



The European Union's IPA Programme for Croatia

Strengthening capacity for the implementation of
RIA Strategy 2013 - 2015

RIA Guidelines



This project was implemented by:
Northern Ireland Co-operation Overseas (NI-CO)
and Government Legislation Office

"We must rigorously assess the impact of legislation in the making, including substantial amendments introduced during the legislative process, so that political decisions are well-informed and evidence-based. The decisions taken by EU Institutions interest us all, so we are putting forward measures which will open up the EU's decision-making process, allowing for more transparency and scrutiny, and providing more opportunities for people to give their views."

Frans Timmermans, First Vice-President of the European Commission

"Small businesses are Britain's engine room and the success of our whole economy is built on the hard work and determination of the people who run and work for them... As part of our long-term economic plan we will sweep away burdensome red tape, get heavy-handed regulators off firms' backs and create a Small Business Conciliation Service to help resolve disputes."

Rt Hon Sajid Javid, Member of Parliament, United Kingdom Secretary of State for Business, Innovation and Skills

"Governments are trying to improve by designing policies, laws and regulation – to make sure to use the right tools to do a good job; in order to maximise the benefits, and minimize the negative impacts; in order to hear the voices of those concerned."

José Manuel Barroso, former European Commission President

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These RIA Guidelines update, amalgamate and replace the original set of RIA Guidelines for civil servants; civil servants in the GLO; external stakeholders, the public and interested parties. Those RIA Guidelines were produced under IPA 2007 Twinning project, Development of Regulatory impact assessment (RIA) System (Twinning number: HR/2007/IB/FI/02, Contract number: 2007-0202-010101). They were published in June 2012, on the GLO website.

These Guidelines contain information on:

- The RIA process, including the Annual Plan of Legislative Proposals and the steps involved in developing RIAs
- The methodology for developing RIAs
- Technical guidance, including advice on the RIA Calculator, Standard Cost Models and other analytical statistical and economic tools to help calculate the costs and benefits of RIA Statements.

Editorial note for the English language version of these RIA Guidelines

Readers of this English language version will wish to note that certain terminology, idioms and grammar have been adopted in preparing these Guidelines which do not correspond to conventional English usage. This is simply to facilitate the rapid translation into accurate Croatian of the text but should not materially affect the overall meaning or sense when read in English.

INTRODUCTION

These Guidelines provide a basic source of information and serve as a technical aid to civil servants and decision makers in the process of developing and producing high-quality legislative proposals and public policy. They also provide information and advice for external stakeholders, consumers and the public on how they can be better informed about and, through active and meaningful consultation, better involved in the development of high-quality national legislation.

The Guidelines provide information and advice on:

- how to prepare Annual Plans of Legislative Proposals;
- how to draft an Initial Assessment; and
- how to draft a Regulatory Impact Assessment (RIA) Report.

They also serve as technical guidance for implementing RIAs pursuant to the Act on Regulatory Impact Assessment (Official Gazette 90/11), further in text: the “RIA Act” and the Regulation on the Implementation of the Regulatory Impact Assessment Process (Official Gazette 66/12), further in text: the “RIA System Regulation”.

The Guidelines also explain:

- What should be included in a Regulatory Impact Assessment (RIA) report;
- The various stages in producing and agreeing RIA reports;
- Who should do what at each stage; and
- Sources of further help and information.

The RIA method is **in** widespread **use** in all member states of the Organisation for Economic Co-operation and Development (OECD) and the European Union (EU). The European Commission has been using RIAs since 2005 on EU legislative initiatives that have significant economic, social and environmental impacts, and also on legislative initiatives that impact future EU public policy and for individual enforcing instruments of public policy at an EU level.

The importance of RIAs in the EU is best demonstrated by the fact that the Impact Assessment Board, which worked under the authority of the European Commission and was responsible for the quality of RIA Reports at an EU level, examined 97 RIAs in 2013 and issued 142 opinions. 41% of RIAs submitted in 2013 were returned for revisions. In 2014, only 25 RIAs were scrutinised because of changes to the Commission and European Parliament.¹ Since 1 July 2015, all draft impact assessments are now submitted to the Regulatory Scrutiny Board which has replaced the Impact Assessment Board.

For more information about the Commission’s Better Regulation agenda, see for example:

http://ec.europa.eu/smart-regulation/guidelines/toc_guide_en.htm

http://ec.europa.eu/smart-regulation/better_regulation/documents/com_2015_215_en.pdf

¹ European Commission, 2014, Impact Assessment Board activity statistics for 2014, European Commission, Brussels. Available on: http://ec.europa.eu/smart-regulation/impact/key_docs/iab._stats_2014_en.pdf [Accessed: 10 July 2015]

1. A REGULATORY IMPACT ASSESSMENT

The OECD states that one of the guiding principles for regulatory quality is to:

“assess impacts and review regulations systematically to ensure that they meet their intended objectives efficiently and effectively in a changing and complex economic and social environment.”

A Regulatory Impact Assessment (RIA) is a straightforward process which helps the development of Government policies and regulation by:

- Identifying the benefits, costs and risks of a proposed public policy and the options available for implementation;
- Provides evidence on the probable consequences of those options and of introducing new legislation; and
- Takes into account the views of a wide range of stakeholders, thus enabling policy development to be better informed as to the most cost-effective means of achieving the policy objectives, as well as greater transparency and accountability which in turn helps lead to greater public confidence in the process and outcomes of public policies.

A RIA is one of the "smart" legislation tools that includes the analysis of all possible costs and benefits of public policy proposals, gathers data and information on the possible consequences of introducing new regulations and consequently contributes to the rational process of creating policy based on good quality evidence.

In order to improve legislative processes, a RIA follows internationally recognised principles of “smart” legislation:

- Transparency,
- Responsibility,
- Proportionality,
- Consistency,
- Direction.

Inclusion and engagement of stakeholders and the public is an important step towards the creation of legislation which follows these principles.

The RIA procedure is therefore a framework for considering questions of public policy and legislative proposals and solutions, which address the following questions:

- What is the policy or problem being considered?
- Which groups are affected by the policy or problem?
- Why is intervention necessary?
- What options are being considered?
- What are the expected benefits, costs and risks of each option?
- What is the preferred option and why - what is the evidence behind it?
- How will the preferred option be implemented?
- How will the effects of the policy changes be monitored and evaluated after implementation?

1.1. What are the benefits of doing a Regulatory impact assessment?

The RIA process helps Ministers and officials make the most appropriate and effective policy decisions by:

- Providing a logical structure to think through policy issues;
- Providing additional information and evidence for the policy making process, thus helping Ministers and their officials to take an overview of the full range of options;
- Identifying the benefits, costs and risks of the possible regulatory interventions, enabling them to be directly compared together with the actions that can be taken to reduce costs and to mitigate risks, which will increase the overall benefit of the policy change;
- Helping take into account the views of a wide range of stakeholders, thereby making the policy development process more robust and transparent, as well as enabling outside interests to add value by providing their insight and specialist knowledge where appropriate;
- Thinking through the potential impacts and thus helping to align proposed policy interventions with other Government objectives;
- Providing a wide justification for why the recommended policy option has been chosen, which can help build public confidence that it is worth doing as the nature of the problem and the expected benefits are clear, and, together with the published RIA, providing a clear method of accountability to the public; and
- Encouraging the responsible Ministry to think about the outcomes and how they will identify, through monitoring and evaluation, whether these have been achieved.

1.2. The legislative framework for RIA in the Republic of Croatia

The RIA Act and the RIA System Regulation govern the RIA system in the Republic of Croatia. The Act came into force with certain exceptions on 1 January 2012. The RIA Act provides a baseline for RIA procedures along with the accompanying methodology and implementation guidelines.

The Act consists of Articles relating to:

- producing an Annual Plan of legislative proposals and planning of the RIA procedure for each proposal,
- initial assessment of the *status quo* that will be regulated by the proposal,
- public consultation,
- drafting RIA Report,
- obligatory consideration of possible non-legislative solutions and other options for legislative solutions while drafting and preparing relevant legislation,
- further development of the RIA system,
- continuous training for civil servants for the purpose of better quality implementation of the RIA system,
- development of institutional capacities for the implementation of the RIA procedure.

The Act therefore defines a RIA as the procedure for adopting decisions on legislation based on evidence and relevant collected data, which will serve as a template for choosing the best solution either by way of legislative provisions or by way of non-legislative alternatives. The RIA should analyse both the positive and negative impacts



of legislation on the economic sector(s) affected, including financial, social welfare and environmental protection impacts as well as an outline of the fiscal impacts, parallel with consulting the public and interested parties.

The RIA System Regulation was adopted by the Government on 14 June 2012 and came into force 8 days after their publication in the Official Gazette. The Regulation prescribes more detailed criteria for the Initial RIA, Initial RIA template, method of implementation of the RIA procedure, RIA Report template, how to conduct consultation and public discussions on the initial assessment procedure and the RIA, and other related areas.

Public participation in the RIA process is a necessary precondition for improving transparency and responsibility. The RIA Statement helps assure the quality of final decisions due to a more open decision-making process which is based on the facts and evidence presented.

The role of the Government Legislation Office (GLO) in the RIA process is to assure:

- the overall adequacy of the Annual Plans of legislative proposals produced by individual Ministries which contribute to the Government's overarching Annual Plan of all legislative proposals produced by the GLO;
- the overall quality of the RIAs that accompany those proposals; and
- the adequacy of the Croatian RIA system as a whole
- by developing relevant and appropriate RIA framework legislation and publishing Guidelines on how to implement and apply these requirements. These Guidelines are produced by the GLO in accordance with the requirements of Articles 15 and 29 of the RIA Act.

More information about the roles of respective organisations involved in the RIA process is at Annex 1.

2. RIA PROCESS

The RIA process divides into two parts:

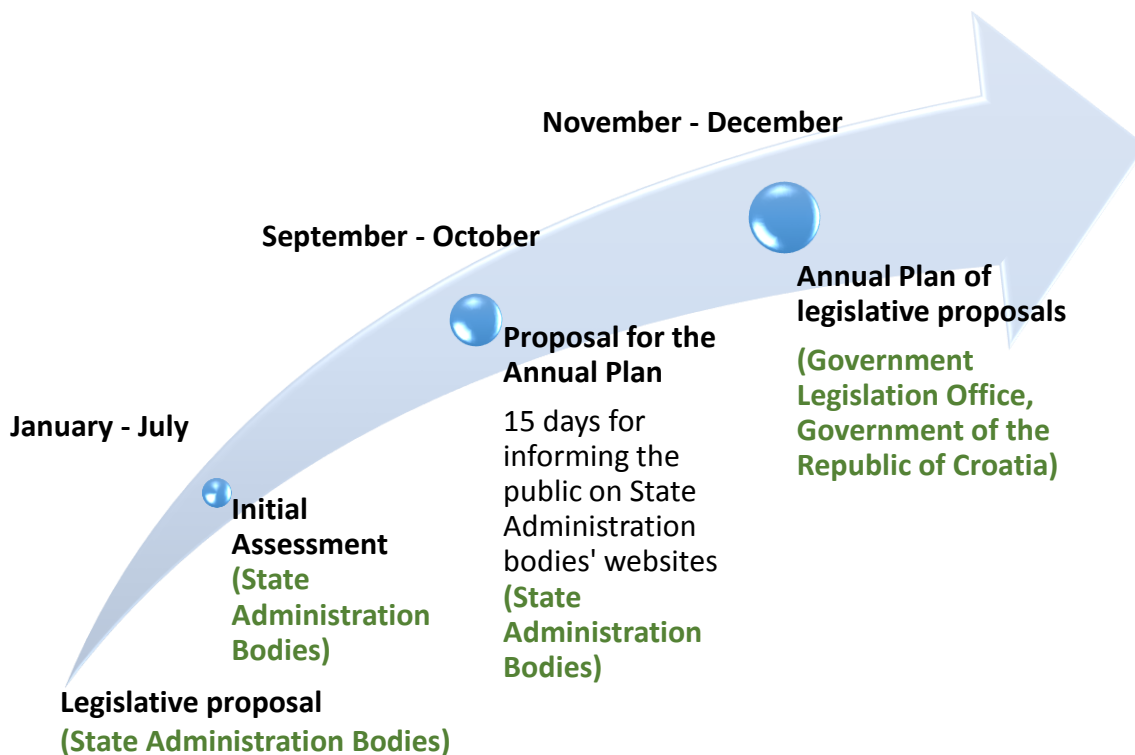
- preparing the Annual Plan of Legislative Proposals
- implementing RIA procedures

2.1 The Annual Plan of Legislative Proposals (APL)

Based on the RIA Act, the Government of the Republic of Croatia, based on the proposal of the Government Legislation Office, adopts an Annual Plan of Legislative Proposals (APL) from Ministerial APLs for the next calendar year.

One of the goals of preparing an APL (and the RIAs for individual legislative proposals) is to increase transparency by encouraging and stimulating the involvement of external stakeholders, consumers and the public in general. Parties that are affected or interested in legislative proposals have the right to participate in these processes. Active consultation will help generate positive contributions from external stakeholders on the proposals put forward, the benefits, costs and risks that may arise from their adoption, how such costs and risks might be reduced or avoided completely and how best the proposals can be implemented, monitored and evaluated. Figure 1 shows the key stages in producing Annual Plans and where public participation is possible.

Figure 1: Preparations for the APL



When can work start on drafting an APL?

RIA Co-ordinators (RIACs) in individual state administration bodies can begin drafting their APLs for the following year at the beginning of the current year, or when information and data on legislative proposals for the following year become available. The APL relates to the following calendar year.

What are the main stages in preparing and finalising APLs?

Figure 2 on the next page sets out the main stages involved in preparing and finalising individual APLs and then the proposal for the Government's overarching Annual Plan put forward for adoption by the GLO. Figure 2 also includes the steps involved in preparing, consulting on and finalising individual RIAs to accompany legislative proposals.

Who prepares the individual APLs?

Each state administration body which is contemplating putting forward legislative proposals for the following calendar year should prepare an APL.

Each state administration body must appoint at least one RIAC who is responsible for gathering information on proposals from across their organisation in order to begin work on the APL. State administration bodies may (not must) appoint more than one RIAC or establish a RIA Unit for this and other purposes connected with RIA procedures.

What does the term "Expert Bearer" mean?

The term "Expert Bearer" (EB) is simply the legal definition in Article 3 of the RIA Act to describe state administration bodies or other organisations that can put forward legislative proposals for adoption by the Government of Croatia.

Must all legislative proposals be included in the Annual Plan?

It is good practice for each EB's APLs to include details of all relevant legislative proposals for the next calendar year and clearly set out whether the preliminary impact assessment shows whether a full RIA is or is not required to accompany each proposal.

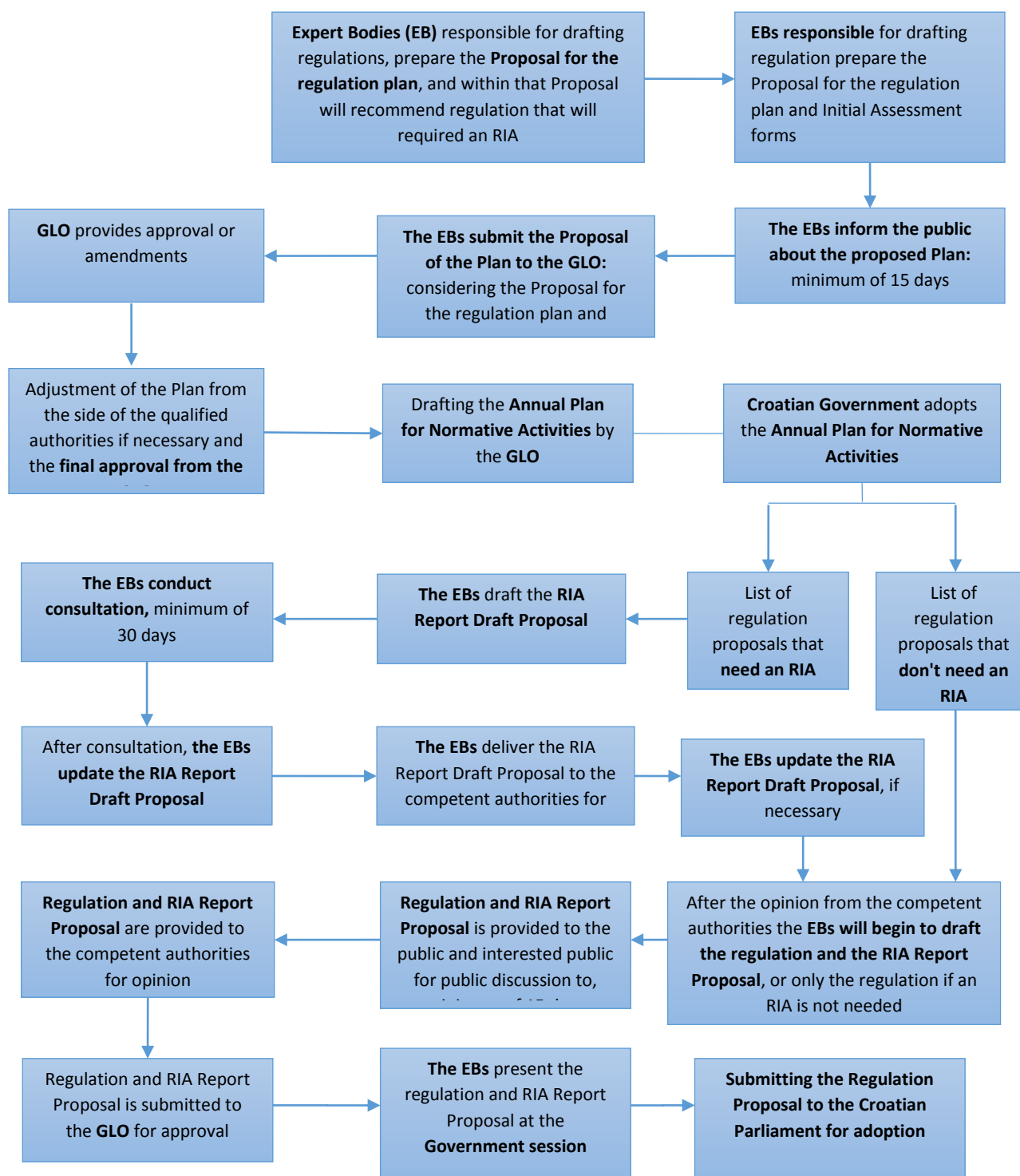
When is a full RIA not required for a legislative proposal?

