

**Regulatory Impact Assessment Methodology** 

Skopje, July 2013

Following on from article 20, paragraph 5 of the Procedural manual of the Government of the Republic of Macedonia ("Official Gazette of the Republic of Macedonia" issues 38/01, 98/02, 9/03, 47/03, 64/03, 67/03, 51/06, 5/07, 15/07, 26/07, 30/07, 58/07, 105/07, 116/07, 129/07, 157/07, 29/08, 51/08, 86/08, 114/08, 42/09, 62/09, 141/09, 162/09, 40/10, 83/10, 166/10, 172/10, 95/11, 151/11, 170/11 и 67/13), the Government of the Republic of Macedonia on its session held on \_\_\_\_\_, has adopted the following

#### REGULATORY IMPACT ASSESSMENT METHODOLOGY

#### 1. Introduction

The regulatory impact assessment methodology (furtherin referred to as RIA) has been fully harmonised to the existing ministerial system for strategic planning and to the procedures for policy coordination and decision- making of the Government of the Republic of Macedonia thus representing an improvement to the existing practices adopted in 2009, as well as harmonisation with the positive practices in the EU and the OECD member-countries.

The strategic priority of the Government of the Republic of Macedonia is to further economic growth and employment with economic reform programs aimed at improving the business climate and strengthening the national and international competitiveness of Macedonian economy. For this purpose, the Government of the Republic of Macedonia has been implementing a series of measures focused on decreasing administrative burdens and on procedural simplification, as well as on improving regulatory quality. Those measures have been particularly focused on the small and medium size enterprises because they represent the drivers of economic development in the Republic of Macedonia. Measures aimed at decreasing administrative burdens through improving the quality of regulation, will contribute to their competitiveness. The RIA process directly contributes to the realization of the aims of such measures and policies.

The commitment by the Macedonian Government in improving the regulatory quality has been confirmed by the Public Administration Reform Strategy and by the Action Plan that stipulate measure and activities aimed at improving the regulatory quality under the RIA. Under this process, the Government of the Republic of Macedonia and its Ministries ensure compliance to the basic principles of good governance, such as:

- *Transparency and openness* through communication and involvement of parties concerned in the entire process, from concept-building, regulation, all through to implementation of policies and legislation;
- Effectiveness and efficacy achievement of desired purpose through comprehensive analysis
  and assessment of impact by the potential problem-solving methods, and seeking solutions
  that would accomplish the purpose with least cost on budgets, organizations and on the
  citizens;
- Harmonisation ensuring synchronised regulatory framework in the relevant and affiliated areas, as well as harmonisation with EU legislation;
- Accountability the transparency and assessment of effectiveness of the implemented and adopted policies and legislation, contribute to the overall rise in accountability of the work carried out by the Government of the Republic of Macedonia.

The RIA process is especially important in the context of Macedonia's priority for accession to the EU and the NATO. In the pre-accession period, the process of harmonisation of Macedonia's legislation to the one of the EU and the NATO member-countries, assumed an analysis of the EU legal acts and their appropriate transposition to the national legislation. RIA has been used as a tool that measured the impact caused by the implementation of the transposed legal acts. With the start of Macedonia's accession negotiations with the EU, the RIA process will gain further momentum as it ensures a structured definition of the short-term and long-term impact by the EU legislation on the national legal system and the obligations arising thereof. This supports the creation of national positions on the negotiation process as well as the identification and appropriate reduction of eventual negative impact on the Republic of Macedonia.

#### 1.1. The purpose of the Regulatory Impact Assessment methodology

The purpose of this methodology is to lay down:

- The implementation process of the RIA and the expected results thereof;
- The process of involvement of parties concerned;
- The organisation and the management of the RIA process, and
- The roles and responsibilities of all participants in the process.

The application of this methodology has been supported by the IT system especially by the especially of the Government of the Republic of Macedonia and by the Single National Electronic Register of Regulations (furtherin referred to as the SNERR).

#### 1.2. The Scope of the Methodology

As per the Rules of procedure of the Government of the Republic of Macedonia, the RIA has been implemented on proposals to pass law submitted to the Government of the Republic of Macedonia, for perusal and for adoption. Exception to this is the legislation adopted under a priority procedure, namely the legislation on ratification of international agreements, the laws harmonising the terminology across legislation, the proposed budget of Government of the Republic of Macedonia, and the law on adoption of the Budget of Government of the Republic of Macedonia.

