

# **MANUAL**

## **On Regulatory Impact Assessment in Moldova**

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## **Chapter I. Introduction**

### **1.1 What is this Manual?**

This Manual is a guide for decision-making authorities and all others involved in formulating, developing and making public policy decisions. It is intended to help them assess the impacts of the proposed action. The principles and techniques in this Manual can be also used for revising existing policies and regulations, thus establishing their efficient and effective harmonization with objectives of the Government.

### **1.2 Structure of the Manual**

The Manual is structured in four chapters:

Chapter I.	Introduction
Chapter II.	Context
Chapter III.	Where to begin/what you need to know
Chapter IV.	Completing the Regulatory Impact Assessment

## **Chapter II. Context**

### **2.1 What is a regulation**

A regulation is any act having the form of laws, decisions/ordinances of the Government and acts of other public administration authorities (referred to as regulatory acts of authorities) that establish rights, obligations (requirements), interdictions as well as regulates relations between public authorities and third parties related to businesses start up, business development and business closure.

State regulation of entrepreneurial activity is based on following principles:

- a) Principle of predictability;
- b) Principle of decision-making transparency and regulatory transparency;
- c) Principle of regulatory impact analysis;
- d) Principle of material and procedural regulation of the start-up, running and liquidation of business through legislative acts;
- e) Principle of proportionality in relations between the state and business.

State regulation of entrepreneurial activity must be based on the following principles of “good regulation”:

- a) **Stability**: Regulatory acts must be based on clear market principles and be consulted and communicated with the affected members of the public before adoption. No regulatory act should establish barriers to entry or any barriers to free market competition, trade, and investment that are not fully justified as necessary in the public interest.
- b) **Cost-effectiveness**: Regulatory acts must be shown to have selected the least cost solution to a clearly-defined problem being addressed.
- c) **Flexibility and performance-oriented**: Regulatory acts must set out the performance to be achieved by those affected by regulation, rather than specifying technologies and the means needed to achieve that performance.
- d) **Proportionate**: Regulatory acts must demonstrate that they will increase public welfare of the country and that the total costs of the regulatory act are justified by the total benefits.

### **2.2 What is Regulatory Impact Assessment**

Regulatory Impact Assessment (RIA) is an analysis of the potential costs and benefits after introducing a certain policy or regulation. RIA represents a tool to reflect on a decision. RIA is a set of logical actions structuring the elaboration and drafting of policies at the general level, and normative acts, in particular. The RIA deepens existing practices for justification of drafts by making analysis more detailed, and by formalizing the results in a report.

The primary responsibility for impact assessment is borne by the authority – author of the regulatory act. The RIA furnishes politicians with complete information for making decisions that contribute to quality governance and a better business environment for economic growth and poverty reduction.

As defined in the Strategy for Economic Growth and Poverty Reduction (SEGPR), it is intended to shift the trends in the public administration from excessive regulation to assessment and monitoring of regulatory impacts on entrepreneurial activity.

RIA implies the need to answer a set of analytical questions:

- What is the nature, magnitude and trend of a problem?
- What are the objectives of the Republic of Moldova?
- What are the main policy options for reaching the objectives?
- What is the possible impact on economic, social and environmental goals of the proposed options?
- Which are the advantages and disadvantages of the basic options?
- What is the lowest cost solution to solving a problem?
- Are the benefits of solutions proportional to the costs?
- How can monitoring and ulterior evaluation be organized?

It has to be taken into account that RIA is complementary to decision taking and cannot substitute it.

### **2.3 Why are Regulatory Impact Assessments important?**

The RIA process provides for coordination at early stages of developing and drafting the policies. RIA demonstrates the transparency in decision taking by the public authorities and allows the involvement of all interested stakeholders in this process. RIA raises the quality of regulations, and explains the need of intervention on the part of the state with the purpose to regulate certain social relations. The benefits of the RIA are as follows:

- Better understanding of the regulatory impact;
- Identification of alternative options for reaching the target;
- Evaluation of the options;
- Transparency and consultancy in decision making;
- Justification of benefits in terms of costs.

### **2.4 How Regulatory Impact Assessment fits into the activity of the public authorities**

RIA is based on the principle of justification of draft acts and further implements the economic-financial analysis, particularly by evaluating the costs and benefits of a new regulation implementation, or lies at the basis of assessment of the existent ones, by way of establishing the need of further regulation, amendment or abrogation thereof.

## **Chapter III. Where to Begin/What you need to know**

### **3.1 Before you start the RIA**

Before beginning an RIA, it is important to plan how you will complete the RIA. You should consider consulting the RIA Secretariat, key stakeholders, professional advisers (e.g. statisticians, economists or lawyers) and be aware of the role of the State Commission in the RIA process. Consultation is a key element of the RIA process and you will need to factor this in at all stages. You should use the RIA template to brainstorm and map out where inputs will be required. This will help to plan the development of the RIA and give an indication of the timing required.