If the preliminary impact assessment shows that a legislative proposal has no significant impacts on the economy, on state finance or competitiveness, business, employment, the environment or health and social welfare then a full RIA is not required.

When should work on the preliminary impact assessment start and who does this?

Work on a preliminary IA should begin as soon as consideration of a legislative proposal is underway. The relevant department or unit within the EB responsible for that area of legislation should do this work. RIACs should advise and support their colleagues and scrutinise carefully the IAs prepared.

Figure 2: Preparation of the Annual Plan of Legislative Proposals



2.2. Legislative proposal

Within the framework of the RIA system and procedures, the first stage begins with a legislative proposal. The department or unit within the EB responsible for the policy area that the legislative proposal covers is also responsible for assessing its potential impacts.

In accordance with best practice in Croatia, the proposal should clearly set out the desired goals and outcomes to be achieved as well as a short explanation of the problem that the proposal will help solve. The proposal should state concisely (e.g. in bullet points) what main legislative changes are proposed.

2.3. Preliminary impact assessment (PIA)

A Preliminary Impact Assessment (PIA) is prepared by the department or unit within the EB responsible for the policy area that the legislative proposal covers in cooperation with the EB's RIAC(s) or a RIA Unit. The PIA must cover the mandatory criteria set out in the RIA Act and RIA System Regulation for all such work. These include legislative and other policy reasons for putting forward the proposal for adoption, the changes that are proposed and other measures and data in accordance with the RIA legislation.

The criteria are:

- the appropriate financial thresholds related to the most significant impacts that are expected in the areas and activities covered by the legislative proposal;
- any expected impacts on specific economic areas, for example the whole economy of Croatia;
- expected impacts on socially sensitive or other groups with special interests and needs; and
- expected impacts on the environment and sustainable development.

The PIA must:

- Describe the problem and why legislation is required for the solution. (At least one non-regulatory option must be presented in the PIA as an alternative to legislation. For more information on non-regulatory options see Sections 3.4 and 4.10 below).
- Identify the sectors, groups or other stakeholders impacted by the problem
- Specify the appropriate legislation and other areas of legislative activity that are connected to the problem or are closely related
- Set out the goals and aims or desired improvements to be achieved and any anticipated obstacles or risks (for example: a lack of resources for implementation of the proposal, poor response from those affected, lack of administrative capacity in the system etc.)
- Determine what the anticipated outcomes and the planned impacts of the changes will be
- Identify who will be directly impacted by the proposed changes now or in the future, and the costs and benefits for all those affected (for example: different economic sectors, business, citizens, voluntary and community groups or others).

Annex 1 to the 2012 RIA System Regulation provides the template for completing the PIA.

If the PIA concludes that a proposal will not have significant impacts, it will not require a full RIA. However, this position can change as a result of further work and consultation as the legislative proposal progresses.

2.4. Drafting and completing the proposed APLs

As PIAs are being drafted for all legislative proposals for the next calendar year, RIACs in individual state administration bodies should start work on their Ministry's proposed Annual Plan (APL).

The process for preparing, publishing and updating the APL is managed and coordinated by individual RIACs. If a state administration body has appointed more than one RIA coordinator, then it is for the relevant senior official within that body to decide which RIAC is to have overall responsibility for the APL.

The APL must contain all legislative proposals which concern domestic (i.e. Croatian) legislation (including those which are for the purpose of harmonizing Croatian with EU legislation). The APL must include a list of all legislative proposals for which a full RIA will be prepared and a list of proposals which will not have a full RIA prepared (and the reasons why).

The draft APL should be prepared in accordance with the template set out in Annex 1 of the 2012 RIA System Regulation and showing, in quarterly periods for the next calendar year, when it is likely that individual legislative proposals will be presented to Parliament following adoption by the Government.

Once the draft is completed, it must be approved internally within the state administration body concerned for publication and consultation.

Once approved, each body should publish and consult on the draft APL for the next calendar year **on their website for at least 15 days during the period 1 – 30 September of the current year.**

It is good practice to plan to publish all PIAs when consulting on the APL. As mentioned above, RIACs should also arrange to publish all PIAs accompanying individual legislative proposals. RIACs should also ensure there are adequate arrangements in place (for example, contact e-mail or postal addresses) to receive comments, opinions or other views on the draft APL itself, and, if significant public interest is anticipated on one or more of the individual legislative proposals, additional contact points for the policy leads concerned to receive comments.

Once consultation is complete, the RIAC will revise and update the draft APL accordingly and submit it for final internal Ministerial or senior official approval.

Once approval is given, the RIAC should submit it to the GLO **by 31 October latest** for its opinion along with all completed preliminary IAs for the relevant legislative proposals.

The GLO will then review each individual final APL and relevant preliminary IAs submitted and, if considered necessary, request amendments as required. The GLO will liaise and co-operate with RIACs on agreeing such changes. The GLO will aim to complete this **no later than 30 November** so that individual Annual Plans can be included in the overarching Government Annual Plan of Legislative Proposals for the forthcoming year.

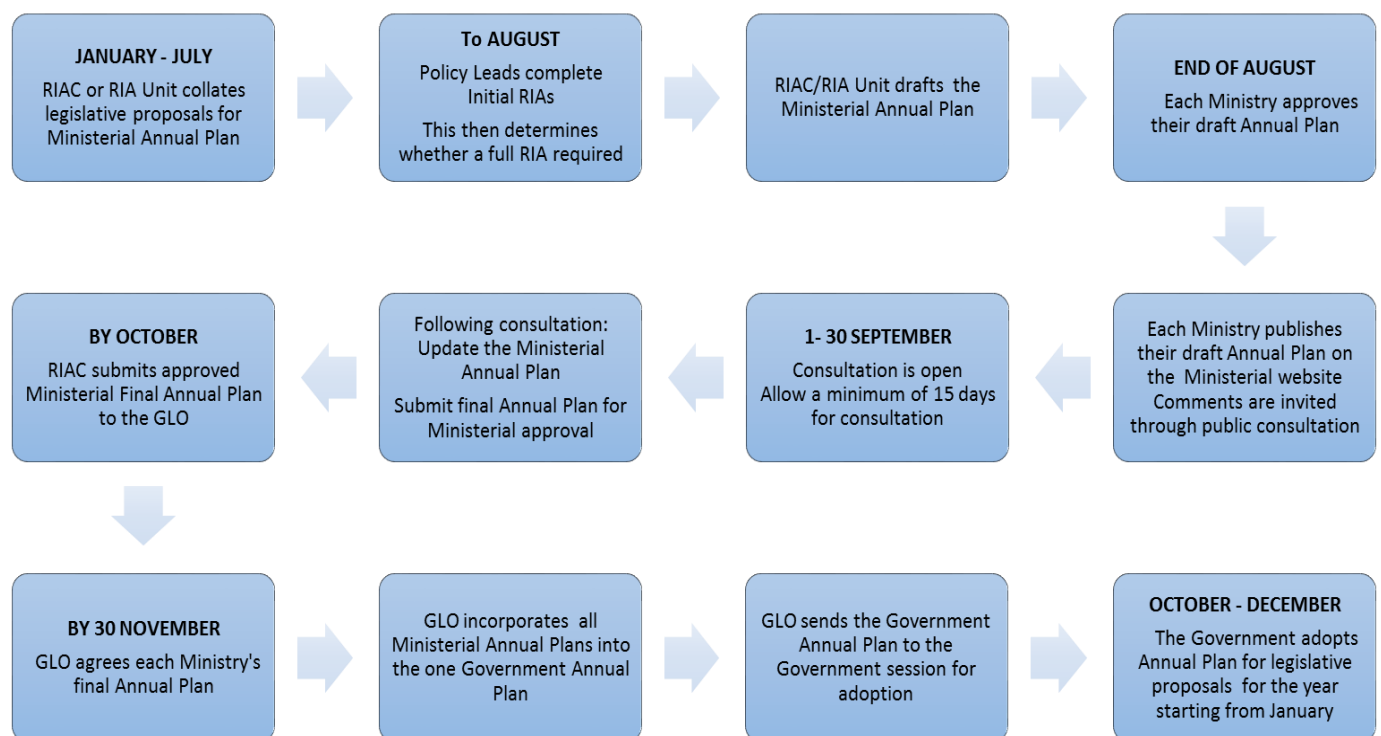
2.5. The Government annual plan of legislative proposals

The overarching Government APL for the next calendar year is collated from individual EB's final APLs and drafted by the GLO in accordance with the requirements set out in the RIA legislation (both the RIA Act and the RIA System Regulation). It comprises a list of legislative proposals that do not require a full RIA and a list of legislative proposals for which a full RIA will be prepared.

The GLO then submits this to the Government for approval and adoption in the last quarter of the current calendar year. Once completed, the Government's Annual Plan for the next calendar year is published on the GLO website.

Figure 3 sets out all the steps from first drafts of legislative proposals through to adoption (or not) by the Government and the Parliament.

Figure 3: Steps in drafting and finalising Annual Plans of Legislative Proposals



Working from the published Government APL, each RIAC for the relevant state administration body will hold two lists of that body's legislative proposals for the year in question.

The first list will set out the proposals, which are judged not to require a full RIA (**List of Non-RIA Legislative Proposals**). This position may change as proposals progress.

The second list will set out the proposals where a full RIA is required (**List of Legislative Proposals with full RIA**). Again, it is possible, though less likely, that this position may change as proposals progress.

2.6. The procedure for progressing Non-RIA legislative proposals

The procedure for progressing legislative proposals, which do not require a full RIA Statement, is more straightforward than those, which do. Once listed in the EB's APL, the next stage is to prepare relevant draft legislation to implement the policy.

Inclusion of an initiative in the list of Non-RIA Legislative Proposals does not remove the need for full public consultation. The need for full public consultation derives from the Article 11 of the Right of Access to Information Act (OG 25/13, 85/15) which obliges the relevant organisation to consult (for no less than) 30 days on legislative proposals.

The Non-RIA Legislative Proposals must be published on a Government e-consultation platform: <https://savjetovanja.gov.hr>

Once consultation is completed, the relevant policy lead in the EB should prepare a summary of the responses, comments and views received, whether these are accepted by the EB or not and what amendments to the legislative proposal and draft legislation are being made as a result, and publish it on their website.

If, as a result of consultation, it is decided that the legislative proposal will have significant impacts, the relevant policy lead in the EB should consult their RIAC or RIA Unit about this, prior to recommending a switch to the full RIA procedure described below.

If the result of consultation shows that the legislative proposal will not have significant impacts, the final version of the draft legislation is then submitted to the Government for approval prior to being presented to Parliament.

The e-consultation platform supports open policy making by:

- Easy access to all public consultations of all government bodies at one place;
- Email notifications of all newly opened consultations;
- Simple ways of commenting on all laws, regulations and acts and a user friendly overview of the legal act under consultation;
- Permanently visible and registered comments, visible to the wider public in order to encourage all users to discuss and debate policy.

2.7. The procedure for progressing legislative proposals which require a full RIA Statement

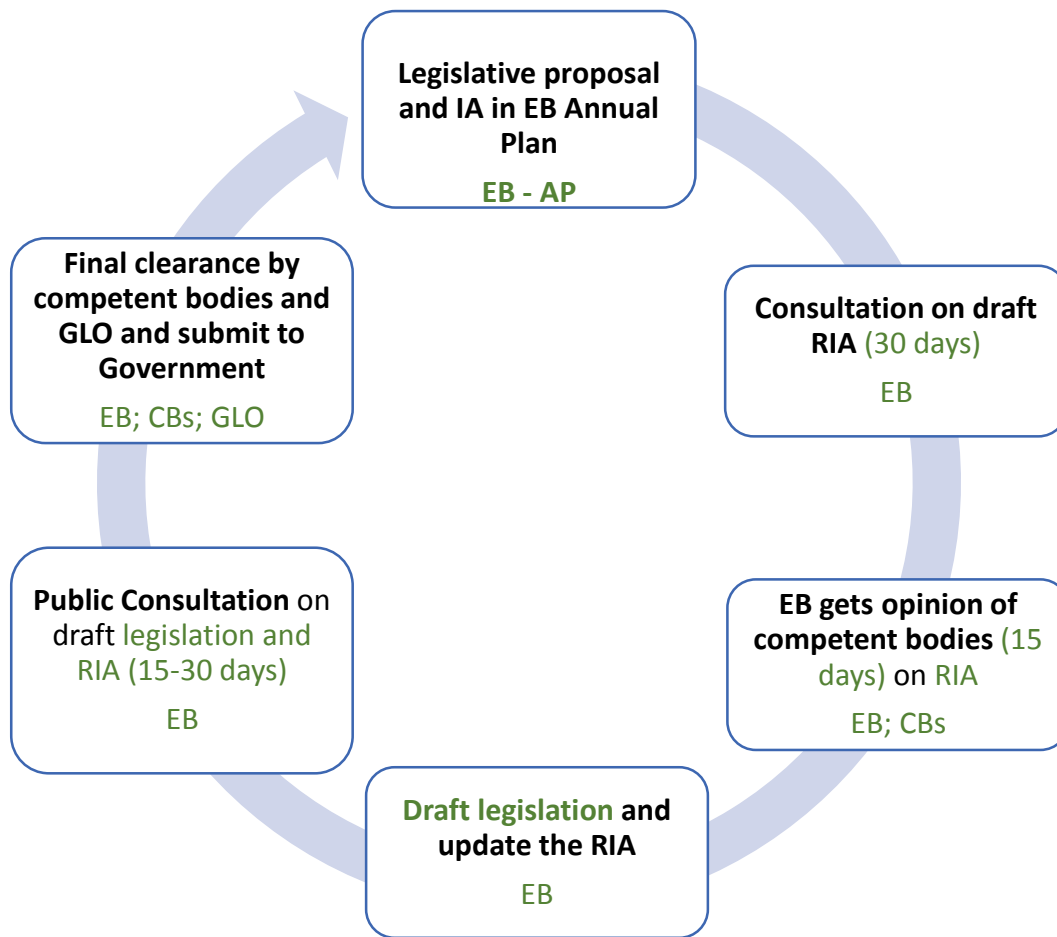
The first step is to develop the draft RIA from the PIA prepared alongside the legislative proposal included in the EB's Annual Plan. EB policy leads should work closely with their RIAC or RIA Unit on all stages of development.

Appendix 3 to the RIA System Regulation sets out the template, which EB policy leads, must follow when preparing this draft. Once the draft RIA Statement has been completed, and any necessary internal clearance given, the EB policy lead should arrange the first public consultation on the RIA Statement. This must be for at **least 30 calendar days** and may be extended if the proposal is likely to generate significant public or media interest.

Figure 4 summarises the steps from the first draft of the RIA to the final RIA Statement.

The draft RIA Statement must be published on the Government e-consultation platform.

Figure 4: Developing the RIA from draft to final RIA Statement



Legend:

CB – Competent Bodies, EB – Expert Bearer, GLO – Government Legislation Office

Following consultation, the EB policy lead updates the RIA Statement in the light of comments and views received and then seeks the views of all designated Competent Bodies (CBs), allowing 15 **working days** for this stage.

The EB policy lead should send the RIA Statement to the relevant official in the CB dealing with their policy area and to the RIAC for that CB. If in doubt, EB policy leads should first ask the CB RIAC for advice.

The **Competent Bodies** set out in Article 17 of the RIA Act are the state administration bodies with competence for:

- Health and Social Welfare (now the Ministry of Social Policy and Youth);
- Economy (now Ministry of Economy, including any other body with relevant competence for an economic area in question);
- Environmental protection (now Ministry of Environment and Nature Protection);
- Finance (Ministry of Finance).

RIACs and policy leads in EBs will wish to bear in mind that the RIA Act was brought into force before the Ministry of Economy was divided into three separate Ministries covering the economy (MINGO), labour & pension system (MRMS) and entrepreneurship & crafts (MINPO).

There is, therefore, no specific reference currently to seeking views from these two new Ministries within the RIA Act.

