enables continued supervision of the quality of implementation of the regulation and goals.

ii. Consultation with interested parties during the IA

Consultation is an important part of the RIA process. It provides important input at various stages of the RIA (problem, objectives, alternatives, impacts, implementation etc.), and that is why it is a cross-cutting activity. Consultation improves the quality of the data, the quality of the analysis (assumptions, impacts etc.), and helps build acceptance and a constituency for reform.

a. Main Benefits of Consultation

- Ensures that the regulatory process is transparent and non-discriminatory
- It is a simple, and often the only way to obtain specific information and data
- It helps reveal how regulated subjects, experts and other stakeholders view and

value a certain problem, and what their opinions are regarding possible regulatory changes.

- It contributes to a clearer definition of the problem, better insight into possible alternatives and real consequences of regulatory proposals, and a decrease in the risk of unforeseen negative consequences
- It helps build broader support for changes to a regulation.

b. **Impediments to Good Consultation**

- Resistance to consultation (from Ministries and sometimes at the political level), and influential business and other stakeholders (i.e., information monopolies)
- Regulatory capture – countered by ensuring wide consultation of key stakeholders
- Secretive regulation making processes
- Inadequate time available
- Insufficient resources
- Poorly organized stakeholders
- Poorly managed consultation processes (stakeholder fatigue, etc.)

Poor quality consultation results in bad regulation, often with unpredictable consequences, which leads to a need to review and reform such regulation in a short period of time.

c. **Minimum EU Standards for Consultation**

In the EU, Stakeholder consultation in the impact assessment process must be carried out according to the Commission's general principles and minimum standards for consultation⁴.

1. Provide consultation documents that are clear, concise and include all necessary information

2. Consult all relevant target groups

3. Ensure sufficient publicity and choose tools adapted to the target group(s)

4. Leave sufficient time for participation

5. Provide – collective or individual – acknowledgement of responses and feedback

⁴ COM (2002) 704. See http://europa.eu.int/eurex/lex/LexUriServ/site/en/com/2002/com2002_0704en01.pdf.

d. Common consultation pitfalls:

- trying to achieve consensus in the public consultation. Consultation should not be used as a mechanism for negotiations with the stakeholders,
- Consulting only with interest groups. Consultation should go beyond interest groups, or those with sufficient resources to support their arguments related to specific policies or regulations,
- Performing only “ex post” consultation. Performing consultation after all the decisions related to the regulation have been made is a waste of resources.

e. Phases of the Consultation Process

Main Elements of a Consultation Plan	
✓	Define the subject and scope of consultation
	What is the subject of consultation?
	What do we want to achieve by consulting ?
	Do we need informal consultation to properly define the problem?
✓	Identify the stakeholders and consultation techniques
	Who will participate?
	Do we have sufficient resources to implement the consultation process?
	Which techniques are we going to use?
	Will we reach those we want to include in the consultation process with the selected techniques?
✓	Decide on the necessary time and questions for the consultation
	When do we consult informally?
	How long is the consultation process going to last?
	Which questions/dilemmas do we need to get an answer to, and are they formulated in a clear and precise way?

f. Consultation Techniques

Consultation can be

- Active (advisory groups, public presentations, panels, focus groups, surveys), or
- Passive (circulation for comment, public notice and comment, public hearing).

How you are going to consult depends on several factors, such as the purpose and significance of the regulatory change, timing of the process, number of interested stakeholders, available resources, and so on.

There is no “best” consultation technique.

Most commonly used consultation techniques:

- informal consultation
- public notice and comment
- circulation for comment
- public hearing,
- focus groups,
- semi-structured interviews,
- panels,
- surveys

Overview of Consultation Techniques

Informal Consultation	<ul style="list-style-type: none"> • Discretionary – ad-hoc • Many forms – meetings, phone calls • Good way to make initial contact • Good way to collect information and build trust • Is not costly • But can lack transparency and may not be inclusive
Public Notice and Comment	<ul style="list-style-type: none"> • Good way to commence consultation • All interested parties are aware and can be involved • Open and inclusive • But participation can sometimes be low
Circulation for Comment	<ul style="list-style-type: none"> • Inviting comments from stakeholders on a previously created list • Often used towards the end of consultation process when stakeholders are known • Possibility of obtaining detailed opinions and data • Relatively low cost • May not be open and transparent (some stakeholders may not be included) • Possible bias selection of respondents (e.g. only those companies that have appropriate professional departments may be able to prepare comments)
Round Tables and Conferences	<ul style="list-style-type: none"> • Often used towards the end of process • Good way to reach out to isolated stakeholders (e.g., rural) • But can be difficult to access • Needs to be carefully managed and focused • Can be costly