## 2. The RIA Implementation Process

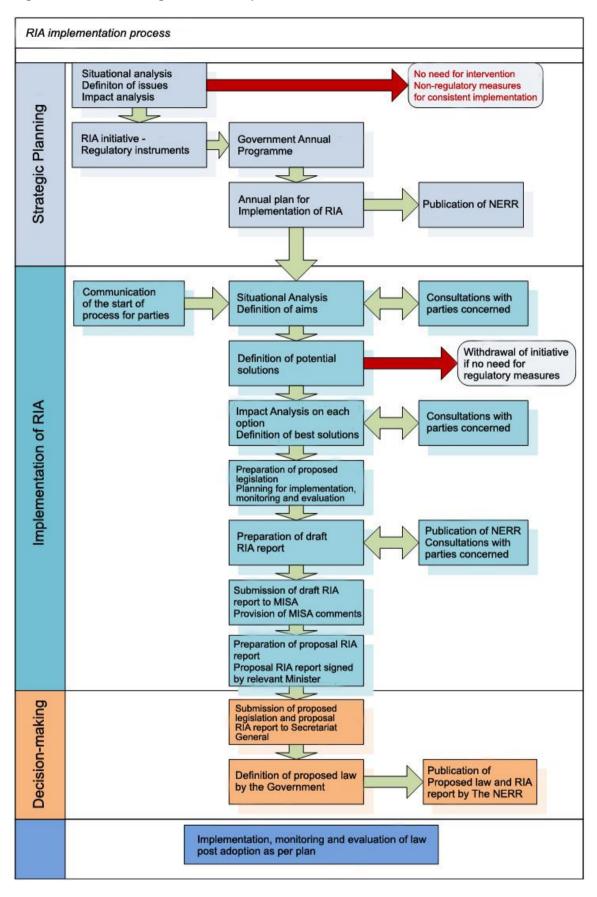
The underlying principle of the RIA is to ensure gathering of relevant and accurate information on the positive and negative impact from the potential methods of problem-solving, and on the proposed methods of achieving the purpose of the proposal to pass the law. Quality implementation of the RIA contributes to effective and efficient implementation of laws, thus ensuring implementation of Government policies.

The regulations guarantee the basic principles of the democratic society, the respect of basic freedoms and rights, at the same time ensuring implementation of reforms in societies. Nonetheless, regulations are not always the only way of achieving desired results. In certain circumstances, other measures would be more appropriate in ensuring results, such as information campaigns and trainings, self-regulation of certain areas and other measures known as non-regulatory measures. The RIA process provides a realistic view on the need for regulatory and non-regulatory solutions of problems.

The RIA process ensures involvement of all parties concerned and the relevant information they possess can make a significant contribution to improving the quality of regulations. The involvement of all parties concerned ensures the possibility of an enhanced implementation and observance of regulations, whereas the publication of RIA results contributes to the transparency of both the regulatory process and the work by the Government of the Republic of Macedonia.

The RIA represents a component of the process of planning, preparation, monitoring and the evaluation of policies and regulations in ministries. The RIA process starts at the strategic planning phase and is implemented before the preparation of proposed regulations. A figure below gives a schematic outline of the RIA process.

Figure 1. Outline of stages of the RIA process



#### 2.1 Planning of the RIA implementation process

The planning process is done within the strategic planning process performed by Ministries. As per the Methodology for Strategic Planning and as per preparations of the Annual Plan of the Government of the Republic of Macedonia, the Ministries shall plan their annual programs having in mind Government's strategic priorities, the situational analysis of the sectors they govern and the results thereof, the obligations arising from strategic documents (The National Development Plan, the Stabilisation and Association Pact, the Accession Partnership, the National Programme on Adoption of the EU legislation, and other documents), as well as the priorities and aims of the relevant Ministry.

Based on those analyses, Ministries shall determine possible solutions to problems or situations detected during the situational analysis of areas governed by Ministries. In this phase, Ministries shall discuss the ways of implementing possible solutions and shall make decisions on whether there is a need to produce new regulation or whether to amend existing ones.

If the area already governed by an existing law or a regulation or the existing solutions, do not produce desired results, Ministries shall then peruse options for introducing non-regulatory measures rather than amending or adopting new regulation.

If a decision is made that the most appropriate option for solving the problem would be to adopt new regulation or to amend an existing one, such initiative would be embedded in the proposal on the Annual Programme of the Government of the Republic of Macedonia. Each initiative taken forward would result in Ministries planning appropriate financial and human resources necessary for implementing the regulation.