However, the RIA Act (Article 11) already permits MINGO to seek views from other bodies with relevant competence for a specific economic area. There is therefore no legislative bar to the EB policy lead seeking views from colleagues in MRMS or MINPO where a legislative proposal concerns their interests.

If the proposal has identified impacts on market competition, then the EB policy lead must seek views from the Competition Agency. Further information on this is set out in the RIA Methodology below.

It may, in practice, be simplest for the EB policy lead to discuss first with colleagues or RIACs in those relevant bodies whether the legislative proposal does impact on their interests and seek views from the Ministries and Competition Agency as appropriate.

Competent Body RIACs should liaise with relevant colleagues within their Ministry on the response sent to the EB policy lead. Views must be sent within 15 working days of receipt of the request from the EB policy lead or RIAC.

RIACs in other Ministries and EB policy leads developing RIAs will wish to be aware, and plan accordingly, that they cannot impose a shorter deadline for obtaining responses from Competent Bodies. If a matter is urgent, they should notify and discuss this with the Competent Bodies own RIACs or RIA leads first.

Where a RIA Statement concerns a legislative proposal from within a Competent Body itself, there is no need to seek the separate approval of that CB to the RIA Statement.

Once the views of the relevant Competent Bodies have been obtained, the EB policy lead revises the RIA Statement as required and prepares the draft legislation for further public consultation.

This public consultation can last for **between 15 and 30 calendar days** and must include at least one public presentation of the legislative proposal with supporting documentation including the RIA Statement. EB RIACs and policy leads will wish to note that the RIA Act does not currently permit consultation to last longer than 30 calendar days. EB RIACs and policy leads will wish to take account of this when preparing the documents for formal consultation.

Following this consultation phase, the EB policy lead again prepares a summary response on the views and comments received, whether these are accepted or not and what revisions to the legislation and draft RIA Statement are included. Once accepted internally, this summary response is published on the EB's website.

The EB policy lead then re-submits the draft legislation and RIA Statement to the state administration bodies (including Competent Bodies) and to the GLO for final approval. The RIA Statement is final when the GLO gives a final approval, after the RIA Statement has, as appropriate, been updated to reflect comments from the GLO.

Once received, the legislative proposal is submitted to the Government for approval and presentation to Parliament.

2.8. What to do where a legislative proposal is unplanned

There will often be a need during a calendar year to prepare legislative proposals which have not been listed in the Government APL. This can apply as a result of new policy developments not foreseen at the time the APL was drawn up, a change of Government policy or matters which require urgent action. In these situations, **the EB policy leads must nonetheless implement the preliminary IA process to accompany that proposal**, based on the Government Conclusion Act on Adopting the Annual Plan of Legislative Proposals for each calendar year.

The EB policy leads should seek the views of the GLO on the preliminary Impact Assessment prior to drafting its legislative proposal. The GLO will check the preliminary Impact Assessment and seek adjustments and additional input as required.

The one key difference for unplanned legislation is that the preliminary IA should be published on the EB's website for a minimum of 15 days, after formal GLO approval, in order to inform the public about a particular initiative. This is required before full public consultation on the Legislative Proposal itself can go ahead.

Once consultation is completed, the relevant policy lead in the EB should prepare a summary of the responses, comments and views received, whether these are accepted by the EB or not and what amendments to the legislative proposal and draft legislation are being made as a result, and publish it on their website.

If the results of that preliminary IA shows that a full RIA Statement is not required, the EB policy lead will continue drafting the relevant legislation in line with the procedures for Non-RIA legislative proposals set out above.

If the results show that a full RIA Statement needs to be prepared, the EB policy lead will immediately begin the full RIA process described above in line with the relevant provisions of Articles 18 – 23 of the RIA Act and the RIA System Regulations.

This process should not be regarded as the norm for legislative proposals and its use should be kept to the absolute minimum necessary.

2.9. What to do where there is a need for urgent or emergency legislation

The Croatian Parliamentary Rules of Conduct (OG 81/13), according to Article 204, allows an urgent procedure to be followed for the adoption of new legislation.

A clear explanation of the need to adopt the urgent procedure should be set out in the legislative proposal. This procedure is also applied to the transposition of EU Directives or Regulations into national legislation.

The draft legislation prepared and presented constitutes the final legislative proposal. In such case, the first and second Readings of the legislation in Parliament are combined.

It is important to note that a preliminary Impact Assessment must be prepared as part of any urgent legislative proposals.

There are certain situations under Article 13 of the RIA Act that allows for the RIA requirements, following the relevant Government decision, to apply to:

- A regulation (primary or secondary legislation) which is required urgently to address significant impacts on economy, social welfare, environmental protection or the fiscal obligations of the Republic of Croatia;

- Existing primary legislation already in force;
- Secondary legislation already in force or in the process of being drafted.

In these cases RIAs may be done partly or fully, based on the EB's own assessment. It is important to note that a preliminary Impact Assessment must be prepared as part of any emergency legislative proposals.

The one exception to this rule is where the proposal concerns action to eliminate or reduce the risk of damage to public health or safety, national security etc.

RIACs and EB policy leads will therefore need to work closely on preparation of this IA to accompany the presentation of the legislation itself to Parliament.

TRANSPOSITION OF EU REGULATIONS OR DIRECTIVES TO NATIONAL LEGISLATION

EU Member States compile general information on how to transpose and implement EU legislation effectively. An example of how the UK approaches this is available on the UK government website (www.gov.uk) and reflects the current UK Government's approach and desire to reduce regulatory burdens. The guidance ("*Transposition Guidance: How to implement EU Directives effectively*") was published in April 2013.

3. THE METHODOLOGY FOR DEVELOPING A RIA STATEMENT

Best practice and the experience of the European Commission and Member States demonstrate that the RIA process can be implemented in an appropriate, prompt, and systematic manner, if the process is planned 'step by step' beforehand in accordance with Figure 5.

Figure 5: A “step by step” plan for developing a RIA Statement

1	Work Plan
2	Problem Definition and Setting Objectives
3	Identifying Options
4	Considering Alternatives to Legislation
5	Comparison of Options
6	Consultation about the draft RIA Statement
7	Collecting the Opinions of the Competent Bodies
8	Drafting the Legislative Proposal and the Final RIA Statement
9	Consultation about the Legislative Proposal and the Final RIA Statement
10	Quality Assurance – RIA Checklist
11	Submitting the Legislative Proposal and the Final RIA Statement for Adoption
12	Key Questions for answer in the RIA

3.1. Work plan

The RIA process is a result of multidisciplinary teamwork. This job cannot be performed by one officer in a Ministry responsible for drafting regulations working on their own. A RIA includes various analytical tasks, planning tasks, consulting tasks and public discussions. The first step towards completing an RIA is planning the implementation of the process.

For regulations that are included in the RIA list of the APL **it is generally desirable and advisable to adopt a Work Plan and organize the programme with the support of a Working Group and a small internal team within the EB.**

The purpose of the Work Plan is to map the RIA process in a satisfactory manner within a given timeframe. The aim is to plan the necessary human resources, all stages in the RIA process, including consultation and communication with stakeholders and Competent Bodies, in a professional and competent manner.

The Work Plan for the RIA process is prepared by the EB policy lead responsible for drafting the legislative proposal, in the directorate or sector that has responsibility for adopting the regulation. The head of the directorate or sector, who generally allocates work to civil servants within that area, formally adopts the Work Plan for implementing the RIA.

The Work Plan for implementing an RIA includes:

- Proposal for appointing members of the Working Group and the core team of civil servants,
- Timetable for the working group and core team of civil servants,
- Plan for consultation and communication activities.

3.1.1. Proposal for appointing members of the Working Group and the core team of civil servants

The proposal for appointing members of the Working Group and the core team of civil servants determines the available human resources for implementing the RIA. Since human resources are finite, it is necessary to set out promptly the number of civil servants and external experts who will be part of the Working Group and their key roles and responsibilities.

The proposal for appointing members of the Working Group provides the EB policy lead with adequate information about who is involved in drafting the legislation and the RIA in a professional and appropriate manner. Members of the Working Group are persons with expert knowledge, experience, professionalism and information that can contribute to the work on the RIA and the legislative proposal.

The Working Group, as a rule, should be an interdisciplinary body and include representatives from the business community, civil society organizations, academic community or other physical and/or legal persons that can actively contribute with their expertise, proposals, comments and suggestions to the Working Group's activities.

The main task of the Working Group is to review the RIA process and review the regulatory drafting process and to assist the EB policy lead in each step in preparing the documentation required. EB policy leads should always invite representatives of the Croatian business community (such as Croatian Employers' Association, Croatian Chamber of Commerce, Croatian Chamber of Crafts etc.) and trades unions to be members of the working group if the legislative proposals affects their interests. This is to ensure compliance with the tripartite accord in place between the Government of Croatia, the Croatian Employers' Association and trade unions on promoting Social Dialogue.

The core team of civil servants consists of civil servants from the competent directorates or sectors, and if necessary civil servants from other directorates or sectors within the EB or other Ministries as necessary for the regulation and RIA process. The core team members work logistically, professionally and operatively on the RIA process and on the regulatory drafting process, and actively work on drafting both RIA documents and draft legislation. The core team does not need to be static in terms of membership. The number of team members can increase or decrease according to the requirements and tasks to be carried out. The EB's RIAC (or another member of the EB's RIA Unit) is a mandatory member of the core team. The core team and the RIAC are responsible to the head of the directorate or sector that is responsible for the overall implementation of the RIA process and for drafting the legislation for the proposal.

3.1.2. Timetable for the Working Group and core team of civil servants

The timetable is pre-determined by the adopted APL. The APL will set out in which quarter of the calendar year each legislative proposal is expected to be presented to Government for approval. That time goal represents the end of the RIA process for the Working Group and the core team. Typically, therefore, each legislative proposal will have its own internal timetable and deadlines and a schedule of activities in accordance with the **available time and resources for completing this work**.

The EB policy lead shall approve an outline timetable proposal for the Work Plan before the first official meeting of the Working Group. At the first official meeting of the Working Group the timetable will be considered, adjusted and harmonized. The timetable shall contain specific steps in the RIA process and in the regulatory drafting process along with a clearly defined timeframe. The relevant RIAC will actively participate in assisting the drafting of the timetable proposal and implementing the final timetable.

3.1.3. Plan for consultation and communication activities

The consultation process is an **essential and integral** part of the RIA process. **Without consultation, it will not be possible to draft the final RIA Statement.** Since consultation is conducted throughout the development of the RIA, it is necessary to pay particular attention to the stages of consultation.

Primarily, the **plan for consultation activities** consists of a comprehensive list of stakeholders from competent state administration bodies and the public sector, and other stakeholders from the business and civil sector, depending on their interest in the area of the legislative proposal under consideration.

The RIA process should actively encourage transparent and open participation from the public, interested national and local community groups and external stakeholders. Therefore, it is recommended that EB policy leads draft a short, summarized plan of consultation activities and determine the method of consultation, in accordance with RIA legislative requirements.

While it is up to the working group to decide the precise means of consulting, it is recommended that every consultation is available electronically on the Government e-consultation platform (<https://savjetovanja.gov.hr/>) to ensure wide dissemination and availability. More detailed consultation can be held on a one-to-one basis or in groups, round table forums, public meetings etc. depending on the nature of the legislative proposal and the degree of public and media interest it is likely to generate.

In the plan for consultation activities it is important to pay attention to the consultation deadlines that are prescribed by the RIA Act.

Public consultation on the draft RIA Statement needs to be conducted **for a minimum of 30 calendar days**. This minimum period can be extended if desirable.

Public consultation on the final legislation and RIA Statement needs to be conducted **for between 15 and 30 calendar days**. However, this period cannot be extended.

3.2. Problem definition and setting objectives

Problem definition and setting objectives begins with the following activities:

- **Analysis of the current position that will be regulated by the legislative proposal.** This should include results from monitoring and evaluating how the current legislation is working (where there is already existing legislation in place in Croatia, which governs the area of this new legislative proposal).
- **Examining the legislative proposal in terms of the likely content of the new regulation from the preliminary Initial Assessment and setting objectives.** Legislative activities develop where either new legislation is called for or current legislation needs to be amended to achieve specific Government goals. New or revised legislation will be adopted to implement the Government's desired programmes, to implement international responsibilities, or harmonize domestic legislation with EU legislation. Its purpose is to intervene in sectors where there are irregularities, deficiencies or needs that have been recognized in the sector, economic area or other parts of public activity that require Government intervention.
- **Conducting informal consultation with interdisciplinary bodies and other stakeholders, depending on the administrative area to which the legislative proposal applies.** Informal consultations will enable the EB responsible for drafting new legislation to examine the opinions and positions of the interdisciplinary bodies and others, internal and external stakeholders, on the problem and objectives that are to be achieved. Informal consultation is an important part of the RIA process. It is conducted using active methods such as letters, e-mail, work meetings, round tables, or using passive methods such as publishing materials on the EB's website. In order to conduct informal consultation on time, the EB's RIAC will indicate if there is a need for consultation while drafting the plan for consultation activities. The RIAC will assist in coordinating and monitoring the process for informal consultation with stakeholders.

The purpose of defining the problem is to try to describe why the problem has arisen. In many cases, the real cause of the problem may not be immediately obvious.

A common example where state intervention is required is where economic developments in the market are not able to maintain a level of service quality, not able to guarantee that market mechanisms (e.g. competitiveness) work efficiently and effectively, or not deliver adequate quality and safety of certain products and/or services. At this point government intervention is necessary in order to correct market failures or distortions.

In order to help define the problem in the best possible way it is necessary to answer the following questions, which serve as a guide for describing the problem:

- What is the problem that requires action?
- What type of problem is it that requires action?
- What is the scope of the problem?
- What are the basic causes of the problem?
- Who is impacted by the problem, how and to what extent?

The problem can be assessed in relation to size, costs, performance, trends, etc. At this initial stage, data on the scope of the problem should be compiled and collated from already completed analytical reports and information, statistical reports, monitoring reports, statistical data from domestic and international academia and institutions etc. Members of the working group and members of the core team can help suggest sources of data and information that will assist in describing the problem for the purpose of informal consultation and further formal consultation with interested public and stakeholders.

The scope and magnitude of the problem consequently impacts the choice of setting objectives and options for solving the problem. The aim of describing the problem in this way is to determine a baseline in order to set objectives.

Setting objectives provides a clear course of action and determines the desired outcomes to be achieved. The objectives always define an imagined future state in time which the changes to legislation should achieve. The objective presents characteristics of the desired state and therefore should be clear and realistic and in line with available resources and time constraints.

Objectives can be graded across several levels such as strategic, programme and project objectives. They can also be defined in terms of medium- and longer-term time periods linked to known Government, EU and international commitments, priorities and agendas. Objectives should be phrased to meet the requirements for “SMART” legislation described in these Guidelines.

3.3. Identifying options

Options represent a series of possible ways in which a problem under consideration can be corrected, removed or avoided. The draft RIA Statement will therefore need to set out an assessment of the expected costs and benefits of all the options considered and should be capable of being measured and evaluated.

When identifying suitable options, the EB policy lead working with the core team and RIAC, **must prepare at least two regulatory and two non-regulatory options** for solving the problem under consideration (Article 18, the RIA Act).

Non-regulatory options mean that there will be no new or amended legislation. Non-regulatory options include an obligatory "do nothing" option and at least one other. The 'do nothing' option simply presents how the current problem and situation may develop further without intervention by the EB.

Other possible non-normative solutions are actually alternatives to legislation. The most common non-normative options are: **influencing market change, information campaigns, educative programmes, fiscal and financial incentives, self- regulation, co-regulation and others.**

Further information on alternatives to legislation can be found in sections 3.4 and 4.10 of these Guidelines.

Regulatory options include new or amended legislation. In other words, the problem will be solved or its impacts reduced through legislative intervention. The most common normative options are: **new regulations or amendments to existing regulations at either the primary or secondary legislation level.**

It is possible to identify various possible options by considering the following questions:

- To what extent has the "do nothing" option been considered?
- In the "do nothing" option, is the development of the problem and its possible solution recognizable?
- Is there a second non-regulatory option presented as an alternative to regulation?
- Have the regulatory options been considered, including the regulation draft proposal for which the regulatory impact assessment is being conducted?
- Are the listed options explained in a clear and understandable manner?
- Are the listed options feasible given the resources, fiscal and economic costs?

In order to determine the possible options, it is useful to keep in view national and international experience, and the opinions and positions of relevant stakeholders obtained through informal consultation. In order to identify options, the most common ways to collect additional sources of information are:

- Analysis of available national and local research,
- Available analytical background and comparative analysis,
- Available research,
- Available evaluation of implemented public policy, including monitoring reports
- Informal consultation,
- Initial consultation,
- Expert opinions,
- Work experience of fellow civil servants,
- Results of implemented pilot projects and other initiatives,
- Creative thinking and viewing the problem from another angle.

If there are no available data, EB policy leads should consider with their working group members whether research should be commissioned to support further work on the proposal in question (and its monitoring and evaluation).

3.4. Alternatives to legislation

Where regulation supports growth, it can be hugely important for business. Extensive and unnecessary legislative control can stifle development by drawing away time and money that could be spent on customer service, product innovation or developing smarter business practice. "Bad" or unnecessary regulation imposes excessive costs, ties people up in red tape, blocks innovation or threatens important freedoms. The numbers and frequency of new regulation is seen by business, particularly by small and medium-sized enterprises (SMEs) as one of its biggest problems – particularly SMEs who can struggle to cope with the cost of change.