#### **3.1.1 Using the Regulatory Impact Assessment to plan**

When developing governmental policies, you should use the RIA at the very beginning to help to plan governmental interventions. The RIA is a ‘fluid and living document’ and should evolve as thinking evolves about the proposed way forward. This includes using the RIA template to propose ideas and to help identify gaps in thinking, information and data. This will help plan how these gaps can be filled and who needs to be consulted. Here are some questions to think about when planning your RIA and filling it out for the first time

- 1) What are we trying to do? What is the goal?**
- 2) Why are we trying to do it?**
- 3) Who are the stakeholders?**
- 4) What is the result?**
- 5) What are the constraints?**
- 6) What outcomes do the priority stakeholders want?**
- 7) What are we prepared to do? Or what are we not prepared to do?**
- 8) What assumptions are we making?**
- 9) Where are the gaps? How can we fill the gaps?**
- 10) Who needs to participate in developing the proposal? What do we need from others?**
- 11) What sequence do they need to be done in?**
- 12) What resources do we have available?**
- 13) What are the risks and barriers to success? How can we reduce them?**
- 14) What contingency arrangements do we need?**
- 15) What's the plan?**

#### **3.1.2 Regulatory Impact Assessment Template**

The RIA template is a framework for developing proposals for a norm o policy in a logical and systematic way. It is a tool to assist the development of a proposal in a methodic format to help in assessing the major impacts and consequences and in reducing the risk of failure and unintended consequences. Below is the RIA template to be followed when preparing a RIA:

<b>Regulatory Impact Assessment Template</b>		
<b>Code</b>	<b>Section of RIA</b>	<b>Content of section</b>

<b>1.0</b>	<b>Title of RIA</b>	
<b>1.1</b>	Give the RIA a title that is easily understood and identifiable e.g. if it is accompanying a draft law then give the RIA the same name as the name of the draft law.	What is the official name of the proposal? Is it called something different in the media? What title can be used that will be easily understood by the public, specialists and all of government?
<b>2.0</b>	<b>Problem/Goal/Objective</b>	<i>Suggestions – maybe you want to deal first with Section 3.0 and than return to the present section.</i>
<b>2.1</b>	Define the desired outcome of the proposed intervention.	What is the aim of the intervention? If applicable, what are the broad strategic aims relevant to government priorities?
<b>2.2</b>	If relevant, precisely state specific results or objectives that the intervention is trying to achieve.	What measurements can be used to define the goals?
<b>3.0</b>	<b>Motives for intervention</b>	
<b>3.1</b>	Include brief and relevant information about the background of the proposal.	What is the history of this proposal? What is the context of the need for proposal? Are there any wider issues to be aware of?
<b>3.2</b>	Explain the issue that is being addressed and the need for government action.	Why there is a need for government intervention? What is the problem being addressed? How important is the problem? Differentiate between the problem and symptoms. Is the government intervention necessary?
<b>3.3</b>	Describe the current regulatory environment.	What norms exist that affect the problem being addressed? Why is more intervention required? What are the over-laps between the proposed intervention and existing norms? Can existing norms be abolished as a result of the proposed action?
<b>4.0</b>	<b>Possible Options</b>	
<b>4.1</b>	Describe the options being considered including the “Do Nothing” option as the baseline for comparison.	Have all the possible alternatives been considered? Have self-regulatory or voluntary-regulatory options been considered as well legislative regulatory options?
<b>5.0</b>	<b>Assessing the Options – Impact Analysis</b>	<i>This section will analyze the impact of each option. Below is an indication of some of the questions that should be answered for each option.</i>

5.1	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?
5.2	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?
5.3	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?
5.4	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?
5.5.	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 public authorities?
5.6	For each option include a cost benefit analysis of the impacts. This should be quantitative but can have some qualitative assessment too.	What are the benefits and costs of each option?  <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>
6.0	<b>Engaging with stakeholders</b>	
6.1	Include a summary of the consultation process and responses.	Who has been consulted? Who will be consulted? What has been the feedback? (Give a summary of responses) Are there any plans for future consultations? If



		so what are they?
<b>7.0</b>	<b>Implementation, Enforcement and Sanctions</b>	
<b>7.1</b>	Give a detailed explanation of the implementation plans for each option.	<p>What will be the process of implementing the options?</p> <p>Who will be tasked with implementing the option?</p> <p>How will they do this?</p> <p>What are the costs for implementing the option?</p> <p>What is the level of compliance that is being aimed for?</p>
<b>7.2</b>	Explain the enforcement mechanism that will be used for each option.	<p>Who will enforce the option?</p> <p>How much will it cost to enforce?</p> <p>What is the institutional capacity required to conduct the enforcement activity?</p> <p>Where does the proposed enforcement procedure fit in with other enforcement procedures that are conducted by the same body?</p> <p>What other enforcement processes impact upon the same groups that are being impacted upon by the proposed option?</p> <p>Is there any duplication of effort in enforcement processes?</p> <p>Are there any unnecessary burdens that could be simplified?</p>
<b>7.3</b>	Describe the proposed sanctions for each option.	<p>What will be the sanction for not complying?</p> <p>How realistic are the sanctions?</p> <p>Are they for deterrent purposes? Are they for enforcing punishment?</p> <p>Are there any unintended consequences of the sanctions?</p> <p>Will there be a “lead in time” or “period of grace” before the sanctions will be enforced?</p>
<b>8.0</b>	<b>Monitoring and Evaluation</b>	
<b>8.1</b>	State the processes for ensuring successful delivery and implementation of the proposed options.	<p>Who will conduct the monitoring and evaluation?</p> <p>Who will be accountable for the success of delivery/implementation? To whom will they be accountable?</p> <p>When will it happen? How frequently?</p> <p>What will happen as a result of the monitoring/evaluation?</p> <p>Can a Sun-setting clause be introduced?</p>
<b>8.2</b>	Give the methodology for measuring the success of the proposed course of action.	Here are some questions that the monitoring process should consider:

		<p>What were the aims/objectives of the proposed regulation?</p> <p>Is the problem still the same? Is there a new issue?</p> <p>Has the proposed action addressed the issue and met its aim/objectives?</p> <p>Are changes to the norm required?</p> <p>Has the norm had any unintended consequences?</p> <p>Has the norm disproportionately impacted on any group/sector?</p> <p>Has the scope of the norm been too broad? Or has it been too specific?</p> <p>Has the enforcement process been effective, efficient and consistent?</p> <p>What does it cost to enforce the norm?</p> <p>What does it cost to comply with norm?</p> <p>Do the benefits outweigh the costs?</p>
<b>9.0</b>	<b>Summary and Recommendation</b>	
<b>9.1</b>	Include a table that summarizes the positive and negative impacts of each option.	<p>Answer the following for each option in the Summary Table:</p> <p>What is the option?</p> <p>What are the costs of the option?</p> <p>What are the benefits of the option?</p> <p>Are there any other considerations to note?</p> <p>What is the overall impact of the option?</p>
<b>9.2</b>	Give an explanation of the chosen recommended option based on the summary table and analysis in the RIA.	<p>Why has the recommended option been chosen in comparison to the other options?</p> <p>What were the key determining reasons for this choice?</p>
<b>9.2</b>	Agree with the RIA Secretariat and announce a deadline	When RIA would be revised after its implementation?
<b>9.4</b>	The Head of responsible authority for the proposal must sign the declaration of the RIA.	<p>Has the Head of the authority seen and read the RIA?</p> <p>Does the Head of the authority agree with the analysis in the RIA?</p> <p>Does the Head of the authority agree with the recommended course of action?</p>

### 3.1.3 Initial consultation and evidence gathering

When developing the proposal it is important to build relationships with key stakeholders at an early

stage. Informal consultation can not only help develop these relationships, but they can help to develop proposals before going out to wider consultation. This provides an informed and easier way to begin the formal consultation exercise. However care should be taken to choose stakeholders carefully to not form a skewed proposal based on limited consultation. Therefore it is important to make the results of your informal consultation and your initial thinking available for comments wider and publicly by posting them on the website. This website will act as the window to notify any

stakeholder that consultations have started and that if there are any comments or objections to the latest thinking, then these can be directly addressed well in advance of the proposal being finalized. This will help mitigate risk and the possibility of a proposal failing. It will also provide protection against authorities who may be accused of unfair practices, favoritism or bias when initially developing the proposal.

A stakeholder analysis during the planning stage should be produced to help reduce these risks by identifying relevant stakeholders early. Stakeholders include officials in other Ministries, as well as stakeholders outside of government.

The RIA process is a tool that will communicate proposals to different stakeholders as they develop. This helps to avoid unintended consequences and resolve important issues at an early stage of development, before much time and resource has been invested in the proposal.

### **3.1.4 Cross-cutting issues**

Often the interventions of one authority have an impact in an area or activity of another authority. Ensuring that different parts of government are not duplicating, contradicting or wasting their efforts presents a significant challenge for authorities that can ultimately impact on the delivery of government intervention. As well as authorities working together and consulting "horizontally" there should be "vertical" dialogue with service providers and those at the front line of delivery to ensure the proposal will deliver as intended.

The RIA will be used to monitor and assess the activities and impacts of government at a strategic level by the RIA Secretariat. It provides an opportunity to identify linkages between activities in different authorities for greater overall government efficiency. The RIA Secretariat will report any outstanding or disputed cross-cutting regulatory issues to the State Commission for adjudication.

### **3.1.5 Timescale and deadlines**

The overall timescale for development and implementation of proposals varies depending on a range of factors, including the urgency or political priority of the issue, whether legislation is required and the methodology adopted.

The RIA process will help officials complete this task in a systematic, methodical and efficient manner. The amount of effort invested in producing an RIA should reflect the significance of the proposal. The RIA should be proportionate in detail to the impacts of the proposal.

In ascertaining the significance of the proposal, the RIA goes through two phases of development and a set of threshold criteria which are explained in 3.2. This will help in planning the input required to complete the RIA within the time constraints.

## **3.2 Stages of Regulatory Impact Assessment Process**

The RIA is a "fluid and living" document. As has been explained earlier, the RIA should be started at the very beginning of proposal formulation and be used to help plan the task of developing

proposals. The level of analysis within the RIA should be proportionate to the impacts of the proposal. The greater the impact, the more detailed assessment and quantification of the impacts will be required.

There are two stages to the RIA in the development of the proposal. These are the *Preliminary RIA (Analysis)* and *Final RIA (Analysis)* and are explained in the following sections. The assessment in the *Preliminary RIA (Analysis)* will be put through questions, known as the *Threshold Criteria*, which will filter proposals so that only those with significant impacts require a *Final RIA (Analysis)*.

This process is to ensure that resources are focused on proposals that are of significance and that require in-depth analysis. The RIA process does not require the same level of analysis for *every* proposal from *all* authorities.

The *Preliminary RIA (Analysis)* and *Final RIA (Analysis)* will have quantitative analysis of the impacts. Consultation will help assess and quantify any qualitative impacts and information gaps. The RIA should be used as a consultation document and can include questions to be answered by stakeholders where relevant and necessary. Public consultations should be used to verify and validate the assessment of impacts as well as find out the impacts that are not known or unclear.