Focus Groups	<ul style="list-style-type: none"> • Predefined group of participants who are encouraged to talk about their experiences and opinions in relation to the subject of the consultation • It is desirable that the participants communicate between themselves. • Moderator/s guide the discussion in order to find out the opinions, beliefs, experiences and reactions to the subject of the consultation • Easy and quick to organize • Relatively low costs of organization, • Enables the participation of regulated subjects at an early phase of the impact assessment • Useful as a complement to other methods • Relatively detailed and in-depth analysis
Semi-structured Interviews	<p>In semi-structured interviews (unlike structured questionnaires in which the questions have been predefined) the questions are mostly formulated during the interview itself</p> <p>Objective – to obtain general as well as specific quantitative and qualitative information</p> <ul style="list-style-type: none"> • can be organized relatively quickly • can point to some unknown problems or unforeseen regulatory questions • in comparison to focus groups, semi-structured interviews permit an individual approach to the examinees, and enable discussion of confidential or sensitive issues • the main disadvantage of this technique is the non-representative structure of participation
Panels	<ul style="list-style-type: none"> • The panel technique implies identifying and creating groups of subjects (individuals or businesses) with which periodic consultation is performed using questionnaires. • The questionnaires can be semi-structured (contain a part with closed and a part with open questions) or closed (a fixed number of questions and possible answers). • Panels permit the monitoring of regulatory changes over time • Costs depend on the size of the panel, way of interviewing, way of selection of the examinees, etc.
Surveys	<ul style="list-style-type: none"> • Surveys cover a range of different techniques, with different types of question, ways of interviewing, and so on. • Objective – surveys gather quantifiable qualitative data • Advantages <ul style="list-style-type: none"> • relatively reliable data • possibility to recycle data • Disadvantages <ul style="list-style-type: none"> • high costs and time necessary to implement • cannot reveal information or opinions that have not been taken into consideration by the author of the questionnaire • Often surveys are not the right way to address the problems faced in the RIA process, and their use should be carefully considered.

g. Analysis and evaluation of consultation

Analysis of received input, and presentation of results	
✓	Will the received input be published?
✓	Do we need assistance in analyzing the gathered information?
✓	Do we need to consult again?
✓	How will the conclusions of the consultation process be published?
✓	Has the consultation changed our understanding of specific issues?
✓	Did we prepare a report on the consultation process?
✓	Did the participants receive feedback on the consultation's results?

8. PREPARATION OF THE RIA REPORT

The RIA report is the result of the analysis. In cases of minor changes to laws or bylaws, it is often relatively easy to explain the problem, and even to quantify benefits and costs. However, with major changes, and especially with legislation that regulates very complex, multilayered fields, RIA reports need to focus on the most significant changes. Whether the report will have five or thirty pages depends on the proportionality and precautionary principles; that is, on the importance of the regulatory changes. Presented below is the recommended generic RIA report format. This template is designed to remind those preparing RIA reports of the key questions that need to be answered.

REGULATORY IMPACT ASSESSMENT REPORT FORM	
MINISTRY OR REGULATORY BODY	
REGULATION TITLE	
Section 1: Defining the Problem <ul style="list-style-type: none">✓ What problem is the proposed legislation intended to solve?✓ What are the causes of the problem?✓ What are the consequences of the problem?✓ Who is affected by the existing problem, in what ways, and to what extent?✓ How would the problem evolve without regulatory changes ("status quo" option)?	
Section 2: Objectives <ul style="list-style-type: none">✓ What are the general policy objectives?✓ Describe the consistency of these objectives with existing Government strategies or programs, if applicable.	

Section 3: Options

- ✓ What are the possible options for meeting the objectives and solving the problem? (always consider the “status quo” option; it is also recommended to include a non-regulatory option unless there is an obligation to regulate).

Section 4: Impact Analysis

- ✓ Who is likely to be affected by the regulation and in what way? List positive and negative impacts; direct and indirect impacts
- ✓ What costs will regulation impose on citizens and businesses (especially small and medium enterprises)?
- ✓ Do the anticipated positive consequences of the regulation justify the anticipated costs?
- ✓ Does the regulation support the creation of new businesses in the market, and support market competition?
- ✓ Include an assessment of administrative burdens and business barriers.

Section 5: Fiscal Impact Assessment

- ✓ Does the implementation of regulation require financial funds, and if so how much?
- ✓ Is the financial investment one-off, or spread over a certain period of time? Explain.
- ✓ Will the implementation of the regulation produce international financial obligations? Explain.
- ✓ Are the necessary financial funds provided for in the current fiscal year’s budget, or are they planned in the next fiscal year’s budget?
- ✓ Does the regulation require adoption of by-laws that will produce financial obligations?
- ✓ Will implementation of the regulation generate income for the Montenegrin budget?
- ✓ Explain the methodology used in calculating financial costs/revenues.
- ✓ Were there any problems in precise calculation of financial costs/revenues? Explain.
- ✓ Were there any remarks on the draft regulation by the Ministry of Finance?
- ✓ Were the received remarks incorporated into the regulation? Explain.

Section 6: Consultation

- ✓ Was external expertise was used; and if yes, how?
- ✓ Which groups of stakeholders were consulted, in which phase of the RIA process, and how (public or targeted consultation)?
- ✓ Note main results and how stakeholders' input was taken into account; or why it was not taken into account.

Section 7: Monitoring and Evaluation

- ✓ What are the potential obstacles to implementation of the regulation?
- ✓ What measures will be undertaken during implementation in order to reach the goals of the regulation?
- ✓ What are the main indicators that will measure achievement of the goals, or progress towards them?
- ✓ Who will be in charge of monitoring and evaluation of the implementation of the regulation?

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