To address these issues, alternatives to legislation must form part of any proposed solutions put forward in RIAs. As a minimum, the Government expects at least two non-regulatory alternative options to be part of all RIA processes.

Alternatives to legislation include:

“Do nothing” is regulation intervention actually needed or can the same goals be achieved through existing regulation, better compliance with or better enforcement of the existing legislation? (Note that a proposal to simplify existing regulation becomes a legislative option)

Another alternative to regulation is to use **information and education** to empower consumers to take their own informed decisions. Business and consumer behaviour can be changed through more informed consumer choice, independent recommendation schemes, ratings systems, food labelling.

In Croatia, an information campaign was introduced to raise awareness of drivers about safe driving and the importance of taking no alcohol before or while driving. The campaign consisted of video clips run by a national television in prime time, yellow pages in daily newspapers and on the web of local internet pages.

In Croatia, an information campaign “No to drugs addiction” covered elementary schools with the aim of informing students about the risks of using drugs, which can be addictive. This was a targeted campaign aimed at teenagers in schools since they are more likely to experiment with drugs for various reasons.

Economic instruments can be used to modify behaviour by adjusting the economic incentives facing businesses and consumers. This approach allows individuals to make their own decisions, based on their estimates of whether the benefits of acting in a certain way justify the costs. For example using taxes (e.g. the duty on cigarettes), subsidies, quotas or permits.

Changes to the taxation system in Croatia are implemented by changing legislation. Bearing in mind that a tax drives the economic behaviour and responses of businesses and citizens, such changes can be viewed as an economic instrument leveraged through supporting legislation.

Self-regulation is an approach in which industry, a specific occupational group or profession imposes requirements on itself. In essence, rules are developed, administered and enforced by the market, or by their direct representatives.

Examples include:

- **Codes negotiated with wider interests** consist of rules negotiated, or at least discussed between an industry body and government, consumer organisations and other interested parties. For example in the UK there is a code for dealing with press complaints (the Press Complaints Commission).

- **Unilateral codes of conduct** are adopted by individual businesses that impose some form of self-restraint on the way they treat customers. Examples include retailers adopting a returns policy that is more generous than the statutory minimum.
- **Customer charters** cover all aspects of an individual business's dealings with its customers. They can encompass defined levels of performance across activities important to customers, penalties where standards are not met and public reporting of performance.
- **Voluntary agreements** are agreements between firms to change their behaviour (e.g. to add less salt to packaged food, to reduce CO2 emissions on cars).
- **Co-regulation** differs from self-regulation in that it involves some degree of explicit government involvement. For example *Treatments you can Trust*, covers independent providers of non-surgical Botox and Dermal filler procedures (UK).

In Croatia, for example, based on the Act on Legal Profession (OG 09/94, 117/08, 50/09, 75/09, 18/11), the Croatian Bar Association issues a Bar Tariff on lawyers' services. The Bar Tariff is issued after the Minister of Justice has approved the draft Bar Tariff.

Codes of Practice include:

- **Statutory Codes** which have a legislative backing. They typically allow, or require, a risk-based, proportionate, targeted and flexible approach to enforcement and compliance.
- **Approved Codes** have a special status which can be used in court. The code provides a "safe harbour" in that complying with it is a defence to a claim.
- **Recognised Codes** have their origins or foundation in statute, but are administered and enforced with no government involvement. For example, in the UK, the Law Society produces a professional code for solicitors.

3.5. Comparison of options

The RIA process continues by identifying the most significant positive and negative impacts for each regulatory or non-regulatory option, and in particular the impacts on the areas of economy, including financial impacts, health and social services and environmental protection.

The RIA therefore informs decision-makers on the expected impacts for each option in order to facilitate the decision-making process. Basing the final decision adopted on the evidence presented will help convince the public, business and society as a whole that the legislative proposal is the best way forward to address the problem or achieve the desired policy outcomes.

The expected probability of the impacts arising needs to be estimated against the following measures:

- none,
- probably small,
- significant and
- highly significant.

Anticipated impacts on the economy are assessed by the expected impacts on:

- A specific economic area,
- Economy as a whole,
- Market competition.

Expected impacts on a specific economic area are assessed through gauging the expected impacts on the small business sector according to the following criteria:

- Employment costs in business entities,
- Requirements for investments related to the operation of small and medium businesses,
- Operating expenses and operation of small and medium businesses,
- New administrative costs for small and medium businesses,
- Creation of new public authorities,
- Impact on property rights and
- Other expected impacts on the economy if they are considered significant at the discretion of the EB concerned.

Expected impacts on the economy as a whole are assessed in relation to the economic objectives that the regulation will impact on, particularly related to the following criteria:

- Economic competition and inflow of investments,
- Economic growth,
- Environmental sustainability,
- Achievement of social goals: social and economic equality, gender equality and regional equality,
- Specific regions and sectors,
- Macroeconomic environment,
- Market competition and
- Other expected impacts on the economy if they are considered significant at the discretion of the qualified authorities.

The business entities referred to in the assessment of a specific economic area refer to:

- Micro economic entities - with less than 10 employees
- Small businesses - from 10 to 49 employees
- Medium businesses - from 50 to 249 employees and
- Major corporations - more than 250 employees.

Expected impacts on socially vulnerable groups and other groups with special interests and needs, and the impact on health and social status of citizens are assessed in relation to the determined expected impacts on a specific economic area and the economy as a whole. These impacts are assessed in relation to the following criteria:

- Employment and labour market,
- Standards and rights related to job quality,
- Social inclusion and protection of special groups of people,
- Gender equality, equal treatment or equal opportunities,
- Protection / exposure of personal data of individuals,

- Public health and safety,
- Crime, Terrorism and Security
- Access to social protection, health and education systems and the consequences,
- Culture and
- Other social impacts, if they are considered significant at the discretion of the EB policy lead, RIAC or relevant Competent Body.

Expected impacts on the environment, the relevant assessment of likely impacts are estimated against the following criteria:

- Climate,
- Energy use,
- Air quality,
- Water quality, sea and water resources
- Soil quality and resources
- Biodiversity (flora and fauna) and landscape diversity
- Use of land,
- Renewable and non-renewable resources
- Waste management
- Environmental risks and the protection of industrial installations,
- Protection and safety of food and animal feed,
- Protection from the effects of genetically modified organisms,
- Protection from the effects of chemicals and
- Other expected impacts on the environment if considered significant at the discretion of the qualified authorities.

Assessing the impact on sustainable development includes a considered accumulation of mutual impacts on the economy, socially vulnerable and other groups and on impacts on the environment.

The following table sets out a range of questions that EB policy leads and RIACs should consider have been adequately and robustly addressed in the final RIA Statement.

IMPACTS	QUESTIONS
ECONOMIC IMPACTS	
Free market and competitiveness	What are the impacts of options on free traffic of goods, services, capital and labour? Can the option lead to deterioration of choices for consumers, higher market prices, and creation of new obstacles for suppliers and service providers, encouraging of uncompetitive market behaviour, creation of the monopolistic market?
Competitiveness, trade and inflow of investments	What is the impact of the options on the competitiveness of Croatian economic subjects in the single EU market and region? What are the impacts of the option on market barriers? Does the option encourage inflow of investments?
Operative costs and business of SMEs	Will the option lead to additional costs for economic subjects due to the new adjustments, compliance and fulfilment of the legislative conditions?

	<p>How the option affects the costs of economic subjects i.e. procurement of resources (raw materials, machinery, labour, energy, etc.)?</p> <p>Will the option include stricter business regulation?</p> <p>Will the option make access to finances more difficult?</p> <p>Does the option influence investment cycle and money flow in the investment project?</p> <p>Can the option influence product advertising (e.g. in a way which limits or forbids marketing)?</p> <p>Can the recommended option impact negatively on the creation of new business entities or have an adverse impact on their continuing to trade?</p>
Administrative obligations and obstacles for economic subjects	<p>Does the option influence the requirements on companies for more information, reports and other information to the state administration (for example, the kinds of data to be provided, the volume, reporting frequency, complexity of the procedure for data provision)?</p> <p>What is the impact of administrative obligations, especially on SMEs?</p>
Fiscal commitments of the state	<p>Does the option have an impact on the state budget?</p> <p>Does it cause additional obligations for the Government or other state institutions?</p> <p>Does the option require changes or restructuring in the public sector and how will that reflect on the state budget?</p> <p>Are the funds for the implementation of the option secured in the state budget and what impact is expected to the projections of the state budget (will the provisions increase or decrease demands for funds)?</p>
Property rights	<p>Does the option affect property rights (land, movables, and real estates)? Is the acquisition, sale or utilisation of property rights limited?</p>
Research and Innovation	<p>Does the option encourage or limit R&D?</p> <p>Does it make implementation and dissemination of new production methods, technologies and products easier?</p> <p>Does it affect intellectual ownership (patents, stamps, author rights, and other intellectual property rights)?</p> <p>Does it encourage or limit research by academic or industrial organisations?</p> <p>Does it encourage improvement of effectiveness/efficiency in the utilisation of resources?</p>
Consumers and Households	<p>Does the option affect consumer prices?</p> <p>Does it affect the quality or availability of goods/services that consumers have on their disposal or impact on consumer confidence?</p> <p>Does it affect the information available to consumers or their safety?</p> <p>Does it have significant consequences on the position of individuals/households, either as a long-term consequence either directly or indirectly?</p>
Regional Development	<p>Does the option have expected impacts on regional development in the country; for example, in terms of opening new or closing existing working places, or in terms of deterioration of the state's transfers towards regions and counties?</p>
Macroeconomic Environment	<p>Does the option influence economic growth or employment?</p> <p>How does the option contribute to the improvement of conditions for investment in and functioning of the market?</p> <p>Does the option have direct impacts on macroeconomic stability?</p>

SOCIAL IMPACTS

Employment and Labour Market	<p>Does the option make creation of new working places easier?</p> <p>Does it lead, directly or indirectly, to the loss of existing working places?</p> <p>Does it have special negative consequences for certain professions, groups of workers or the self-employed?</p> <p>Does it have special impacts on different age groups?</p> <p>Does it affect job opportunities?</p> <p>Does it affect the functioning of the labour market?</p> <p>Does it affect the harmonisation of the private, family and personal life?</p>
Standards and rights related to quality of the working place	<p>Does the option affect the quality of the working place and environment?</p> <p>Does the option affect availability of training, retraining (new qualification) and additional education for workers or unemployed people?</p> <p>Does the option affect the health, safety or dignity of workers?</p> <p>Does the option affect, directly or indirectly, current rights and commitments of workers?</p> <p>Does the option affect, directly or indirectly, current rights and commitments of employers?</p>
Social Inclusion and Protection of Special Groups of People	<p>Does the option affect access to the labour market and change of the working place?</p> <p>Does it result, directly or indirectly, in higher equality or inequality?</p> <p>Does the option affect equal access to goods and services?</p> <p>Does the option affect access to mediators for the job search or services of general economic interest?</p> <p>Will the public be better informed on the subject after implementation of the recommended option?</p> <p>Does the measure affect special groups of individuals (for example, most vulnerable or groups with highest risk regarding poverty; children; women; old and helpless; persons with special needs; unemployed; national, linguistic and religion minorities, asylum seekers), companies and other organisations, religion communities or special locations?</p> <p>Does the option significantly affect citizens of other nationalities or foreign seasonal workers?</p>
Gender equality, Equal Treatment, Equal Opportunities	<p>Does the option affect non-discrimination, equal treatment and opportunities for all?</p> <p>Does the option have different impacts on women and men?</p> <p>Does the option promote equality between women and men?</p> <p>Does the option imply different treatment of individuals or groups based on their gender, racial or national origin, religious beliefs, disability, age or sexual orientation?</p> <p>Can the option lead to indirect discrimination?</p>
Individuals, Private and Family Life, Personal Data	<p>Does the option impose additional administrative requirements on individuals and does it increase administrative burdens (for example, issuing public documents, additional filling of forms, additional certificates of other public institutions and organisations, does it limit the rights of individuals etc.)?</p> <p>Does the option affect the privacy of individuals (including their place of living or communication)?</p> <p>Does it affect the right of choice and freedoms of the individuals?</p> <p>Does it affect family life or legal, economic or social protection of family?</p> <p>Does it affect children's' rights?</p>

	Does the measure includes processing of personal data or does it impact on the rights of individuals to access their personal information?
Management, Inclusion of Public and Stakeholders in the Decision Making Process, Media, Ethics	<p>Does the option affect, limit or encourage the inclusion of stakeholders in decision making processes, as envisaged by special national and European legislation (for example, The RIA Act, Codex for the consultation with the public in the processes of the adoption of the Acts, other regulations and official documents)?</p> <p>Does the option treat all participants and stakeholders equally with due respect regarding diversity? Does the measure affect cultural or linguistic diversity?</p> <p>Does it affect autonomy of social partners in the areas for which they are competent? Does it affect, for example, collective negotiation at any level or on the right to collective action?</p> <p>Does the option affect public institutions and administration, for example, their competences?</p> <p>Will the option affect the rights of individuals and their relationship with public administration?</p> <p>Does it affect access by individuals to legal institutions?</p> <p>Does the option give more opportunities to the public for better informing themselves on the specific problem? Does it affect access by individuals to information?</p> <p>Does the option affect civil society bodies, other organisations, or political parties?</p> <p>Does the option affect media, pluralism of media, or freedom of speech?</p> <p>Does the option affect ethical issues (cloning, use of human body or body parts for financial profit, genetic researches, use of genetic information)?</p>
Public Health and Security	<p>Does the option impact on the general health of individuals/whole population, their life expectancy through impacts on the social-economic environment (working environment, income, education, professional occupation, diet)?</p> <p>Does the option increase or decrease frequency of health risks due to the presence of substances that are harmful in the natural environment?</p> <p>Does it affect health due to the changes in noise levels or the quality of air, water or soil?</p> <p>Will it affect health due to changes in the expected utilisation of energy and/or waste management?</p> <p>Does the measure affect health factors connected with life style as for example diet, physical activity and consumption of tobacco products, alcohol or narcotics?</p> <p>Are there especially affected risk groups of people (due to their age, gender, disability, mobility, regional or social group)?</p>
Crime, Terrorism and Security	<p>Does the option affect national security by creating security failures which increase crime or terrorism threats?</p> <p>Does the option open up the possibility for detection of criminals and/or their potential benefits from crime?</p> <p>Can the option increase the number of criminal activities?</p> <p>Does it affect the capacity of police forces?</p> <p>Will it affect rights to freedom and security, to a fair trial or the right to defend oneself if accused of a crime?</p> <p>Will it affect the right of victims and witnesses?</p>
Access to Social Protection,	<p>Does the option affect services in the sense of quality/access for all?</p> <p>Does it affect education or the mobility of workers?</p>

Health and Education systems and the consequences of them	<p>Does the option affect access of individual to public/private education or vocational education and specialisation?</p> <p>Does the option affect financing/organisation/access to social and health services?</p> <p>Does the option affect Universities and academic freedoms or self-government?</p>
Culture	<p>Does the option affect the preservation of cultural heritage?</p> <p>Does the option affect cultural diversity?</p> <p>Does the option affect inclusion of citizens in cultural manifestations or their access to cultural resources?</p>
ENVIRONMENTAL PROTECTION IMPACTS	
Climate	<p>Does the option affect the emission of greenhouse gasses (for example, carbon dioxide, methane and similar) to the atmosphere?</p> <p>Does the option affect the emission of substances that harm the ozone layer?</p> <p>Does it affect human capacity and capability to adjust to climate changes?</p>
Transport and Use of Energy	<p>Does the option affect energy resources for the needs of the economy?</p> <p>Does the option affect combinations of fuels (coal, gas, nuclear energy, renewable resources) used in the production of energy?</p> <p>Will it increase or decrease demand for transport (travel, freight and cargo)?</p> <p>Will the measure increase or reduce demand for energy and fuel?</p>
Air Quality	<p>Does the option affect emissions of acids, photochemical or harmful air pollutants that can affect human health, damage crops or buildings or lead to pollution of the environment (soil, rivers and similar)?</p>
Biodiversity, Flora, Fauna and Landscape	<p>Does the option decrease the number of biological species/specimens in certain areas (for example, deterioration of biodiversity) or does it increase the number of species (for example, by promoting their preservation or habitats)?</p> <p>Does it affect protected or endangered species, their habitats or ecologically endangered areas?</p> <p>Does the option in any manner affect migration routes, ecological corridors or protected ecological zones?</p> <p>Does the option affect the aesthetic quality of a protected environment?</p>
Quality of Water and Water Resources	<p>Does the option affect the quality of drinking water or groundwater?</p> <p>Does the option increase or decrease the quality of the water in coastal and marine areas (for example, due to the discharge of sewage, nutrients, oils, heavy metals or other pollutants)?</p> <p>Does it affect the available drinking water resources?</p>
Quality of Soil Resources	<p>Does the option affect the acidity, pollution or salinity of the soil?</p> <p>Does the option affect soil erosion?</p> <p>Does the option result in the loss of usable surface soil (for example, due to construction work) or increase the usable surface soil (for example, due to decontamination)?</p>
Use of Land	<p>Will the option create new, until now, unused land (e.g. new greenbelt land) that will be used in future?</p> <p>Does the option affect land designated as endangered due to ecological reasons (for example, re-designation of agricultural land as suitable for construction, or changes in agricultural use)?</p>

Renewable or Non-renewable Resources	<p>Does the option affect the utilisation of renewable energy resources (wind, water, sun, sea) or renewable food resources (for example, fish) such that these resources are used up faster than they can renew on their own?</p> <p>Will implementation of the option increase or decrease the consumption of non-renewable resources (for example, groundwater, minerals and ores)?</p>
Ecological consequences for business and consumers	<p>Does the option affect sustainable production or consumption?</p> <p>Does the option affect the relative price of products that are ecologically (non) compatible?</p> <p>Does the option encourage or limit the use of ecologically (non)compatible goods or services through changes in legislation on capital investments, credit, insurance services etc.?</p> <p>Will companies be more or less likely to pollute the atmosphere due to changes in the way they conduct their business?</p>
Generation of waste/use/recycling	<p>Does the option affect the production of waste (in terms of domestic and business waste, city waste, agricultural waste, radioactive or toxic waste)?</p>
Possible Ecological Risks	<p>Does the option affect the ability to prevent fires, explosions, accidental leaks, or other kinds of ecologically damaging events?</p> <p>Does the option affect the risks of unauthorised or unintentional discharges into the environment of ecologically harmful or genetically modified organisms?</p>
Animal Welfare	<p>Does the option affect animal health?</p> <p>Does the option affect animal welfare (for example, the humane treatment of animals)?</p> <p>Does the option affect the security of animal foodstuffs or feed?</p>
International ecological impacts	<p>Does the option affect the environment or measures to protect the environment in neighbouring countries or in other EU Member States (for example, new initiatives in coastal regions or plans to construct dams across rivers, which flow through other countries)?</p>

Expected impacts on market competition must be assessed using the questions prepared by the Competition Agency set out below.