### 3.2.1 Preliminary RIA (Analysis)

All proposals will have a *Preliminary RIA (Analysis)*. The *Preliminary RIA (Analysis)* is begun when the assessment of the impacts of the proposals has been developed so that the *Threshold Criteria* can be assessed. The *Preliminary RIA (Analysis)* will have some quantitative analysis and an indication of the magnitude of the impacts, costs and benefits.

### 3.2.2 Threshold Criteria

The assessment of impacts in the *Preliminary RIA (Analysis)* should be filtered through the questions below – the *Threshold Criteria*. If the answer to ANY of these questions is YES then the analysis in the *Preliminary RIA (Analysis)* should be developed to a *Final RIA (Analysis)* (see 3.2.3). If the answer to ALL of the questions is NO then the RIA does not need to be developed any further and is now complete. The result of the Threshold Criteria must be agreed with the RIA Secretariat. Below are the questions that should be answered for the Threshold Criteria.

The *Threshold Criteria* questions are:

- Will the annual proposed cost on business exceed X lei?
- Will the proposal have a disproportionate impact on a particular sector or group?
- Will the regulatory act cost X lei to public services front-line staff?
- Is the regulatory act politically sensitive?

### 3.2.3 Final RIA (Analysis)

The Final RIA (Analysis) is developed from the Preliminary RIA (Analysis) (see.3.2.1) only when the assessment in the latter meets the Threshold Criteria (see 3.2.2).

A Final RIA (Analysis) is required when the impacts of the proposal are of significance and therefore the proposal requires substantial analysis beyond the Preliminary RIA (Analysis). This will include the need for an additional public consultation and greater quantification within the assessment.

The Final RIA (Analysis) will require specialist input and a longer period of time to conduct the appropriate assessment. You must involve the RIA Secretariat when completing the Final RIA (Analysis) and consult stakeholders on a regular basis.

### 3.2.4 What happens when the RIA has been completed?

The completed RIA will have undergone formal public consultation and all the major impacts will have been fully quantified and analysed. There will be sufficient knowledge and information of the impacts of the proposals, feedback from stakeholders and the implementation and evaluation methods and resources for the proposals. It is at this stage that an informed decision based on the evidence that has been found will be made. The final decision of which proposal is to be followed should be explained with a summary of all the options considered and their respective impacts, both positive and negative.

When the RIA has been completed it must be approved by the RIA Secretariat and the State Commission. When it has been approved then the Head of responsible authority will sign the RIA and then the RIA will be published.

At the time of publication, the RIA Secretariat will also agree a “Sun Set” date for the RIA with the authority. The “Sun Set” date is the when the RIA will be reviewed by the RIA Secretariat and authority to see if:

- a) The proposal has been implemented with the projected impacts in the RIA;
- b) The circumstances and hence need for the proposal have changed since the RIA was published;
- c) The proposal is now out-of-date and not necessary.
- d) Any other findings of regulatory importance.

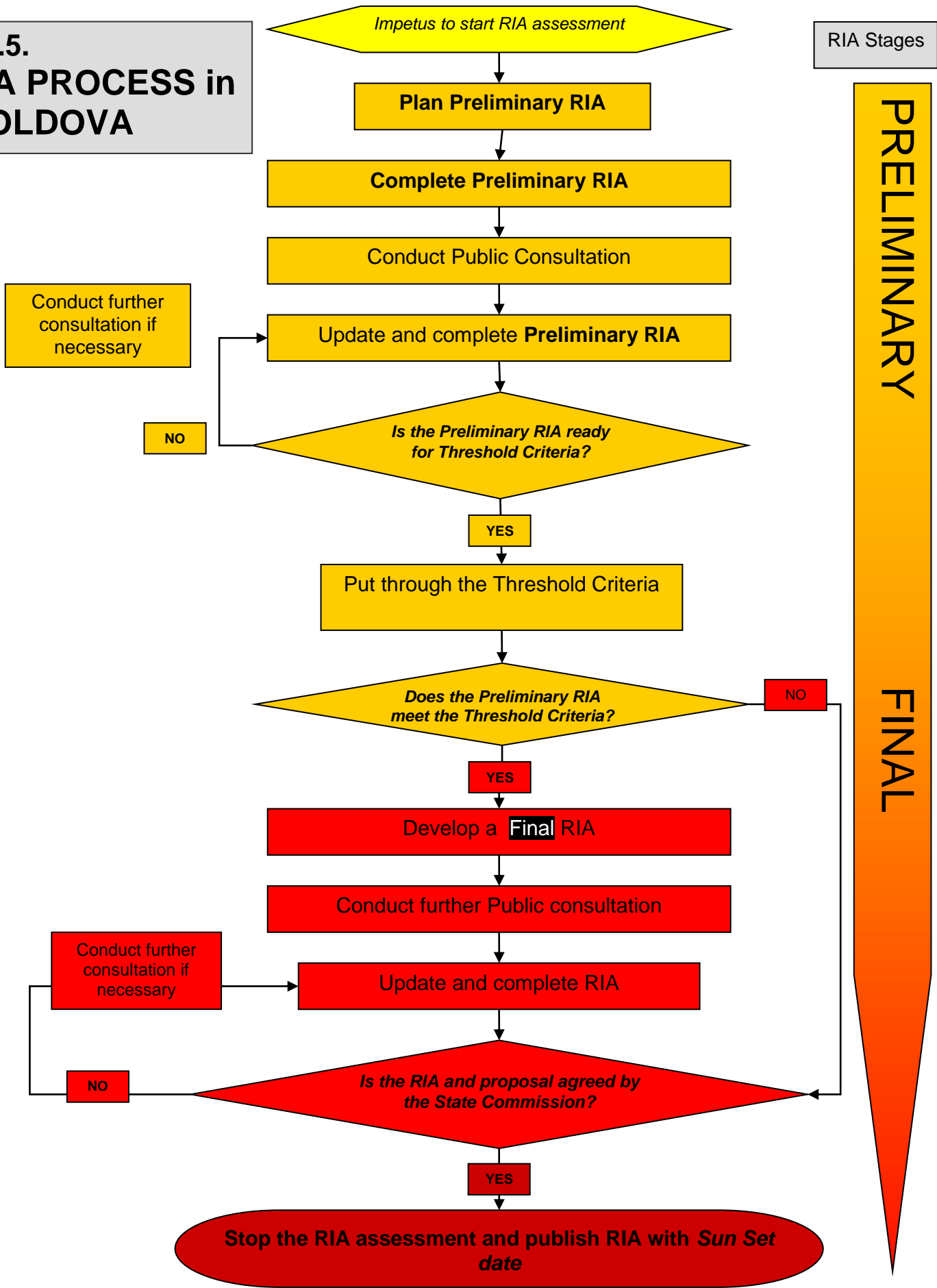
Depending on the outcome of the review the RIA and proposal will either:

- i) Have another ‘Sun Set’ date agreed by the RIA Secretariat and authority.
- ii) Have the RIA assessment updated or completed again by the authority.
- iii) Have the RIA and proposal abolished through the necessary procedures.

If a stakeholder or member of the public would like to dispute the RIA assessment then they must submit a petition to the State Commission.

### 3.2.5. RIA PROCESS in MOLDOVA

RIA Stages



## **Chapter IV. Completing the Regulatory Impact Assessment**

### **3.3 What is the aim of the proposal and setting the objective**

It is important to be clear about what the proposal is trying to actually do, before deciding how do it and how it will be implemented – what is its' purpose? It is critical to have the aim clearly defined before embarking on the rest of the RIA. If the aim is incorrect then the analysis of proposals will be difficult to complete and ultimately the intervention will not have the desired outcome and could have unintended consequences. Sometimes it is easier to go to section 4.2 to define the problem and then return to this section.

The aim of the proposal can be broad and strategic with more detailed objectives underneath it. It should state what the desired outcome is and should not presuppose the intervention. For instance:

- ✓ Aim: Reduce labour exploitation in the textile industry.
- × Aim: Ban exploitation of labour in the textile industry.

Objectives will not be relevant for all proposed aims, however they are more likely to be necessary for complex proposals with many intended outcomes. Objectives should be specific, measurable, achievable, realistic and time-related i.e. SMART. For example:

- ✓ Objective: Decrease pollution of chemical disposals by 15% by the year 2015.
- × Objective: Significantly reduce chemical pollution.

Questions to answer in the RIA template:

<b>Aim/Objective</b>	<i>TIP – You may wish to do Section 3.0 first and then return here.</i>
Define the desired outcome of the proposed intervention.	What is the aim of the intervention? If applicable, what are the broad strategic aims? What is the purpose of the intervention?

### **3.4 Being clear about the rationale for government intervention**

There must be a good understanding of the reason for intervention before examining how to intervene. The RIA must give an explanation of why the current situation is unsatisfactory supported by evidence. It should make a convincing case for the need for action. This explanation should be objective and should also declare any representations for action by stakeholders with vested interests. This will demonstrate clearly what problem exists that any intervention is addressing.

When defining the problem it is important to not confuse the problem with the symptoms of the problem. Confusing the two can result in the wrong course of action or inappropriate action that could result in the situation becoming much worse.

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|---|
| <ul style="list-style-type: none"><li>✓ Problem: A reliable survey has shown that the lack of awareness and information about an existing law is resulting in low compliance of the law – this may result in an education campaign.</li><li>× Problem (Symptom): It is known that there is low compliance of a law by the public – this may result in a costly penalty regime with large enforcement costs.</li></ul> |
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The magnitude and scale of the problem should be detailed and why the problem has risen now. This will help complete a *Risk Assessment* of the current situation – how serious is the problem that is being addressed? This will include the probability of the risk occurring, the frequency it may occur in a given period, the potential effect it will have and hence the need for intervention.

- |   |
|---|
| <ul style="list-style-type: none"><li>✓ Risk Assessment: Every year there are 200 deaths and 1000 serious injuries in the work place. As well as the tragic loss incurred by families and relatives, this is estimated to cost business \$20m p.a. in insurance premium increases, loss in productivity and staff recruitment and retention. Two years ago there were 20 deaths and 200 serious injuries. This represents a 900% increase in deaths and 400% increase in serious injuries over two years.</li><li>× Risk Assessment: There is a possibility that people may incur a serious injury and in some cases loss of life in the work place. There have been some reports of deaths increasing and businesses have also given feedback that this has had a negative impact on their fixed costs, such as insurance premiums, and productivity due to the disruption of their workforce.</li></ul> |
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Relevant background information must be included to explain the context for government intervention. The context should include the existing regulatory landscape and assess interventions that already exist as well as other interventions that have an impact on the problem that is being addressed. Any opportunities to simplify existing interventions and requirements should be identified here to assist in the overall burden of government interventions on business, groups and sectors.