When defining such initiatives, Ministries shall provisionally determine the level of potential impact by the suggested regulation, and shall determine the parties concerned as well as the data necessary for completion of required analyses and the resources necessary to implement the RIA process.

The planning of RIA implementation is based on the principle of proportionality, i.e. the larger the expected impact on the proposed regulation – the more detailed and comprehensive RIA needs to be undertaken for the respective proposed regulation.

Based on the above activities, Ministries shall prepare an Annual plan for RIA implementation which shall be done in parallel to preparations for initiatives related to the draft Annual plan of the Government of the Republic of Macedonia. The annual plan for RIA implementation shall give an outline of activities necessary, the dynamics in RIA implementation as well as the preparations of the proposed legislation, and an overview of parties concerned and involved in the process. The annual RIA plan shall also provide timely information to the parties concerned on their appropriate involvement in the process. The annual plan for implementation of the RIA shall contain information on:

- The title of proposed legislation:
- Brief summary on the issue;
- The purpose of proposed legislation;
- The month of submission of proposed legislation to the Government of the Republic of Macedonia (as per the Annual Programme of the Government);
- The timeframe for RIA implementation and for the preparation of the proposed legislation:
- Necessary human and financial resources for implementation of the RIA;
- Parties concerned and involved in the process:
- Ways of involvement of parties concerned, and
- The timeframe for implementation of consultations.

The Ministry shall publishe the *Annual Plan for Implementation of RIA* on the SNERR on the 15<sup>th</sup> day from the day of adoption of the Annual Programme by the Government.

Ministries shall follow the Annual plan for Implementation of RIA and update it depending on the updates on the Annual Programme of the Government of the Republic of Macedonia. Updated versions of the Annual Plan for Implementation of the RIA shall be published on the SNERR on the 15<sup>th</sup> day latest from the day of adoption of the updated version of the Annual Programme by the Government of the Republic of Macedonia.

#### 2.2. Implementation of the RIA

For the purposes of ensuring timely implementation of the RIA process on each proposed legislation embedded in the Annual Plan for the Implementation of RIA, ministries shall prepare an activity plan with the relevant dynamics.

In order to ensure timely dissemination of information to parties concerned, ministries shall publish, up to 5 days prior to the start of the RIA process, a notice on the start of the process and the preparations for the proposed law. The notice shall be published on the Ministry web-site and on the SNERR web-site, and shall contain the following information:

- Title of ministry;
- Title of the proposed law:
- Brief description of the issue;
- Purpose of proposed law;
- Timeframe for completion of the proposed law;
- Mechanisms for ensuring involvement of parties concerned;
- An announcement for a public review and a public debate that would take place;
- E-addresses of the SNERR and the web-site of the ministry wherefrom parties concerned could download an electronic version of the proposed law and the draft RIA report:
- Postal and/or email address for comments and suggestions by the parties concerned;
- Contact person at the ministry, and
- Other information beneficial for the effective participation of the parties concerned in the preparation process of the proposed legislation.

On the side of Ministries, the following steps shall be taken in the course of the RIA process:

#### 2.2.1 Situational analysis, definition of issues and goals

Based on findings from the situational analysis within the strategic planning process, ministries shall perform a detailed situational analysis in order to define the essence, the nature and the range of issues. This analysis shall determine the reasons contributing to the existence of the issue, the current regulations affecting the issue and the linkages to international agreements ratified in accordance to the Constitution of the Republic of Macedonia. The analysis shall be done based on the data collated or based on reports by the ministry or by other state body, or based on data obtained from local municipalities, statistical data or via contacts and consultations with parties concerned, the overall aim being to determine available evidence supporting the defined issue.

Based on the situational analysis, the goals or the effects of implementation of the proposed legislation shall be laid down. The goals shall be realistic and linked to Government policies and priorities, and also laid down clearly and measurably. Such defined goals represent the foundation for future analyses to be used in determining possible solutions and measures for their achievement.

#### 2.2.2. Definition of possible solutions (options)

Once the goals and the effects of the proposed laws are laid downs, ministries shall determine possible solutions (options) and instruments that would contribute to realization of such goals. During the definition of possible solutions, any potential opportunities shall be perused for introducing additional or non-regulatory measures (instruments) that would contribute to an efficient implementation of the proposed legislation and to an appropriate achievement of defined goals.