If it is expected that the proposal will have a significant or highly significant impact on market competition, this must be flagged in the Preliminary Impact Assessment or subsequent RIA documentation.

The Competition Agency examines RIA proposals to ensure they do not breach Croatian competition legislation and that RIA proposals prepared by individual EBs adequately address competition issues. To help EB policy leads and RIACs, the Competition Agency has simplified the questions to be answered in this part of the RIA procedure.

Where the sponsor of the legislative proposal ticks YES to one or more of the filter questions listed below the proposed legislative proposal and PIA or RIA Statement should be sent to the Croatian Competition Agency for assessment, together with the completed competition checklist, for their expert advice and opinion.

The Sponsor of the bill (draft new law or regulation)		
Basic information about the new law or regulation		
Existing regulation and current environment checklist	YES	NO
Is this a regulated industry/market?		
Are there any regulatory barriers in the relevant sector/market? (Such as a limited number of firms - <i>numerus clausus</i> .)		
Are there structural, financial, technical or other barriers in the relevant sector/market relating to the provision of goods or services?		
Is there a legal entity, such as a local self-government unit or institution that is entrusted with the discharge of public services and at the same time performs or may perform an economic activity in the market?		
Is there an undertaking that is granted advantageous position over others in the market (e.g. it may hold exclusive rights, enjoy favourable ways of financing or may have access to privileged data etc.)?		
Effects of the proposal on competition		
Does the proposal bring benefits for competition on the basis of the comparison of the current regulatory content with the desired results?		
Is there a negative impact on competition, such as:		
leading to a discriminatory position of undertaking/s (e.g. by introducing restrictions for or placing in an advantageous position of a particular undertaking or a category/group of undertakings regarding the entry to and/or operation on the market)		
granting exclusive rights to a particular undertaking or a category/group of undertakings,		
erecting barriers to entry and other restrictions that hinder operation of undertaking/s in the market (such as structural, financial, technical regulatory and other barriers),		
setting the prices the undertaking may charge for the provision of goods or services		
other restrictions that lead or may lead to distortion of competition in a relevant market		
Contact for enquiries		

Note: The "Suppliers" or "entrepreneurs" referred to in accordance with Article 3 of the Competition Act, are considered to be companies, sole traders, craftsmen and other legal and natural persons performing economic activity involved in the production and / or transport of goods or services, government bodies and local and regional self-governments, that directly or indirectly impact the market, as well as any other legal or natural persons (associations, sports organizations, institutions, owners of copyright or related rights, and others) that operate in the market.

3.6. Consultation about the draft RIA Statement

Each stakeholder and individual (legal and/or natural person, interested group and citizen) is able to participate in the consultation and public discussion process. Doing so enables them to provide comments, suggestions and

opinions based on their own areas of interest and experience and suggest ways in which the options considered might be further developed or improved.

Consultation on the draft RIA Statement shall be conducted for at least 30 calendar days. It is good practice for the consultation process to be transparent, open and comprehensive. Therefore consultation must be for a minimum of 30 days and the EB policy lead may decide that the consultation period should be extended depending on the complexity of the matter, the degree of interest likely to be generated in the proposal and expected media interest and activity.

Consultation begins with the mandatory publication of the Information on the implementation of consultation on the draft RIA Statement on the central Government e-consultation website – savjetovanja.gov.hr. The form to be used for this is an integral part of the RIA System Regulations requirements. EBs should therefore use the form provided at Appendix 4 to the RIA System Regulations. The form provides the basic information on the implementation of the consultation process, information on the authority responsible for drafting the proposal, the legal sources, the immediate stakeholders and other stakeholders, and how the public and other interested groups (e.g. consumers, community groups) can participate in the overall consultation process.

The Information provided must include details of the subject of consultation, the consultation period, the deadline by which comments should be submitted, where these should be sent and other contact details in the EB for receiving comments, suggestions and opinions.

During the consultation period, the EB policy lead is responsible for conducting one or more public presentations on the subject matter of the consultation with assistance from the appointed RIA Coordinator and depending on the complexity of the subject area that is being regulated. Public discussions can be organized in the form of round tables, public presentations on the subject or focus group meetings with interested stakeholders. For each of these approaches, it is useful to prepare an agenda, list of participants, and issue invitations on time. Also, it is important to actively guide the discussion during the public presentation and make suitable arrangements to record the feedback of participants.

Once the consultation period is finished, **the EB policy lead should prepare a summary report** of the consultation. The summary provides information about the comments and opinions received, the consultation process and the outcomes of that consultation (i.e. whether the EB accepts the suggestions and comments or not, what changes are being made as a result including to the preferred option and the next steps) and publish this report on the website. The EB policy lead can also adopt other appropriate ways of communicating the consultation outcomes, for example, to publish it on its website, if this will help clarify what suggestions have been accepted or rejected and why.

Once the consultation process has been concluded, the draft legislation and the draft RIA Statement need to be updated based on the accepted opinions, suggestions and comments in the consultation and any new information or data, which have become available about the proposal.

3.7. Collecting the opinions of the competent bodies

Once consultation has closed and the consultation report completed, the EB policy lead then proceeds to complete the draft RIA Statement for submission, together with the draft legislative proposal, for approval by the relevant Competent Bodies.

The **Competent Bodies** set out in Article 17 of the RIA Act are the state administration bodies with competence for:

- Health and Social Welfare (now the Ministry of Social Policy and Youth, MSPM);
- Economy (now Ministry of Economy, MINGO, including any other body with relevant competence for an economic area in question);
- Environmental protection (now Ministry of Environment and Nature Protection, MZOP);
- Finance (Ministry of Finance, MFIN).

If the draft RIA Statement has identified impacts on market competition, small- and medium-sized enterprises (SMEs) or the labour market, it should also be submitted to the:

- Competition Agency (AZTN),
- Ministry competent for entrepreneurship and crafts (MINPO), and
- Ministry competent for labour, and the pension system (MRMS).

Competent bodies shall deliver their opinions on the draft RIA Statement in 15 working days from the day it is received.

Having received the opinions of the Competent Bodies in question, the EB policy lead then incorporates these as required within the amended draft RIA Statement and the legislative proposal as necessary.

In practice, it may be simplest for the EB policy lead to discuss first with colleagues or RIACs in those relevant bodies whether the legislative proposal does affect their interests and seek views from the Ministries and Competition Agency as appropriate.

3.8. Drafting the legislative proposal and the final RIA Statement

After consultation is complete and the opinions of the Competent Bodies obtained, the EB policy lead continues work on completing the final legislative proposal and the final RIA Statement.

The final legislative proposal needs to be drawn up based on the original concept proposal for legislation. That concept proposal will have set out the basis and scope of the subject matter that is to be regulated. That concept proposal will have already identified (within the preliminary IA) the main chapter headings for the final legislative proposal with a short explanation of the problem that is intended to be solved and the goals that are intended to be achieved.

The head of the competent directorate or sector within the EB has management oversight and responsibility for the legislative drafting process. In practice, this work will be undertaken by the EB policy lead, actively supported by the core team of civil servants and members of the working group (if such a group has been established by the EB). Contributions from other external experts or state administration bodies can be sought too as appropriate about the final legislative proposal.

The final RIA Statement is an updated version of the draft RIA Statement reflecting the suggestions, comments and opinions accepted as part of consultation together with new or revised analytical information to update the draft RIA Statement. The final RIA Statement should also include the recommended option.

The RIA Process will not fulfil its purpose and will not justify the resources spent if the option that will bring the greatest benefits compared to the likely costs is not recommended.

Therefore, **the recommended option should be the option that is ultimately likely to deliver the greatest benefits in comparison with the likely costs that are expected to arise.** Determining the recommended option must be based on thorough analysis, clear and concise presentation and explanation of the available data and information relating to the problem under consideration and proper and complete consultation conducted with the public and relevant external stakeholders.

In short, **the recommended option must be based on objective rather than subjective criteria, detailed analysis and - wherever possible - on robust, relevant and verifiable data.** It will need to set out separately the details of how the recommended option is to be implemented, its results monitored and evaluated and over what time period. The main results of the analysis and key data that show why this option has been selected as the recommended option must be presented concisely.

Fulfilling these requirements will facilitate understanding and approval of the recommended option by Government and Parliament as presented in the RIA Statement.

3.9. Consultation about the legislative proposal and the final RIA Statement

Once the EB has completed the final legislative proposal and the final RIA Statement, it then proceeds to hold a second round of consultation on these proposals. This needs to be made available for **public discussion to the public and interested parties for at least 15 calendar days and no more than 30 calendar days.**

Each EB publishes the legislative proposal and a final RIA Statement on the Government e-consultation platform. The form in Appendix 4 of the RIA System Regulation should be used (as before) for this consultation. The form provides the basic information on the implementation of the consultation process, information about the EB responsible for drafting, legal sources, immediate interested stakeholders and other groups, and how the public and other interested parties (e.g. consumers, community groups) can participate in the overall consultation process.

The information provided must include details of the subject of consultation, the consultation period, the deadline by which comments should be submitted, where these should be sent and other contact details in the EB for receiving comments, suggestions and opinions.

EB policy leads and RIACs should note that the current RIA Act **does not allow** this second round of consultation to extend beyond 30 calendar days.

During the consultation period, the EB is responsible for conducting one or more public presentations on the subject matter of the consultation with assistance from the appointed RIAC (or indeed others such as members of the working group if one has been established), and depending on the nature and complexity of the proposals. As before, public discussions can be organized in the form of round tables, public presentations on the subject or focus group meetings with interested stakeholders. Again, it is useful to prepare an agenda, list of participants, and send the invitations on time (bearing in mind the limited period available for the consultation to be

concluded). Also, it is important to actively guide the discussion during the public presentation and make arrangements for the feedback of participants to be recorded.

After the consultation has ended, the EB policy lead responsible for the proposal prepares (as before) a summary report. The report should reflect the comments and opinions received, the consultation process and the outcomes of that consultation (i.e. whether the EB accepts the suggestions and comments or not, what changes are being made as a result including to the preferred option and the next steps) and arranges publication of this report on the consultation website. The EB policy lead can also adopt other appropriate ways of communicating the consultation outcomes, for example to publish on its own website, if this will help clarify what suggestions have been accepted, and what suggestions have been rejected and why.

Once the consultation process has ended, the EB policy lead revises the legislative proposal and the final RIA Statement on the basis of the changes that have been accepted from the consultation and any new information or data which have become available relating to the proposal.

3.10. Quality Assurance – RIA Checklist

Once the legislative proposal and final RIA Statement have been amended, the EB policy lead should complete the RIA Control Checklist, which provides summary information about the proposal and provides a check that all necessary stages of the RIA process have been addressed and finished. The full RIA Control Checklist is set out at Figure 6 below.

The following checklist must be completed for all RIA Statement submitted to the GLO for approval.

Figure 6: RIA Control Checklist for the RIA Statement

RIA CHECKLIST			
Expert Bearer of Drafting:			
Statement Title:			
Name and Surname, Contact Information of the person that completes the Statement:			
Date:			
No.	Elements for Checking	Yes	No
Draft of the Statement Proposal/Statement Proposal			
1.	Preliminary Assessment (PIA)		
2.	Draft RIA		
3.	Final RIA Statement		
Title of the PIA or RIA			
4.	Title of the Statement is included and clear		
5.	Name of the drafting EB is included		
6.	The date is included		
7.	EB contact details are included		
Definition of problem			
8.	The Problem is clearly and concisely explained (max. 500 words)		
9.	Non-experts can understand the text		

Setting objectives		
10.	Goals are clearly and concisely explained	
11.	Expected results through achievement of the goals are clearly and concisely explained	
Identifying options		
12.	Main solutions i.e. policy options are established	
13.	There are 2 normative options	
14.	There are 2 non-normative options including the option “not to do anything”	
15.	There is a recommended option	
Comparison of options		
16.	Identified costs for every option	
17.	Identified benefits for every option	
18.	Summarised table completed	
19.	There are data, evidence, facts and analysis to support the options	
20.	Main data, evidence, facts and analysis are clearly set out	
21.	Main benefits for every option are compared	
22.	Main costs for every option are compared	
23.	Economic impacts are fully evaluated	
24.	Social impacts are fully evaluated	
25.	Impacts on environmental protection are fully evaluated	
26.	Options are sustainable	
Consultation – PIA, Draft RIA, Final RIA Statement		
27.	Summary on the manner of consultation and the period when consultation was conducted	
28.	Information is clearly and concisely presented	
29.	Published on the central website and the EB’s web page (if appropriate)	
30.	Contains a summary of the consultation held	
31.	Presents a clear overview of the consultation and processes undertaken after consultation	
32.	Represents clear summarised overview of all opinions obtained through consultation	
33.	Describes whether opinions obtained through consultation have been adopted or not	
Recommended Option		
35.	Recommended option identified	
36.	Clear comparison of all options made	
37.	All benefits compared	
38.	All costs compared	
Implementation and Evaluation		
39.	Monitoring – fully explains how the recommended option will be implemented	
40.	Monitoring – explains how the recommended option will be evaluated	
41.	Monitoring – a timeframe for monitoring is set out	
42.	Implementation - explains how the recommended option will be implemented	
43.	Implementation – implementation costs are collected and included in the data base	
44.	Evaluation – reference to when evaluation will commence is set out	
45.	Evaluation – date for formal evaluation of the final legislative proposal is set out	
Comments		



46.	PIA/RIA is used as an efficient communication tool for all as to the scope of legislation		
47.	Everything written is understandable		
48.	Information is presented in a clear and concise manner understandable to the average reader		
49.	Comments are forwarded to the RIA coordinator and the EB		
Where an answer is "No", denote the question number and explain the reason			

3.11. Submitting the Legislative Proposal and the Final RIA Statement for Adoption

After the second round of public consultation and completion of the necessary amendments to the final legislative proposal and the final RIA Statement, and following any necessary internal clearances within the EB, the RIA Act and RIA System Regulation require that the EB policy lead submits these to the line ministries and other relevant public administration bodies for their final opinion. They are also sent to the GLO for their opinion and approval.

EB policy leads should note that neither the final legislative proposal nor the final RIA Statement accompanying it can be submitted for adoption to the Government of the Republic of Croatia nor can the regulation be included in the meetings of the working bodies of the Government of the Republic of Croatia unless the RIA Statement is final.

The RIA Statement becomes final after the final RIA Statement has been given a positive opinion from the Competent Bodies and approved by the GLO.

4. TECHNICAL GUIDANCE FOR REGULATORY IMPACT ASSESSMENT

This section introduces step by step technical instructions for establishing and estimating probable impacts that may occur with changes in legislation, including the probable costs, benefits and risks to accompany legislative proposals.

A RIA gives decision makers an opportunity to make knowledge-based decisions supported with empirical analysis of policy solutions and alternative options. Properly prepared and completed RIAs describe the expected consequences of decisions and enable decision makers to compare outcomes of planned changes before introducing them. It is also possible to take preventive action to reduce or remove risks and unwanted co-impacts before they occur.

To ensure the full potential of the RIA is realised, the process of analysis should be systematic and impartial – all possible impacts, both, costs and benefits, should be included in the analysis and taken into consideration. Unwanted results, risks and costs can be partially reduced or even fully neutralized only after proper and objective acknowledgement and estimation. Basic analysis of possible costs and benefits of a legal initiative require proper quantitative data and qualitative information.