- |   |
|---|
| <ul style="list-style-type: none"><li>✓ Regulatory Landscape: Recognise a new registration form that is being introduced and that could be used for your aim, instead of devising a new registration/compliance scheme.</li><li>× Regulatory Landscape: Not being aware of an existing measure that already impacts in a similar way on the group that you are aiming to influence, and therefore creating duplication and unnecessary burdens. For instance implementing another registration form for businesses.</li></ul> |
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Questions to answer in the RIA template:

<b>Rationale for Intervention</b>	
Include brief and relevant information about the background for the origination of the proposal.	What is the history to this proposal? What is the context for which this proposal is required? Are there any wider issues to be aware of?
Give an explanation of what the issue is that is being addressed and the need for the government action.	Why is government intervention required? What is the problem being addressed? What is the magnitude of the problem? Differentiate between the problem and symptoms. Is government intervention necessary?
State the regulatory environment that this new proposal is being introduced into.	What norms exist that have a bearing on the problem being addressed? Why is more intervention required? What are the over-laps between the proposed intervention and the impact of existing norms? Can existing norms be abolished as a result of the proposed action?

### 3.5 Possible options

If the problem has been accurately and clearly defined, and the goals are clear, it will be easier to think effectively about possible options. How government is going to intervene is just as important as knowing if government should intervene. A solution is often to introduce legislation but this may not be the best option and alternatives must be considered when brainstorming and developing possible options.

Here are some options to consider:

<p><b>A. Do Nothing</b></p> <ul style="list-style-type: none"> <li>☞ Should government intervene or is some other body or mechanism better placed to address the problem e.g. market forces?</li> <li>☞ Will intervention make things worse?</li> <li>☞ Is the problem temporary and could it go away naturally?</li> <li>☞ Will intervention transfer the problem somewhere else?</li> </ul> <p><b>B. Review Existing Interventions</b></p> <ul style="list-style-type: none"> <li>☞ Is the problem due to existing interventions?</li> <li>☞ If so what has gone wrong with the existing intervention e.g. scope of legislation or implementation of policy?</li> <li>☞ Consider if this can be resolved by:               <ul style="list-style-type: none"> <li>? Simplifying the intervention</li> <li>? Targeting the intervention to certain areas</li> <li>? Improving enforcement procedures</li> </ul> </li> </ul>
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- ? Improving the awareness of the intervention amongst stakeholders
- ? Abolishing the current intervention

### **C. Self-Regulation**

- 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

### **D. Voluntary Guidelines and Codes of Practice**

- 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?
- Can all stakeholders easily participate in the voluntary scheme?

### **E. Information and Education schemes**

- Should the public be allowed to exercise its own judgment?
- *Therefore* is government's role to assist the public in making an informed decision?

### **F. Economic Incentives**

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

### **G. Risk-Based Insurance or Risk Pricing**

- Can insurance markets be used to change behaviour by making stakeholders insure themselves against risks?

### **H. Sun-setting**

- 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'?

*NB – Sun-setting is sometimes a useful way of minimising regulatory requirements by including a clause that will terminate the proposal after a set period of time, unless some specific action is taken to keep it in place.*

These are some alternatives to consider and all possible solutions to addressing the core problem should be considered when brainstorming. These can then be fine tuned into possible options as the proposal develops.

Question to answer in the RIA template:

Possible Options	
Describe the options being considered including the 'Do Nothing' option as the baseline for comparison.	<p>Have all the possible alternatives been considered?</p> <p>Have self-regulatory or voluntary-regulatory options been considered as well legislative regulatory options?</p>

### 3.6 Assessing the options – analysis of impacts

The possible options need to be analyzed by comparing the impacts of each course of action. The baseline for these impacts is the “Do Nothing” option, where the impacts of the status quo can be used in the comparison of options.

Before beginning to conduct the full assessment, it is important to have a measure of the scale of the proposal and significance of the problem. The assessment within the RIA should be proportionate to the significance of the proposals and their impacts. i.e. a proposal with a small impact will not have an extensively researched analysis of the impacts. However a significant proposal will have a detailed assessment of the impacts.

Reliable evidence is required to conduct the analysis of the proposals. This evidence can be obtained through various methods – from research paper studies to conducting surveys. A key form of evidence gathering is through consultation. It is difficult to conduct a fully comprehensive consultation with all stakeholders and interested parties if the consultation only occurs once. The RIA should be used to conduct consultations, informal and formal, throughout the policy making process (see section 4.5).

At the *Preliminary RIA (Analysis)* stage there will have been a significant amount of analysis and consultation, including a 30 day public consultation, which can give confidence to the reliability and analysis of the evidence and impacts of the proposals. The analysis and consultation will be proportionate to the impacts of the proposals. The level of depth and detail should continue to be worked on until the Ministry is satisfied that the scale and magnitude of the impacts is known.

Based on this information the *Preliminary RIA (Analysis)* will undergo the set of questions in the *Threshold Criteria*. The *Threshold Criteria* defines whether the proposals within the RIA are significant. The RIA will continue to be developed until the RIA Secretariat can agree with the robustness of the assessment within the *Preliminary RIA (Analysis)* and can agree with the answers to the *Threshold Criteria* questions i.e. whether the proposals are significant.

The *Threshold Criteria* questions are:

- Will the proposed annual cost on business exceed X lei?
- Will the regulatory act have a disproportionate direct or cumulative impact on a particular sector or group?
- Will the regulatory act cost X lei to public services staff?
- Is the regulatory act politically sensitive?