Ministries shall proscribe at least three possible solutions (options), one of them being 'do nothing'. When the proposed regulation aims to solve more serious problems, or when major changes are being introduced in a particular area, or when changes span across several areas, in such cases several possible solutions (options) need to be perused with a combination of regulatory and non-regulatory measures (instruments).

The starting point in defining possible solutions (options) shall be the "do nothing" option. The analysis of this option aims at showing how existing regulation would develop should the Government

of the Republic of Macedonia not adopt an appropriate regulation or should it not introduce other measures. This measure shall ensure the basis for comparison with other possible solutions (options).

In cases when the analysis of the "do nothing" option concludes that a previously defined issue could be resolved by a consistent implementation of existing regulations or by introduction of non-regulatory measures, ministries shall then prepare a notice of withdrawal of the respective initiative from the Annual programme of the Government of the Republic of Macedonia and shall duly explain the reasons behind withdrawal while proposing another set of measures necessary to achieve desired goals.

## 2.2.3. Analysis of costs, impact and benefits from defined possible solutions (options) and their comparison

In analyzing the defined possible solutions (options), several methods and analytical tools shall be used, such as the cost and benefit analysis, the cost and efficacy analysis, the multi-criteria analysis, risk analysis, the standard costing model, and other relevant analyses. The defined possible solutions should be analyzed by using the same methods and analytical tools, for reasons of comparison.

The purpose of such analyses shall be to obtain a clear picture of costs, positive and negative impact and the benefits arising from each individual potential solution thus determine the option that would produce desired goals with minimum cost (on the budget, organizations and on citizens) as well as clarify unwanted effects.

Each of these potential solutions could cause different type and level of costs and effects that shall then be defined as precisely as possible. The analysis shall define:

- Costs/benefits on the budget;
- Costs on organizations, especially SMEs, other groups and citizens (depending on whom the proposed legislation refers to);
- Impact on the economy, the social life, the environment, the public health and other types
  of impact in respective areas;
- Costs and resources needed to implement, monitor, evaluate and control each potential solution;
- Acceptance/resistance during implementation, and
- The negative or undesired effects and impact.

Based on the comparison of defined potential solutions (options), ministries shall put forward solutions that most effectively contribute to achieving the goals of the proposed legislation, and produce benefits with minimum cost and unwanted effects. Based on the proposed solution, the text of the proposed legislation shall be prepared.

## 2.2.4. Planning the methods of implementation, monitoring and evaluation

After completion of the analysis of options, the consultations held with parties concerned as per paragraph 4 of this methodology and after the preparation of proposed legislation, the ministries shall initially analyze all aspects relating to implementation of the proposed potential solution.

The aim is to produce a general overview on mechanisms and activities for implementation, monitoring and evaluation of the proposed solution (option) and on the proposed legislation, thereunder provisionally determining the following:

- Theses of bylaws to be adopted (if necessary) in order to implement the proposed legislation:
- Budget required to implement the law (provision of additional human resources, equipment, facilities, etc if needed);
- National governance bodies with responsibility for, or included in, the implementation;
- Activities to be undertaken by each national body in building capacity for implementation of the proposed legislation (education and training, workshops and seminars, guidelines etc.);
- Monitoring methods and indicators measuring the degree of implementation of measures suggested by the proposed legislation and the achievement of defined goals;
- Mechanisms and provisional deadlines for the evaluation of legislation.

Upon adoption of the law by the Parliament of the Republic of Macedonia, ministries shall prepare a detailed plan on its implementation, monitoring and evaluation.

## 3. Preparation of the RIA report

#### 3.1. Purpose and content of the RIA report

Based on analyses completed during the RIA process, the ministries shall prepare a draft RIA report (furtherin referred to as the Report), which outlines the process and the results of the RIA implementation, for the purposes of getting an accurate and relevant data on possible positive and negative impact, available during the discussions on the draft law and the conclusions drawn thereof. The report helps ministries prepare the Memorandum and the materials supporting the proposed legislation, and to be submitted to the Parliament of the Republic of Macedonia, in line with the Rules of procedure of the Government of the Republic of Macedonia.

The report shall be prepared in accordance with the Decision on the format and content of the RIA Report. The draft report shall include ministerial overviews on the entire RIA process, and shall detail the results of the situational analysis completed on a comprehensive level in the area(s) in question, the potential solutions (options) of issues and the achievement of goals, as well as an analysis of positive and negative impact on economic, financial, social levels, the impact on the environment, and other impact depending on the area regulated by the proposed legislation.