4.1. Issues of proportionality, analysis detail and terminology

The necessary level of detailed analysis depends on the scope of the expected consequences. More extensive impacts – benefits, costs and risks – should receive deeper and more detailed analysis. The most significant expected benefits, costs and risks of options demand more time and effort invested in the analytical process to evaluate all the expected impacts.

The EB Policy lead has limited resources and time at its disposal. Good planning of the RIA process and clearly defined priorities enable optimal utilisation of available resources. In the working plan, the Head of the Directorate/sector approves the resources and time for the each step in the RIA process. **The initial concept proposal (known as a regulatory thesis) and the accompanying Preliminary Impact Assessment are used as a starting analytical basis and give primary information regarding the size of the problem and instructions as to what level of analytical detail should be undertaken.**

This preparatory analytical work results in transparent information on the expected economic, social, fiscal, environmental protection and ecological impacts of possible options. Analysis must be clear and understandable to all interested parties and to society as a whole. A RIA should not contain too technical or professional terminology unless clearly explained. The definitions and terminology should be understandable and appropriate for the average citizen.

The results of the analytical work are presented in a PIA and in a RIA Statement. The structure of the Statement must follow a clear and logical sequence:

- an explanation of the problem(s) and their causes;
- a statement of the reasons why certain measures to solve the problem should be undertaken;
- a description of alternative options to solve the existing problems and to achieve the preferred goals; and
- an explanation of the reasons for preferring one option over the alternatives.

The level of analytical detail depends again on the level of sophistication required to reach a decision and the extent of the possible impacts that will result. The more significant a decision is, the greater the level of analysis required. All professional and technical terms must be explained in the Statement and analysis to make the assumptions presented intelligible to a wider audience.

Ultimately, the guiding principle here must be that a RIA Statement must be understandable to the average citizen and others who are not experts in the relevant area.

4.2. Defining the target groups – who implements the proposal, who complies with the proposal

The first step in exploring possible impacts caused by legislative changes should be to establish, and, where possible, narrow down, the affected **target groups** and defining broadly the expected impacts.

One change in legislation may cause several parallel impacts to several target groups. There will likely be other interested parties who have to **implement** the change and enforce the decisions, usually government agencies or non-governmental bodies carrying out relevant policies, and there will always be an interested party who has to **comply** with those changes to the legislation. Often the circle of those who comply with planned legislation is broader and more diverse and may consist of a range of possible private bodies, enterprises or citizen groups.

Before continuing with the description of the detailed impacts and calculating the numeric benefits and costs of selected options it is useful to define the broader areas of impact and possible subcategories (a list of key questions for the RIA is included in the Table in section 3.5 above). It is important to take into account that each option may bring with it several simultaneous impacts affecting several target groups. Very often, changes in legislation require government to intervene and may affect the state budget (and thus appear as a cost of implementing the preferred option) and simultaneously the same change may have social, economic or environmental impacts depending on the nature of benefits planned to be achieved by the legislative proposal.

4.3. The benefits, costs and risks of possible options

As already explained, an integral and essential part of the RIA process is the analysis of expected costs and benefits in order to establish, in a transparent manner, where the balance between the benefits and costs may lie.

Benefits, costs and risks are related to the long-term policy intervention.

For example, if a new school is built, the cost of construction is a fixed cost. The costs created due to the employment of the workers represent variable costs and the education that the school enables for its attendants represents a continuous benefit.

Benefits

Expected positive impacts, as proposed by the EB and targeted to solve the problem, are defined as benefits. Benefits may improve the general situation for both private and public interested parties and stakeholders, for administrative staff and government institutions, individuals and social groups, non-governmental organisations, enterprises and broader business sectors, and society as a whole.

Benefits may be presented in a variety of ways. They may occur as an improvement to public health, improved access to material goods, or an increase in the level of net wealth, income or as more intangible positive measures, such as an improvement in the level of education, social welfare or the environment. There may be specific economic benefits for entrepreneurs, small and medium size enterprises, for business communities or the broader business sectors that enable them to widen their influence on the market as a whole or the economic sector most particularly affected. Other types of business benefits include a decrease in administrative burdens and costs, simplification of administrative processes and procedures, a decrease in the overall tax burden, a decrease of the par fiscal fees, or new opportunities for improving capital investments or increasing profit margins.

Benefits for society as a whole can be achieved through:

- an increase in the quality of the public health system services,
- more efficient public administration and more accessible public services,
- better approaches to social welfare and education,
- decreases in the rates of crime or a general increase in public security,
- improvements in the quantity or quality of cultural events,
- an improvement in equality and equal opportunities, through an increase in overall social inclusion etc.

Benefits for the environment and the sustainable development can be achieved through:

- more efficient energy management and utilisation of land,
- saving waste management,
- increase of the possibilities for the utilisation of the renewable energy sources and etc.

Costs

Expected negative impacts are defined as costs. Costs may be expressed in direct monetary terms or more generally as a worsening of the situation for individuals, social groups, organisations and state institutions, entrepreneurs, the opportunities to do business or society as a whole. For individuals, costs may occur as a reduction in their income, or limit their freedom. For private companies costs may occur as direct increase of administrative burdens, a decrease in their profit margins, or increase in capital expenditure, or opening up markets to new external competition. Costs can arise either in the form of losses or in the form of unachieved benefits. Costs can be grouped differently by different characteristics but most often they are based on the division regarding those who will bear the costs (whether direct or indirect) and their relationship to the degree of utilisation of the resources involved (fixed and variable costs).

Direct (individual) costs are those that can be directly assessed where such costs arise and who they will affect. Direct benefits, accordingly, are benefits that affect persons or institutions in a direct manner and can easily be linked to the legislative proposal.

Indirect (general, mutual) costs cannot be linked directly to the legislative proposal. Indirect costs may not also clearly identify where and on whom they fall. They may arise as a result of different criteria, procedures and methods proposed. Indirect benefits affect persons or institutions differently and often the source of these costs cannot be directly related to the intended outcome. Indirect impacts can also occur through changes in the social, economic or natural environment.

Risks

A risk is the probability of an unwanted consequence that may or may not happen, combined with the extent of the potential loss that may be incurred. By definition, risks represent negative impacts. By accepting the risk and uncertainty of the outcome a positive outcome can be achieved. Entrepreneurship is an example of the conscious acceptance of risk and potential loss in order ultimately to realise an entrepreneurial venture that will bring positive outcomes, income or an increase in welfare.

A risk is the impact of uncertainty on objectives. Impacts can be positive, negative, or may differ from expected results. A risk can also have the possibility of achieving the desired objectives. In this context, risks should be recognised in the RIA process.

Some risks can be predicted and estimated. In such cases it is possible to plan certain means in advance in order to alleviate or indeed remove them. It is therefore essential that the RIA process recognises potential unplanned consequences and includes these in the assessment. A clear definition of risks is an important step in the RIA process and it may promote better interest and engagement of relevant stakeholders during non-formal and formal consultation. Engagement of stakeholders may facilitate early identification and more precise definition of all the risks and also open new possibilities to alleviate or neutralize such risks.

4.4. Quantitative and qualitative measurement of the expected impacts

As far as possible the costs, benefits and risks **should be expressed quantitatively, preferably monetarily**. Quantitative expression allows very specific comparison of alternative options. It is therefore desirable, whenever possible, to express numeric indicators of the costs and benefits to the economy on the basis of the annual averages/indicators and measurable sizes with the obligatory reference to the data source. Single costs and benefits that are occurring just once are expressed individually with reference to the data source.

If the costs and benefits cannot be expressed monetarily, then the expected impacts of possible options are expressed descriptively i.e. qualitatively. Impacts described in this way can still be compared, but precise comparison becomes more difficult as it is based on more subjective evaluation and criteria.

One way of dealing with the benefits and costs that cannot be determined quantitatively or numerically is evaluating options based on an importance scale of 1 to 10. By assigning a rating from 1 to 10 according to the importance of the options considered enables an approximate and subjective comparison to be developed. The criteria for rating the options should be based as far as possible on objective data, information or previous analyses. The criteria adopted for ranking the options presented should be clearly and objectively explained.

AN EXAMPLE of calculating non-monetised impacts in the environmental and health sectors

When a policy affects something that does not have a market valuation, it may still be helpful to monetise the effect to be able to compare different options. So, for example, if a policy proposal would safeguard an area of natural beauty, this is a benefit of the policy but is difficult to put a valuation on it directly.

This can be done through looking at society's preferences or in the way people may be expected to behave or the price a consumer may be willing to pay for a particular product (known as "revealed preferences"). An example would be looking at differences in prices between similar houses in similar areas, the only difference being that some houses overlook the sea and others do not. The difference in prices between them would then be the cost of the view, as observed through looking at what people are willing to pay to secure that view.

Looking at revealed preferences is not always possible, as the information does not exist or it is too difficult to isolate the effect of the preference. In this case, values can be assigned to a given intervention by looking at stated preferences. This would mean directly asking people the question about the value they would place on a product, and averaging across all of those asked to get an average societal value.

Stated preferences are a method often used in valuing environmental and health benefits and costs. Using the example above of a policy that safeguards an area of natural beauty, people can be asked whether they would be interested in visiting the area and what they would be willing to pay to go to a national park there. This would give people's stated preference.

Health is a more difficult product to place a value on. Some countries do use monetised health values, based on the value placed on a life. This can be difficult to get, as the subject itself involves subjective and emotive values. The UK has done this through looking at what people would be willing to pay to reduce the likelihood of death on roads and trains. A value of a life can then be derived from this, which can then be used to value health interventions.

An alternative would be to look at the insurance pay outs on life insurance. However, this can be controversial, and it is also unlikely that the societal value of a life will be the same in every country. Alternative assessments can be used based on the number of lives saved, or the health benefits, resulting from policy interventions and compare them. This would allow for comparison between different options, but would not allow for easy comparison if there are further benefits and costs that can be monetised, or where there are qualitative costs and benefits.

It is important throughout this to be transparent. Explaining assumptions and judgements about them clearly will allow people to look at why the final proposal is presented as it is. This is especially important for RIAs being published for public consultation, where such information will help people responding to the consultation to see the likely effects, and use them to inform their response to the consultation accordingly. It may also be helpful to display some sensitivity analysis at this stage.

In some cases the benefits of options will be known in advance. Where this happens, the options are compared according to the criteria set out for implementation. Since the benefits for all options are known in advance, least-

cost analysis can be applied for the comparison of the options. The analysis requires the most economical approach to be adopted which will achieve the set goals with an additional review of the potential risks.

An assessment of the costs, benefits and risks associated with a proposal and the options for implementing it invariably means that the RIA process will involve a lot of **assumptions**. It will therefore be impossible to claim with absolute certainty that something will or will not happen or that all the estimated costs, benefits and risks will arise as a result of implementation of the proposal.

The basis for making robust assumptions is therefore the extent of available information, knowledge about the current position and experience of its implementation, as well as analysis and statistical trends. If there is no existing experience or the availability of information is limited, then a theoretical or scientific or professional justification of the relevant assumptions will be used.

The expected impacts on individual economic sectors follow the same general principles. Which sector is affected will be determined by the legislative proposal. Selecting the relevant sector should be made on the basis of the **NACE** (hrv.: Nacionalna klasifikacija djelatnosti). Sectors are defined on the basis of the broad economic activity concerned. Every sector has sub-sectoral divisions. NACE has been adopted by the Croatian Government and is published in the Official Gazette. The current NACE divisions are available at:

http://narodne-novine.nn.hr/clanci/sluzbeni/2007_06_58_1870.html

http://narodne-novine.nn.hr/clanci/sluzbeni/2007_07_72_2278.html

4.5. Option appraisal - deciding whether possible options give rise to benefits, costs or risks

Every possible option will have specific consequences. For example, specifying a minimum price of a product that is above the current market price will have, consequently, direct costs for consumers of the product.

A change in the period of mandatory education will have direct impacts on the state because it will be necessary to secure resources for the additional year(s) of education. However, it should also result in benefits for students because it will increase their overall education levels that will consequently increase their potential income later in their careers. An increase of a minimum product price or the costs for extending education periods, covered by the state budget, represent direct impacts.

If prolongation of the mandatory education period were to increase national productivity through a more educated workforce, leading to increased international competitiveness and thus higher salaries and higher GDP, which in turn leads to higher tax revenues for the state, then those are examples of indirect impacts.

If the state imposes additional administrative burdens on companies and these create extra costs for the enterprises concerned, these are direct impacts. On the other hand, if these additional burdens also have the effect of discouraging new businesses to enter the market, (because the costs of entry are now too great), then these are indirect impacts.

Unplanned consequences might occur through changes to public policy. For example, if there is an initiative to implement new financial incentives for hospital construction which is based on a range of indicators that do not cover all the services that a hospital may provide, that can lead to a situation where proposals for new hospitals only focus on the indicators identified. By limiting the focus to a pre-determined range of indicators, there would

likely be a detrimental longer-term impact on services that are not included. Such an unplanned consequence can be mitigated where information regarding all relevant aspects of hospital activity are included.

AN EXAMPLE OF UNPLANNED CONSEQUENCES: Prohibition of smoking in public places in the UK

During the implementation of the smoking prohibition in the United Kingdom some unplanned consequences emerged. It was expected that people who smoked would visit public houses (pubs) less often, decreasing in that way the pubs' incomes. In fact, not only did smokers reduce their pub visits, they also started visiting friends etc. in their homes where the smoking prohibition was not in force. As a consequence, the unplanned exposure of children and other members of the household who lived there resulted in certain unexpected health implications and costs.

Unplanned consequences can be considered as a form of risk which requires management to decrease or remove entirely the likelihood of the unplanned consequences occurring. The action that is taken to mitigate these unplanned consequences should be proportional to the likelihood of them occurring and the significance of the impacts that would arise. Unplanned consequences which affect a large number of people and impose large costs are more important to mitigate than those which affect a small or negligible number of people and/or impose insignificant costs. How such consequences are managed can be tracked by continuously collecting and analysing available data or information that can help support the actions taken to mitigate the likelihood of them occurring.

4.6. Evaluating the expected value of the benefits, costs and risks

There are several methods for analysing the expected values of benefits, costs and risks, such as:

Expected value	This method is used when there is uncertainty in accurately calculating the identified benefits and costs and their potential trends. The expected value is calculated by multiplying the range of possible values by the likelihood or probability of their occurring.
Range of values	This method is used when there is uncertainty in accurately calculating the identified benefits and costs and their potential trends but there is a wide range of values that could arise. In this case, it is possible to identify all the values that may arise and indicate which is the most likely or probable value. That will lie inside the range of all the possible values and be judged the most credible or likely. In practice, it is usually the middle (or average) value given.
Analysis of sensitivity	This method is used when the benefits and costs are based on a range of assumed values. For example, if a minimal price for a product is imposed, costs will arise for consumers who want to continue buying the same product. It can be expected that the number of buyers will decrease but the extent of that decrease may not be known. In order to calculate the direct costs that buyers will have to bear, the expected number of buyers that will continue buying product is multiplied by the

price increase. From this, a full range of potential costs can be calculated according to estimates of how many buyers will continue to buy the product depending on what price increases are considered.

The impacts of a certain option can sometimes be predicted using current domestic and international experience. Such an approach allows plausible assumptions to be made about expected impacts, their expected costs and benefits or the basis for further analysis. Responses obtained during consultation can help further develop the assumptions, which will improve the overall quality of the costs and benefits assessment.

There is a range of economic valuation techniques². The choice of technique will depend on the particular impact under consideration and on the availability of data. In some instances, it may be possible to apply several techniques to the valuation of the impact, which can provide a useful cross-check on the reliability of the estimates obtained. Many 'missing' market values occur in the environmental benefits and costs, and the remainder of this section discusses the use of valuation techniques in relation to environmental impacts.

There are three main methods for calculating economic values:

- **Using market prices;**
- **Using information on individuals' preferences;**
- **Benefit transfer.**

Valuation using market prices

Change in productivity

This method values environmental change by observing physical changes in the environment and estimating what difference they will make to the value of marketed goods and services. This approach is applicable in calculating direct and indirect use value. Water pollution can reduce fish catches, and air pollution can affect the growth of crops. In both instances, the environmental impact reduces marketed output, which may be valued using market prices.

Human capital cost valuation

This method may be used to value the impact of environmental hazards on human health. Environmental 'bads' such as air and water pollution or the use of pesticides reduce the quality of the human capital stock, and therefore lower the economy's productive capacity. To apply the human capital cost method it is first necessary to determine the relation between the hazard and human health, by expressing the health impact in terms of premature death, sickness or absenteeism. Sickness can then be valued using medical and health care costs. Absenteeism is valued in terms of lost earnings (this assumes that earnings measure the contribution that the absent worker would have made to output).

Valuation using information on individuals' preferences

² Economic Impact Assessment (EIA) for Small and Medium Enterprises (SMEs) Manual, BIZimpact II project: Improving Information to the Croatian Business Community, 2014., Zagreb. Available at: <http://www.bizimpact.hr/download/documents/read/economic-impact-assessment-eia-for-small-and-medium-enterprises-smes-manual> 47

Often it will not be possible to link the environmental impact to a change in marketable output. In these cases, the willingness to pay has to be estimated indirectly, using a range of other techniques, such as:

Replacement cost or preventive expenditure method

The economic value that individuals attach to the environment can sometimes be inferred from the cost of preventing unwanted environmental impacts, or of restoring an asset to its original state after it has been damaged. For example, the costs of air pollution-related acid depositions could be estimated using the costs of restoring damaged physical infrastructure, or the costs of soil erosion could be estimated using the costs of providing preventive terracing.