If the assessment in the *Preliminary RIA (Analysis)* shows that the proposal will be significant by answering “yes” to any of the questions in the *Threshold Criteria*, then the RIA will require further analysis and will need to be developed into a *Final RIA (Analysis)*. The *Final RIA (Analysis)* will require greater consultation including another full 30 day public consultation and more detailed analysis of the impacts of the proposals. Only significant proposals will require this level of detail and work.

Some analysis will require input from experts such as economists and lawyers, especially when developing the *Preliminary RIA (Analysis)* for the first time and when conducting in-depth analysis for the *Final RIA (Analysis)*. The analysis should focus on quantitative impacts of each option. Qualitative assessment should only be included where quantification cannot happen – however technical methods for quantifying the most difficult impacts may exist and you will require help from specialists to analyse these.

It is often more difficult to assess the benefits of the proposals rather than the costs. However it is important to assess both adequately in order to find out the net benefit of the proposals – if the costs outweigh the benefits then why is government intervening in the proposed way?

Questions to be answered in the RIA template:

<b>Assessing the Options – Impact Analysis</b>	<i>This section will analyse the impact of each option. Below is an indication of some of the questions that should be answered 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	What are the wider consequences, positive

option.	<p>or negative, of the options?</p> <p>Does the option contribute to a cumulative impact on a group?</p> <p>Are there any unintended consequences that stakeholders have identified?</p>
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.	<p>What are the risks of failure?</p> <p>What contingency plans are there to combat these risks of failure?</p> <p>What are the risks of the proposed action for particular groups, especially vulnerable groups, which could impact on the successful delivery of the proposal?</p> <p>What measures are there to minimize these risks?</p> <p>What are the resource implications of these measures? And if necessary have these resources been agreed?</p>
State the organizations such as public bodies that will be affected by the proposals.	<p>Which institutions will be affected?</p> <p>How will they be affected?</p> <p>For instance, will coordination and consultation be required with local public authorities?</p>
For each option include a cost benefit analysis of the impacts. This should be quantitative but can have some qualitative assessment too.	<p>What are the benefits and costs of each option?</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>

### 3.7 Engaging with stakeholders

Cu excepția anumitor circumstanțe, scopul intervențiilor guvernamentale este de a avea un impact pozitiv asupra factorilor de decizie sau cel puțin de a minimaliza greutățile. Totuși în pofida bunei credințe și a planificării guvernul poate avea un impact asupra factorilor de decizie pe care nu l-a prevăzut. Consultarea factorilor de decizie începând cu prima etapă a elaborării propunerii poate contribui la diminuarea acestui risc – riscul de eșuare și impacturi și sarcini de prisos.

The successful delivery of proposals relies on effective consultation and partnership with key stakeholders. For instance businesses are more likely to be receptive to a new proposal that they have had an input in and helped to shape, rather than one that is imposed on them with no consultation. Stakeholders are those inside of government as

well as those outside and it is important to include them in consultation strategies otherwise there could be duplication or contradictory actions coming from government. Conduct a stakeholder analysis and map out who your stakeholders are and how important they are to the success of your proposal.

The RIA process not only gives this opportunity to develop effective relationships with stakeholders, but it is also a useful communication tool that can improve public perception through its *transparency*. It clearly shows the objective analysis of a problem and the proposed solutions which can help give confidence to the public and stakeholders.

The formal public consultation will be for a minimum period of 30 days via the *Screening RIA* which must be published on the Ministry website. The *Screening RIA* will also be publicly published while it is being developed and before it has been processed through the *Threshold Criteria*. After the *Threshold Criteria* the *Full RIA* will be publicly consulted on for a further 30 days and will be made available. The *Full RIA* will involve more targeted consultation following the previous consultations and the focus that will have been identified by the assessment in the *Screening RIA*. However there are a range of consultation exercises that the Ministry should employ including informal meetings, workshops, pilots and surveys.

Questions to be answered in the RIA template:

<b>Engaging with stakeholders</b>	
Include a summary of the consultation process and responses.	Who has been consulted? Who will be consulted? What has been the feedback? (Give a summary of responses) Are there any plans for future consultations? If so what are they?

### 3.8 Implementation and Sanctions

An important part of analyzing the options is how the options will actually be implemented and what the proposed sanctions will be to encourage compliance. Failure to plan ahead for implementation is one of the main reasons for the unsuccessful delivery of regulatory acts. Communicating these plans and obtaining feedback from stakeholders and those whose duty it is to implement and enforce the regulatory act is vital.

All enforcement mechanisms should be considered and that includes self-enforcement, for instance empowering the public to enforce a ban on smoking cigarettes instead of employing enforcement officers with penalties and charges that could take up valuable time of courts and the legal system. There can also be a phased enforcement procedure to encourage behavioral change. Will a ban on smoking be accompanied by an awareness raising campaign and a period of time when it will not be enforced while the public are educated about their rights? This may help with the implementation and avoid genuinely

innocent and potentially large numbers of the public and businesses falling on the wrong side of the law unnecessarily. It can also give business the time to adjust and pilot ways of introducing the new law in a protected environment for a limited period of time.

Enforcement bodies must also be encouraged to raise their standards of performance. For instance, by publishing clear standards or charters for delivery that the public can be made aware of and can expect a certain level of performance

All of these considerations can help with the ensuring successful implementation of proposals, efficient and targeted enforcement procedures and avoid any unintended consequences.