The draft report shall outline the consultation process and shall state the parties concerned and involved in the process, as well as the method of their involvement, the views recorded during the public hearing, the suggestions and comments received in writing or published on the SNERR and on the E-democracy portals. The draft report shall enlist opinions, comments and suggestions that would have been embedded in the proposed legislation, as well as those that had not been accepted by the ministries with respective reasons for the decline.

The draft report shall also contain a description of the proposed solution enabling achievement of aims under the proposed legislation, as well as the methods of implementation of the proposed solution, including the monitoring and evaluation of the proposed legislation.

The style of the draft report shall be concise and clear, avoiding complex terminology in order to achieve clarity on the entire analytical process of RIA implementation.

## 3.2. The position of the Ministry of Information Society and Administration and the publication of the publication of the RIA Report

In order to obtain the views, suggestions and positions from all parties concerned, ministries shall publish the draft report and the draft text of the proposed legislation on the SNERR, within 10 days prior to the submission of the report to the MISA.

If the report contains classified information under the regulations stipulating classification of information, ministries shall comply with those regulations and shall not publish the report on the SNERR. The covering page of the report shall display a mark signifying that the report contains classified information.

After relevant commentaries are embedded by the parties concerned, the draft RIA report as signed by the state secretary of the relevant ministry, shall be submitted to the Ministry of Information Society and Administration for their review. This ministry shall then prepare their view within maximum 10 days from receipt of the draft RIA report from the issuing ministry.

Upon receipt of the view by the Ministry of Information Society and Administration, the reporting ministry shall prepare a proposal report signed by the respective minister thus guaranteeing the accuracy and the quality of the implemented RIA. Together with the proposed legislation, the ministry shall submit the proposal RIA report and other papers to the General Secretariat of the Government of the Republic of Macedonia.

After confirmation on the proposed legislation by the Government of the Republic of Macedonia, and upon the receipt of excerpts from the minutes of the Government's meeting, the ministries shall then publicise the RIA Report and the proposed legislation, on the SNERR.

#### 4. Consultations with the parties concerned

## 4.1. The purpose of consultations

Consultations with all parties involved are a constituent part of the RIA process and an important mechanism for improvement of efficacy and effectiveness of implemented measures proposed. The consultations contribute to increased transparency of the Government's work and the decision-making process, thus strengthening the principle mechanisms of democracy.

Ministries shall ensure involvement of parties concerned throughout the RIA process, and specifically:

- In the phase involving the situational analysis, the definition of the issue and the need for introducing new regulation, consultations represent a useful method of collating information on existing problems or sharing experiences from implementation of existing regulations;
- In the phase involving the definition of possible solutions (options) and their comparison, consultations should take place after the relevant ministry has laid down and posed the principles of possible solutions (option). The topic of consultations shall be the options, their application, cost effectiveness and potential effects;
- In the phase involving assessment of potential impact by proposed solutions (options), the purpose of consultations shall be to assess the accuracy of assumptions related to the possible impact, the risks, the benefits and the associated effects.

There are two groups of parties concerned: "internal" parties concerned involving the ministries and other statutory bodies, governing institutions and other state bodies that may have shared responsibility or interest in the proposed regulation, and "external" parties involving the businesses, syndicates, NGOs, associations and foundations, civic groups as well as citizens concerned directly by the proposed regulation. Depending on the type of group involved in the consultation and depending on the stage of the RIA process, various methods of involvement and collation of views and suggestions by parties concerned shall be applied.

#### 4.2. Methods of consultation with parties concerned

Ministries shall plan the involvement of parties concerned in as early as the phase of strategic planning and preparation of initiatives for the Annual Programme of the Government, and in completion of the RIA implementation plan.

In the course of the RIA process, ministries shall collate views from respective parties concerned in a timely manner, especially the views relating to the possible solutions (options) to resolve issues and the potential impact, costs and benefits from each potential solution.

In selection of the optimal solution, ministries shall consider the views of parties concerned. An overview of the entire consultation process with the parties concerned and results thereof shall be provided in the relevant chapters of the RIA report.

The figure below depicts the deadlines in the process of RIA implementation.