Contingent valuation method

The contingent valuation method (CVM) relies on direct questioning of people to determine their willingness-to-pay valuation of an environmental impact. A detailed description of the environmental impact is provided, and interviewees are then asked what they would be willing to pay (WTP) for a hypothetical environmental improvement, or to accept (WTA) as compensation for an environmental deterioration. The contingent valuation approach may, in principle at least, capture the total economic value (use and non-use components), whereas other techniques may only provide estimates of direct or indirect use value.

Surrogate market valuation method

Whilst an environmental good or service may not be traded directly, it is sometimes possible to find a good or service, related to the non-marketed environmental item, that is sold in markets. In this situation, the individual may reveal his or her preference for both the market and non-market good or service when making a purchase. It may then be possible to separate-out the environmental component of value from the observed market price, and in this way use this component of market price as a 'surrogate' for the environmental value. There are two main techniques which have been used for applying the surrogate market method: travel cost method and property value (hedonic price) method. Each method is described, together with examples of their application in developing countries.

Travel cost method

Many natural resources (e.g. a national park or lake) are used for recreational purposes. The travel cost method bases its valuation on the money and time costs of visitors to such recreational facilities.

Property value (or hedonic price) method

The hedonic price method is based on the idea that differences in property prices can be used to infer the value which individuals attach to the difference in environmental quality between properties. For example, the difference in the price of two properties which differ only in, say, the local air quality, will provide a measure of the value which people give to difference in air quality. Even when properties differ in other ways, it may still be possible (though it is a complex task) to uncover the implicit prices of environmental quality using statistical techniques to separate out the contribution of each factor to the total market price.

Benefit transfer

Benefit transfer involves deriving estimates of economic value in one context for use in a different context, where the data required for the estimation are not readily available. For example, the value of health damage from air pollution in one city might be used to estimate health costs from air pollution in a different city or,

more controversially, the values derived in one country might be transferred for use in a different country. Though this can provide quick and low-cost estimates, it is subject to a number of limitations (see the Table below).

The Table below summarises the main valuation techniques and lists some of the advantages and disadvantages of each method.

Valuation Method	Advantages	Disadvantages
Change in output of marketable resources and goods	Easily understood and applicable, provided dose-response relation is known. Uses actual market prices	Difficult to isolate the effect of given impact on observed change in production Market prices may be a poor indicator of willingness to pay Only relates to use value
Human capital cost	Epidemiological dose-response data Health expenditure data, and Earnings data are available	Likely to understate full value of health Difficult to isolate separate causal factors in ill health Moral and ethical objections
Cost based approaches (Replacement cost or preventive expenditure)	Ease of application, if relevant technical and cost data are available	Preventive expenditure may understate environmental value Replacement cost may understate full reinstatement of environment quality May not cover non-use values
Contingent valuation	Potentially covers most components of total economic value Practice improving with greater experience in its use	Time-intensive and expensive to implement Biases through use of stated rather than revealed preferences Other biases associated with questionnaire design and survey practices
Travel cost	A fairly well developed and used method	Significant data requirements Problems in reliably interpreting the statistical findings Measures use value only
Property valuation/hedonic pricing	Applicable where there is: Availability of property price data Availability of data relating to determinants of property prices	Assumes market values capture the environmental good's value Problems in segregating the influence on property prices of environmental factors from that of other explanatory variables Measures use value only
Benefits transfer	Time saved and inexpensive Applicable where value estimates are available from other comparable studies	Inappropriate transfer of values from sites where primary analyses were conducted to sites experiencing different, non-comparable conditions

There are three main stages in the application of economic valuation to impacts.³ The first involves the identification of the potential benefits (positive impacts) and costs (negative impacts). The second stage involves the valuation of the identified costs and benefits in economic terms. Third, where the benefits and costs are estimated to continue into the future, the discounting technique is used to convert future impacts into equivalent present day values.

The first step in the financial appraisal is to record on an annual basis the monetary value of the economic benefits and economic costs of the regulation. If the regulation is to last for a specified number of years ('sunset clause'), the benefits and costs should be estimated for each year. Otherwise, the benefits and costs should be estimated for a minimum of 10 years. The difference between the annual benefits and costs is the net benefit flow. Net benefits received in the future are less valuable than benefits received immediately. The reason for this is simply that the benefits received in the future are less certain and even if they are certain to occur, there is an opportunity cost in terms of the delay in receiving the benefits.⁴

In order to combine each year's net benefit flow into a single aggregate figure, they need to be converted into equivalent terms. This is done by the process of discounting, which converts future values into an equivalent present period value. This important process can be explained by using a simple example. Suppose a firm or individual is asked to choose between €100 today and €100 next year. The choice will be in favour of €100 today, which can then be placed in a savings account, earning, say, 10 per cent a year. After one year the interest payment will have increased the savings account balance to €110. So the prospect of €100 a year from now is equivalent to only €100 divided by 1.1 = €90.9 in present period terms. This process of reducing future values to their present period equivalent value is called discounting. If the example is extended to a second year, then we need to allow for the fact that interest will be earned on the previous period's interest, increasing the savings balance to €121 (€110 + €11). The payment of €100 two years hence would therefore be discounted to give a present value of €100 divided by 1.21 = €82.6. A general expression for calculating the net present value (NPV) is:

$$NPV = \sum_{t=0}^n \frac{Bt - Ct}{(1 + i)^t}$$

where Bt and Ct are the benefits (revenues) and costs (expenditures) in each year t , i is the discount rate (rate of interest) and n is the life of the project. The calculation of NPV can be easily undertaken using discount tables.

The NPV criterion follows directly from what has already been discussed, namely that a project is worth proceeding with if its NPV is positive.

³ Ibidem, footnote 2.

⁴ This is equivalent to the opportunity cost of financial saving, where borrowers have to compensate lenders for the income they are forgoing, by paying a rate of interest.

Discounting and Calculation of Net Present Value

Suppose the proposal is expected to give annual benefits for 5 years of € 500. The annual costs are €350. The discount rate is 10%.

Year	0	1	2	3	4
Benefits	500	500	500	500	500
Costs	350	350	350	350	350
Net Benefits	150	150	150	150	150
Discount Factor (for 10%)	1.0	0.909	0.826	0.751	0.683
Discounted Net Present Value	150	136.35	123.9	112.65	102.45
The total net present value = 150 + 136.35 + 123.9 + 112.65 + 102.45 = € 625.35					

The RIA Calculator as a RIA monitoring tool - building an evidence base of costs

Given that there is **limited economist resource to support RIAs** in the Croatian government for the short to medium-term, in-depth cost benefit analysis will be limited. Therefore, it will be important to maintain some basic tools that a non-economist can readily use that help ensure cost benefit analysis is not deemed too challenging. The focus needs to be on developing essential data for officials to use.

Establishing a **unit costs database** that brings together key cost estimates (e.g. education and skills, employment, economy, health) in a single place from national costs and external studies, will provide officials with an “off-the-shelf” menu of costs for the RIA analysis. These costs can be used to inform proposals for the implementation of new legislation, the redesign of legislation or their evaluation. Having access to such information will help officials undertaking a cost benefit analysis estimate the overall costs and benefits associated with the legislative proposals.

THE UK’S UNIT COST DATABASE AND THE IMPACT ASSESSMENT CALCULATOR

An example of what could be developed for Croatia is the **Unit Cost Database** produced by New Economy Manchester. See: <http://neweconomymanchester.com/downloads/3316-150327-Unit-Cost-Database-v1-4-xlsx>

The database contains costs across the following themes: crime; education and skills; employment and economy; fire; health; housing; and social services. The data have been subject to a rigorous validation process, including assessing the robustness of the original source documentation, considering how data have been derived from constituent cost elements, comparing costs to related data, and exploring the availability of more recent/robust sources.

The **Impact Assessment calculator**, produced by the UK Government, with a worked example of what could be implemented in Croatia is: <https://www.gov.uk/government/publications/impact-assessment-calculator--3> Provides help for policy officials to calculate the figures needed for their impact assessment. The calculator automatically generates the main figures needed for the impact assessment summary pages, using the profile of costs and benefits for each option.

The RIA Calculator **helps to simplify the cost benefit analysis process** for officials. The calculator automatically generates the main figures needed for the RIA, using the profile of costs and benefits for each option. It may be

helpful to develop this tool further to support the RIA process in Croatia. Embedding this tool across Ministries involved in RIA development may help to overcome the challenges faced with little or no economist input and limited technical expertise and support in cost benefit analysis.

4.7. Guidance on option comparison and a preferred option

Comparison of the policy options is useful for assessing whether a proposed policy intervention is worth undertaking. If the benefits exceed the costs, then the policy is justifiable.

There are two parts to this:

- assessing whether the proposed policy intervention is worth undertaking,
- cost-benefit analysis.

This can be illustrated with an example in the following table:

Option	Expected benefits	Expected costs
Option 1 “not to do anything”	0 €	0 €
Option 2	1.5 billion €	1.0 billion €
Option 3	0.6 billion €	0.1 billion €
Option 4	2.0 billion €	2.5 billion €

In this table, option 1 gives the baseline scenario. This is what would happen in the absence of any sort of policy intervention. Other options should be compared against this basis.

The first thing that is clear in the above table is that policy option 4, whilst having the greatest benefits, has costs that exceed the benefits, and so is likely to be ruled out on that basis. Policy options 2 and 3 both have benefits that exceed the costs, and both have an expected benefit of €0.5bn, which makes both justifiable. The value of the benefits of Option 2 are greater than the value of the benefits of Option 3. The value of the costs of Option 3 are, however, much smaller than the value of the costs of Option 2.

These options can be compared further using cost-effectiveness analysis, which compares the ratios between the costs and the benefits. In the table above, policy option 2 has a return of €1.50 for every €1 spent (i.e. the expected benefits divided by the expected costs), while policy option 3 has a return of €6 for every €1 spent. This indicates that option 3 should be preferred.

The recommended option in this case is option 3 because it yields the biggest return in relation to the value of the costs invested.

4.8. SME test

The Economic Impact Assessment (EIA) for Small and Medium Enterprises (SMEs) Manual⁵ produced for the Ministry of Entrepreneurship and Crafts (MINPO) has detailed guidance on cost benefit analysis.

The potentially damaging effects of poorly designed regulation on SME performance means that policymakers need to give special attention to improving the regulatory environment for small businesses.

Since small businesses often face higher compliance costs (as a share of turnover) than do larger businesses, good practice gives explicit attention to the potential benefits and costs of the proposed regulation for the SME sector. An increasing number of EU Member States include special provisions for assessing the likely effects of regulations on small businesses, particularly micro-enterprises, where the likely negative (and positive) impacts of a proposed regulation on the SME sector are shown separately from the overall assessment of benefits and costs. This is often referred to as a '**SME Test**'.⁶

Within EIA for SMEs Manual there is a SME test and the following questions are asked:

	SME Test	Yes	No
1	Will the regulation have an effect on the economy and particular economic sectors?		
2	Will the regulation affect the sector's economic performance (e.g. output, employment, productivity, investment, etc.)?		
3	Will the regulation impose additional regulatory costs on the sector?		
4	Will the regulation affect the sector's competitiveness?		
5	Will the SME sector's economic performance be affected by the regulation		
6	Will the regulation impose additional regulatory costs on SMEs?		
7	Will the regulation affect SMEs' competitiveness?		
8	Will the regulation have a significant impact on micro-enterprises?		

The level of detail and quantification in the RIA Statement will be greater than in the PIA. The resources committed to the analysis should be related to the importance of the problem that the regulation is intended to solve, but the RIA Statement must provide sufficient information and evidence to allow the policymaker to make a decision of whether the proposal is 'fit for purpose'.

4.9. The Standard Cost Model

The Standard Cost Model (SCM) is a methodology for assessing the administrative burdens that legislation imposes on business. It is a quantitative methodology which can be adopted by any country and at any level. The SCM can be used to gauge the impact of a single law, designated areas of legislation or to undertake a baseline assessment of the total administrative burdens of all legislation in a country. In addition, the SCM can also be used to assess the impacts of simplification proposals as well as the administrative burdens of new legislative proposals.

⁵ Ibidem, footnote 2

⁶ Annex 3 discusses the experience and practice of including lighter regulation for SMEs as an objective in RIA, in the UK, Estonia and the European Commission.

Further information from the European Commission website⁷ states that administrative burdens are calculated on the basis of the average cost of the required administrative activity (Price) multiplied by the total number of activities performed per year (Quantity). The cost is generally estimated by multiplying a tariff (based on average labour cost per hour including overheads) and the time required per action. Other types of costs (outsourcing, equipment or supplies' costs, etc.) are taken into account as appropriate. The quantity is calculated as the frequency of required actions multiplied by the number of entities concerned.

The core equation of the SCM is $\sum P \times Q$, where P (for Price) = Tariff x Time and Q (for Quantity) = Number of businesses x Frequency)

The SCM can be applied in different but equally valid ways. These differences often explain variation between EU baseline measurement and national baseline measurements.

Factors that can lead to variation and that need to be taken into consideration when interpreting data include:

- differences in scope. EU baseline measurement focuses on the most burdensome information obligations. Some national baseline measurements:
 - measure all information obligations
 - cover only burdens imposed in the country by EU "directives" (and not "regulations")
 - cover not only businesses but also charities
 - do not consider consumer-information labelling obligations to be an information obligation.
 - use of different tariffs. Hourly wages used in EU baseline measurement are taken from the harmonized ISCO tariff covering all 27 member states. National measurements use different tariffs.
- differences in assumptions underlying the process. The SCM is a method for estimating burdens. Different assumptions underlying these estimates can give rise to different results. One example is deciding what should be considered as "business-as-usual costs".

The purpose of the SCM methodology is to produce estimates that allow an order of magnitude of the burdens in different regulatory areas to be identified. Considering the level of detail and the number of parameters, it is not cost-efficient to seek statistically valid results rather than more general estimates.

There is a wealth of further information on national, EU and international websites about the SCM:

- The SCM Network website: <http://www.administrative-burdens.com/>
- International Standard Cost Model Manual: <http://www.oecd.org/gov/regulatory-policy/34227698.pdf>

4.10. Guidance on Alternatives to Legislation

"Do nothing" - it simply means taking no action to address the problem. There are variations of "doing nothing" available to policy makers which amount to the same, or nearly the same result. These are not mutually exclusive (i.e. they can only be achieved if implemented on their own). A combination of non-regulatory options may prove equally effective.

These variations can be termed **"no new intervention"**. No new intervention comprises a range of possible approaches. It includes:

⁷ SCM European Commission's website. Available at: http://ec.europa.eu/smart-regulation/refit/admin_burden/scm_en.htm

- **Use existing regulation better:** A detailed examination of all the current regulatory requirements may yield new understanding or interpretations of the law that would help achieve some or all of the policy objectives desired. The older a regulation is, the more likely it is that today's policy makers will have less breadth and depth of understanding about the legislative requirements in force.

In the UK, there is a **special licensing regime** run by the Home Office for businesses that wish to supply "controlled drugs".

A "controlled drug" is a drug such as morphine which is essential to modern healthcare (for example, in the treatment of a patient who is terminally ill) but which presents risks to society from misuse or diversion. A major revision and consolidation of separate human medicines legislation in 2012 revealed that this licensing regime was not well understood by businesses, including state-funded hospitals, voluntary organisations and charities, across the healthcare sector.

The risk was that supplies of controlled drugs to hospitals and charities might dry up unless suppliers held the correct licenses. The Department of Health therefore convened a special Working Group in 2014 including Government agencies (the Home Office, the Medicines Licensing Agency (MHRA)) and external stakeholders (hospitals, ambulance bodies, businesses and charities providing healthcare). This Group has examined a range of issues including the legislative requirements, which businesses need to hold appropriate licenses and has provided more general help and advice on the operation and effects of the licensing regime.

As a result, to date, no adverse impacts on the supply chain for controlled drugs are thought to have occurred.

- **Simplify or clarify the existing regulation:** This requires detailed examination of the current legislative requirements and clarity that the existing regime is defective with regard to the problem.

Suppose that current regulations stipulate that lorry drivers who transport chemicals must hold a specific training qualification and license but that this does not apply to those lorry drivers who only transport chemical waste. Instead of drafting complete new regulations, it might be possible to make a small amendment to the existing regulations that requires the types of lorry drivers who are required to hold the necessary qualifications and license to be defined in an Annex to the existing regulations. This Annex would then include both those transporting chemicals and those transporting chemical waste. Complete new regulations to bring those transporting chemical waste within the requirements have therefore been

- **Improve enforcement of existing regime:** The powers in the regulations have not been used to maximum effect and the problem to be resolved (for example, ensuring compliance with requirements not to display tobacco products in shops) could be addressed by a new or targeted drive by inspectorates with responsibility for ensuring compliance to encourage and motivate shop owners and retailers selling tobacco products to comply more effectively.
- **Make legal or administrative remedies more accessible or cheaper:** this approach means consulting widely on possible alternatives to existing procedures to simplify or make clearer the legal or administrative requirements and remedies available if a problem occurs. Using the example of "controlled

drugs" above, suppose that businesses found the application process expensive, time-consuming or problematic in terms of ensuring the right documentation was provided. Instead of changing the law, other approaches might be feasible - for example, use of on-line application forms, clearer guidance on the documentation required, worked examples to help show businesses what they need to provide, critical examination of current requirements to ensure they are a necessary and not just a desirable part of the regime (i.e. no "gold-plating"), extending the life of a license once granted, removing or simplifying repeat information requirements when a license is due to be renewed.