Questions to be answered in the RIA template:

<b>Implementation, Enforcement and Sanctions</b>	
Give a detailed explanation of the implementation plans for each option.	What will be the process of implementing the options? Who will be tasked with implementing the option? How will they do this? What are the costs for implementing the option? What is the level of compliance that is being aimed for?
Explain the enforcement mechanism that will be used for each option.	Who will enforce the option? How much will it cost to enforce? What is the institutional capacity required to conduct the enforcement activity? Where does the proposed enforcement procedure fit in with other enforcement procedures that are conducted by the same body? What other enforcement processes impact upon the same groups that are being impacted upon by the proposed option? Is there any duplication of effort in enforcement processes? Are there any unnecessary burdens that could be simplified?
Describe the proposed sanctions for each option.	What will be the sanction for not complying? How realistic are the sanctions? Are they for deterrent purposes? Are they for enforcing punishment? Are there any unintended consequences of the sanctions? Will there be a 'lead in time' or 'period of grace' before the sanctions will be enforced?

### 3.9 Monitoring and evaluating success of delivery

Once the new proposal has been introduced it is important to evaluate it to see if it is having its' intended impact and addressing the issue it was brought in for. This review will be considered and planned before the proposal is introduced. By thinking about how the proposal will be evaluated can help to set up any monitoring procedures that will require the collection of reliable data and evidence e.g. compliance figures and stakeholder surveys.

The appropriate procedures for monitoring must also be considered such as reporting by or to a public body or commission or to parliament. The detail of when the first monitoring exercise will take place and how frequently reviews will be conducted should also be included.

A way of ensuring that a proposal is reviewed and kept up-to-date is by including a **Sun-setting clause** within the proposed legislation or regulation. This provides an automatic mechanism for getting rid of proposals and laws that are no longer required after a fixed amount of time, unless specific action is taken to keep them. This can be appropriate for those measures that are:

- In response to a short-term issue.
- Necessary for emergency action or crisis.
- Where there are significant uncertainties within the proposal e.g. scientific unknowns.
- If the problem is likely to change e.g. due to technological advancement.

Re-introducing regulations can take up time and therefore where sun-setting is not appropriate a robust monitoring process should be set in place.

Questions to be answered in the RIA template:

<b>Monitoring and Evaluation</b>	
State the processes for ensuring successful delivery and implementation of the proposed options.	Who will conduct the monitoring and evaluation? Who will be accountable for the success of delivery/implementation? To whom will they be accountable? When will it happen? How frequently? What will happen as a result of the monitoring/evaluation? Can a Sun-setting clause be introduced?
Give the methodology for measuring the success of the proposed course of action.	Here are some questions that the monitoring process should consider:  What were the aims/objectives of the proposed



	<p>regulation?</p> <p>Is the problem still the same? Is there a new issue?</p> <p>Has the proposed action addressed the issue and met its aim/objectives?</p> <p>Are changes to the regulation required?</p> <p>Has the regulation had any unintended consequences?</p> <p>Has the regulation disproportionately impacted on any group/sector?</p> <p>Has the scope of the regulation been too broad? Or has it been too narrow?</p> <p>Has the enforcement process been effective, efficient and consistent?</p> <p>What does it cost to enforce the regulation?</p> <p>What does it cost to comply with regulation?</p> <p>Do the benefits outweigh the costs?</p>
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### 3.10 Summary and recommendation

The final decision of what course of action will be taken should be clearly stated in the final published *Full RIA*. This can also be completed at the *Screening RIA* stage to help with the consultation exercise. This will be in the form of a clear and concise explanation of the impacts of each option and the reason for adopting the proposed course of action. A summary table of the impacts of the options should be used in the RIA. Here is an example of a summary table:

	Option 1 – Do Nothing	Option 2	Option 3	Option 4
Costs				
Benefits				
Other considerations				
Overall Impact				

A short explanation of the why the proposed action will be implemented must be given based on the information in the summary table. The Ministry must also agree a ‘Sun Set’ date for the RIA with the RIA Secretariat and publish this in this section of the RIA (see 3.2.4).

Finally the Minister responsible for the proposal must sign the following declaration to complete the final published RIA:

<p><b>I agree with the Regulatory Impact Assessment</b></p> <p><b>Signed</b> .....</p> <p><b>Date</b> .....</p>
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When the RIA has been completed, it must be published.

To be answered in the RIA:

<b>Summary and Recommendation</b>	
<p>Include a table that summarizes the positive and negative impacts of each option.</p>	<p>Answer the following for each option in the Summary Table:</p> <p>What is the option?                      What are the costs of the option?                      What are the benefits of the option?                      Are there any other considerations to note?                      What is the overall impact of the option?</p>
<p>Give an explanation of the chosen recommended option based on the summary table and analysis in the RIA.</p>	<p>Why has the recommended option been chosen in comparison to the other options?                      What were the key determining reasons for this choice?</p>
<p>Agree and publish with the RIA Secretariat a “Sun Set” date for the RIA.</p>	<p>When will the RIA be reviewed after it has been implemented?</p>
<p>The Minister with responsibility for the proposal must sign the declaration of the RIA.</p>	<p>Has the Head of the authority seen and read the RIA?                      Does the Head of the authority agree that they are satisfied with the analysis in the RIA?                      Does the Head of the authority agree with the recommended course of action?</p>