**PLANNING** Strategic **Planning** 15 days upon Government Annual Programme for Publication endorsement of the Annual Programme Implementation of RIA Govt Annual programme **IMPLEMENTATION OF RIA** Plan and dynamics for Implementation of RIA Communication to 5 days prior to Publication RIA process start parties concerned Public review Lasts at least 15 days Consultation with Implementation of the **RIA process** parties concerned Invitations out to parties Public hearing concerned at least 5 days in advance At least 10 days prior Draft law and draft RIA Publication to submission of draft Report report to MISA MISA views on draft 10 days upon receipt Provision of view **RIA Report** of draft RIA report Draft law and draft RIA As per stipulated Submission to the SG deadline Report Upon endorsement of Draft law and RIA Publication the proposed legislation Report by the Government

Fig 2. Overview of the RIA process and deadlines

## 5. Organisation and management of the RIA process

For the purposes of quality implementation and management of the RIA process, ministries shall introduce appropriate internal procedures and shall provide capacity for implementation of analytical tools within the RIA process.

## 5.1. Organisation and management of the RIA process in the ministries

Depending on the internal organisation of the legislation preparation process, the RIA process and the respective analyses shall be carried out within individual ministry sectors that are responsible for the specific area, or within the working groups established for that purpose. Head of such individual sectors, or Chairs of the working groups, shall monitor and support implementation of the RIA process and its compliance to the methodology defined, in order to ensure quality analytics and quality RIA reporting.

The state secretaries in the ministries shall decide on how the process would be organised. The state secretary in each ministry shall be responsible for the continuous improvement of the RIA process, achieved by ensuring consistent implementation of the process and the methodology, as well as by ensuring participation at trainings of employees involved in the analysis and in the RIA process.

To ensure quality and internal coordination of the process, and coordination with the Ministry of Information Society and Administration, individual ministries shall nominate and shall appoint a coordinator for the RIA process and a deputy. Ministries that have wider responsibilities in several areas may appoint one coordinator and one deputy for each area.

## RIA coordinators:

- Provide support and advice to sector/working group on the process of RIA implementation, the required analyses, collation of data, consultations and other steps in RIA implementation, for the purposes of consistent implementation of this methodology and the acts governing the RIA subject matter;
- Collate data and prepare the Annual RIA plan;
- Provide advice on exceptions, or suggestions on legislation that is not subject to RIA;
- Provide advice on the RIA report;
- Make basic checks of chapters within the draft report and if appropriate, make suggestions for ensuring consistency in implementation of the methodology prior to the submission of the draft report to the Ministry of Information Society and Administration:
- Collate data required for the preparation during the RIA implementation report , and
- Participate in trainings organised to improve the RIA process and the role of the RIA process coordinators in ministries.

# 5.2. Organisation and management of the RIA process at the Ministry of Information Society and Administration

In addition to implementing the RIA process during the preparation of the proposed legislation in the areas of responsibility for the ministry, the Ministry of Information Society and Administration shall take care about improving the RIA process.

In line with the Government's Rules of procedure, the Ministry of Information Society and Administration shall provide its view on the proposed legislation that is subjected to the RIA. Such views shall be prepared on the basis of the draft RIA report submitted by the relevant ministry. The

view by the Ministry of Information Society and Administration shall include an assessment of the RIA process, and harmonisation of the proposed legislation to the acts governing the subject matter of the RIA.

The Ministry of Information Society and Administration at the request of individual ministries may provide information pertaining to the application of the RIA process, the acts governing the RIA subject matter and analytical tools used to implement the RIA. For the purposes of improving the process, the Ministry of Information Society and Administration may organise meetings, seminars and consultations for the civil servants nominated as RIA coordinators in ministries. In cooperation with the relevant HR management unit at the Ministry of Information Society and Administration, trainings can be organised for the civil servants employed at ministries that are involved in the processes of proposing new legislation and RIA implementation. To ensure efficient consultation among parties concerned, the Ministry of Information Society and Administration shall continuously improve the process management at SNERR.

In order to ensure management and improvement of the RIA process, the Ministry of Information Society and Administration has established an organisational unit.

## 6. Monitoring and improving the process and the methodology

The Ministry of Information Society and Administration, in cooperation with other ministries, shall monitor the implementation and the quality of the RIA process and its methodology. Based on an analysis of the draft RIA reports submitted to the ministries, and based on views on the application of acts governing the RIA subject matter, the Ministry of Information Society and Administration and in cooperation with other ministries, shall issue an Annual report on implementation and development of the RIA process, to the Government of the Republic of Macedonia.

The application of the Methodology on the regulatory impact assessment ('Official Gazette of the Republic of Macedonia', issue 66/09) shall cease validity on the day of publication of the current Methodology.

This Methodology shall be published in the Official Gazette of the Republic of Macedonia'.