Other non-regulatory solutions

In addition to "doing nothing" (the mandatory non-regulatory option which every RIA Statement should contain), and "no new intervention", RIACs and policy leads in Ministries may wish to consider whether the following non-regulatory alternatives help them address the particular policy issue with which they are dealing.

The examples that follow are illustrative and are not designed to be an exhaustive list of all non-regulatory possibilities.

- **Better and/or more widely available public information:** Information and education can help consumers and business make decisions which are better informed. Examples might include:
 - Independent recommendation schemes on products and services, such as those operated by consumer bodies
 - Ratings systems, such as Trip Advisor in the hospitality and leisure industries
 - Labelling schemes, such as nutrition information labels on food products
 - Better information such as food hygiene information displayed at food outlets and restaurants.

Economic instruments and performance-based incentives: these can stimulate and encourage behaviour change in the public or offer business appropriate financial incentives or opportunities to modify their actions. Economic instruments might include tax breaks or tradable permits - or the level of duty imposed on tobacco products which can influence people not to start, or to give up, smoking. Economic instruments enable people to be free to make their own decisions, considering whether the benefits of an action justify any costs involved.

Behaviour may be influenced or changed by:

- Taxes and subsidies, such as research and development funds that are exempt from business tax or reductions in or removal of business rates in specific areas to stimulate economic growth (e.g. "free trade zones") or to encourage new technologies
- Quotas and permits - such as the European Union trading scheme for carbon dioxide emissions from electricity generation and the main energy-intensive industries
- Auctions - such as the state auctioning the right to provide new generations of mobile phone systems
- Stimulating competition by businesses in a given sector (for example, removal of restrictive retail practices which limit the availability of certain products, such as medicines, only being sold from registered pharmacies).

- **Self-regulation schemes:** here, an industry or profession might adopt its own code of practice or conduct to promote and enhance professional and/or ethical behaviours and accepted standards across the sector. Business voluntarily commits to abide by the agreements it requires of itself. It does imply certain costs but those costs are not imposed on business as a result of regulation. Rather business has decided voluntarily to bear these costs itself. Examples of such codes might include:
 - Retailers that adopt a policy for returning faulty or damaged goods that is better than a statutory minimum, or introduce lower levels of salt in food
 - A code of practice covering an entire sector - for example, in the UK, there is a code for dealing with press complaints. A representative body called the Portman Group has adopted a code of practice for responsible marketing of alcoholic drinks by all UK producers
 - Codes of practice negotiated with a range of interested parties, such as the chemical industry's "responsible care" programme
 - Professional codes of conduct such as might apply to chartered surveyors or architects.
- **Co-regulation:** This is similar to self-regulation but government is involved. For example, industry or trade associations might work in conjunction with state or local government bodies and/or consumer or public interest organisations on codes of practice. Again this is similar to self-regulation in that business voluntarily commits to abide by the agreements but these are not imposed on business as a result of regulation. Rather business has decided voluntarily to bear these costs itself. Examples of co-regulation might include:
 - Recognised codes of practice for registered health professionals (e.g. doctors, nurses, pharmacists etc.)
 - Statutory codes of practice, where legislation requires codes to be developed, agreed and promulgated. They typically allow, or require, a risk-based, proportionate, targeted and flexible approach to enforcement and compliance. In this case, the legislation underpinning the code should have set out the costs and benefits of this approach as a preferred option in the relevant RIA. In the UK for example, one such code concerns a statutory body called the Advisory Conciliation and Arbitration Service (ACAS) which has a role in arbitrating disputes between employers and employees on disciplinary and grievance matters in employment law
 - Approved codes, for example a Health and Safety Code on offshore diving projects. The code provides a "safe harbour" in that complying with it is a defence to a claim
 - Trade association codes (which may or may not be approved separately by a public body). An example in the UK is a code for the car repairs and servicing industry which is overseen by the Competition and Markets Authority
 - Standards and accreditation such as the adoption of international standards (ISO 14001) which specifies a process for controlling and improving an organisation's environmental performance.
- **Commitment to review within a defined period of time:** Any non-regulatory option must, as with a regulatory proposal, be capable of being monitored and evaluated. Exceptionally, if information or data about the problem is poor or inadequate at the present time to make an informed decision about how best to address a problem, but there is a reasonable and well-founded expectation that better information or data may be available within a defined period (for example within the next 18 months) interested parties may agree that further work should be deferred until a future date. Care should be taken when considering this option that it is not widely perceived that a decision has been "shelved" for lack of political

will, a lack of commitment generally to address a problem or a common agreement between certain interested parties not to do something which materially affects the interests of other stakeholders impacted by the problem.

EXAMPLES OF ALTERNATIVES TO LEGISLATION:	WAYS OF APPLYING ALTERNATIVES TO LEGISLATION
<p>Self-regulation: An approach in which those that will be regulated impose requirement on themselves.</p> <p><i>For example, a certain industry or profession may decide to develop and adopt its own code of conduct that promotes ethical behaviour.</i></p>	<p>Unilateral codes of conduct Customer charters Unilateral codes for sectors Voluntary agreements Standards and accreditation</p>
<p>Co-regulation: Higher level of self-regulation that involves some degree of explicit government involvement.</p> <p><i>For example, a certain industry can cooperate with the state administration in order to develop its own codes of conduct. That code would usually be implemented by the industry or some professional organisation, instead of the government or state administration.</i></p>	<p>Recognized Codes Statutory Codes Approved Codes Voluntary Codes Trade Union Codes Standards and accreditation</p>
<p>Information and education: Used in order to empower consumers to take their own informed decisions.</p> <p><i>For example, information on the value of nutrients on the packaging provides the consumer with the basis for taking a decision on their own in regards to the content of food (i.e. content of salt, fat, etc.).</i></p>	<p>Informing Education Cycle Scheme of independent recommendations Rating Systems Marking, detecting</p>
<p>Economic instruments: These can be used to modify behaviour by adjusting the economic incentives facing businesses and citizens. This approach allows individuals to make their own decisions, based on their estimates of whether the benefits of acting in a certain way justify the costs.</p>	<p>Taxes Subsidies Quotas and licenses Vouchers Auctions</p>
<p>Without new intervention: It may be possible that it will not be necessary to initiate action by the government or the competent authority. Legislation and the wider regulations (self-regulation, co-regulation), but other alternatives to legislation (information and education, economic instruments) will almost always impose additional costs, so decision makers should carefully assess whether government action is at all necessary.</p>	<p>Use the existing legislation or wider regulation Simplify or clarify the existing legislation or wider regulation Improve the implementation of the existing legislation and regulation Do nothing</p>

Identifying possible non-normative solutions can be done by answering the following questions that can be used as a guide for non-normative solutions or alternatives to legislation:

CHECKLIST FOR ALTERNATIVES TO LEGISLATION

What is the nature of the defined problem?

What are the goals of the policy or the regulation?

Are the goals clearly defined?

What are the incentives for those whose behaviour will be impacted?

How much information that is related to a certain industry (or profession) is required in order to ensure efficient legislation? Who has access to this information (state or private sector)?

Is the area that is being regulated subject to fast changes?

Is it likely that the intention to regulate may lead to concerns regarding operative fairness and fairness in the market?

Are the goals clearly presented to the sector or group that will be regulated? What is the feedback from the stakeholders?

Is the recommended alternative to legislation focused on the defined problem?

To what extent do the interests of those affected by the planned regulation coincide with the interests of the government or public sector?

If they do, are they consistent enough so that self-regulation or co-regulation are possible options?

How much flexibility from all interested stakeholders is needed to reach agreement on a proposal?

Will the impact on certain groups be proportional?

Will the proposal create new costs?

Will the alternative to legislation have an overall positive impact?

4.11. Implementation, monitoring and evaluation

The primary purpose of **monitoring** is to ensure feedback to the EB on the results of the implementation of the preferred option. Monitoring helps provide answers to the question as to whether the measure adopted has indeed provided the benefits identified or solved the problem at issue. Therefore, it is necessary to state how monitoring will be conducted as part of the whole RIA process.

To monitor and evaluate the implementation of the preferred option it is necessary to identify:

- Information and data that will be used for the monitoring process and how often the data will be gathered (For example: monthly, every three months, half-yearly, annually),
- The criteria to be adopted to gauge the success of the proposal in addressing the problem or issue that the preferred option will address,

- Other measures and information that will help to monitor implementation of the preferred option.

REDUCTION OF DISEASES CAUSED BY CONSUMPTION OF TOBACCO PRODUCTS

Monitoring the implementation of this policy can be implemented by defining:

- Information used in monitoring the success of implementation by reference to: changes in the number of patients with diseases caused by consumption of tobacco products (pulmonary diseases, heart diseases and similar) after the legislation came into force; surveys and researches on the number of smokers in the country and changes of their habits (number of smokers, number of smoked cigarettes);
- Criteria of success: targeted decrease in the percentage of diseases caused by consumption of the tobacco products, targeted decrease in the percentage of smokers.
- Other measures: round tables, gathering of the main stakeholders on the annual level in order to monitor implementation of the legislation and spread awareness on the problem during the year.

After finalising plans for monitoring it will also be necessary to **evaluate** the implemented option. In general, evaluation is conducted after implementation of the option. The purpose of evaluation is to evaluate if the implemented option has, **after a defined period of time (for example 3 – 5 years)** solved the defined problem and achieved the goals of the preferred option.

Questions that can help monitoring and evaluation of the initiative are:

- Does the identified problem still exist, and to the same or a lesser extent and is the State's intervention needed again?
- Are significant improvements in the resolution of the problem registered since the regulation came in force?
- Are the goals of the legislation achieved? Are the goals set out in the original final RIA Statement achieved?
- Is the impact of the implemented option i.e. legislation equal to the expectations? Were there obstacles, impacts and problems that were not expected?
- Is the currently valid legislation still appropriate for the resolution of the problem and achievement of the goals of the legislation i.e. public policy?
- Can the experience of implementation of the option be useful in order to improve measures and achieve the goals?

4.12. Technical aspects of consultation

All documents that are published for information, consultation and public discussion should be clear and understandable, with emphasis on the topics that are of particular interest to those consulted and the public, or answers to possible questions that may arise. Also, it is necessary to clearly list the expected benefits and costs of possible options.

Consultation or public discussions must be published on the website of the EB at an appropriate time and should clearly state the time period for submission of comments, suggestions and opinions and to where these should be



sent. Consultation and public discussion should be directed to those who are affected by the problem, or those that are impacted by the possible options, either directly or indirectly;

Planning of public presentation materials should be prepared in advance logistically, financially and professionally;

All submitted comments, suggestions and opinions should be carefully analysed, and once the analysis is completed a report should be drafted with the information on the accepted and not accepted comments, suggestions and opinions;

Officials who conduct the consultation process should consult and coordinate with the designated coordinator for consultation who will provide organizational, professional and technical assistance in the process of informing, consulting, or conducting a public discussion.

ANNEXES

Annex 1: Roles and responsibilities

Government Legislation Office

The Office is **responsible** for:

- co-ordinating and drafting documents (Strategy, Action plan and Report on strategy implementation),
- granting approval to the final RIA Statement and for drafting the implementing regulations adopted under the RIA Act,
- implementing the tasks of professional education and training in the field of RIA and in the field of drafting regulations,
- giving opinions on and drafting the necessary acts, for achieving legal and lexical coherence of Croatian legislation,
- giving opinions on and drafting the necessary acts for the purpose of legal and lexical alignment of Croatian legislation with the European Union standards, at the request of the qualified authority responsible for drafting regulations,
- other tasks related to the RIA system, which are governed by special regulations specifying the scope of work of the Government of the Republic of Croatia and the scope of work of the Legislation Office.

The **GLO will support** individual EBs in developing their RIA proposals by helping:

- Keep active contacts with RIA coordinators;
- Encourage the EB to start RIA processes in line with its Annual Plan;
- Give advice to the RIA coordinators and EB policy leads;
- Give advice to core teams of civil servants included in EB RIA working groups;
- Analyse and comment on received drafts of the RIA Statement;
- Control drafting quality of the Proposals of the RIA Statement;
- Give approval on the Proposals of the RIA Statement.

Based on the requirements of the RIA Act, the Government, on submission of a recommendation from the Government Legislation Office (GLO), adopts the Annual plan of legislative proposals for the forthcoming budget year.

The GLO will take care of the overarching **Government APL** for the next calendar year so as to:

- Take measures in order that all EB's APL are submitted to the GLO within deadlines;
- Consider each EB's proposed APL Plan;
- Assure the quality of the PIAs. If the PIA is incomplete in its contents or answers to the questions, the GLO should ask for supplementary material or additional work on the PIA;
- Suggest to the EBs changes in the Plan;
- If needed, implement additional consultations with the EBs,
- Prepare the Government Annual plan of legislative proposals for the Government approval.

The GLO will check the quality of PIAs and final RIA Statements:

- All PIAs for unplanned legislative proposals;
- All final RIA Statements,
- Ask for clarification and additional information if needed to ensure the quality of documents,
- Not give approval on those PIAs and final RIA Statements which do not meet a minimum standard of quality as set out in the RIA Checklist

Competent bodies

These are **central state administrative bodies** competent for the areas of:

- Health and Social Welfare (now the Ministry of Social Policy and Youth, MSPM);
- Economy (now Ministry of Economy, MINGO, including any other body with relevant competence for an economic area in question);
- Environmental protection (now Ministry of Environment and Nature Protection, MZOP);
- Finance (Ministry of Finance, MFIN).

If the draft RIA Statement has identified impacts on market competition, small- and medium-sized enterprises (SMEs) or the labour market, it should also be submitted to the:

- Competition Agency (AZTN),
- Ministry competent for entrepreneurship and crafts (MINPO), and
- Ministry competent for labour, and the pension system (MRMS).

They are **competent and responsible** for:

- participating in the RIA process by examining and giving opinions on the draft RIA Statement related to the content of the Statement relative to the CB's area of competence, as follows:
- the authority competent for the area of social policy welfare shall give an opinion relative to the established social impact assessment,
- the body competent for the economy shall give an opinion relative to the established economic impact assessment, including financial impact, and if deemed necessary, it shall include in its opinion the opinion of another authority competent for the respective economic sector, such as:
 - body competent for entrepreneurship and crafts,
 - body competent for work and the pension system.
- the body competent for environmental protection shall give an opinion relative to the established impact assessment in the field of environmental protection,
- the body competent for finance shall give an opinion relative to the approximate assessment of the expected fiscal impact on the State budget.

Opinions are prepared and drafted by the civil servants at the CB in charge of the tasks of RIA in cooperation with the relevant organisational units of the CB, depending on the field covered by the draft RIA Statement and, if deemed necessary, through interdepartmental cooperation with other authorities, depending on the established impacts.

An Expert Bearer is responsible for drafting legislation and is a central state administrative body and any other body which according to its regulated scope of work is authorised to deliver legislative proposals to the Croatian Government for adoption.

An EB is competent and responsible for:

- preparing a preliminary Impact Assessment and the Proposal of the Annual Plan of Legislative proposals,
- preparing a draft RIA Statement and a full RIA Statement,
- implementing the RIA process in accordance with the RIA Act and RIA System Regulation
- setting up adequate administrative capacities: appoint one professional person – RIA coordinator or, if deemed necessary, set up a relevant organisational unit.

Annex 2: EB Policy lead and RIA Coordinator

The Head of the directorate/sector (or EB Policy lead) is responsible for the implementation of the RIA process for any legislative proposal that is under the competence of his or her directorate/sector.

He or she is competent and responsible to ensure and manage:

- organising the work for preparing the proposition of the content of the regulation,
- organising the work for drafting a PIA, a draft RIA Statement and a final RIA Statement,
- preparing the Work Plan for the implementation of the RIA process,
- drafting the proposal for appointing members for the working group and the core team of civil servants,
- work plan for the working group and core team of civil servants,
- plan for consultation process
- completing the Work Plan for the implementation of the RIA process,
- actively working with the Working Group and the core team of civil servants,
- regular convening of Working Group meetings and coordination of work with the core team of civil servants,
- managing available resources,
- preparing all necessary material for approval by the Head of the body in regards to RIA (the RIA Statement, the legislative proposal and other additional documents in relation to the Rules of Procedure of the Government of the Republic of Croatia),
- participating in the regular legislative procedure in regards to RIA process

The RIA Coordinator is a professional person responsible for coordinating tasks related to the implementation of the RIA process at the EB. The Coordinator has at least an undergraduate university degree or integrated undergraduate and postgraduate university degree and fulfils other requirements in accordance to the special requirements that regulate the work status of civil servants.

The Coordinator is responsible for tasks related to RIA and is required to cooperate with the organisational unit of the Expert Bearer that is responsible for drafting regulation and with other bodies depending on the expected impacts of the regulation.

Aside from the duties that are prescribed by the provisions of the Law, the coordinator performs the following activities:

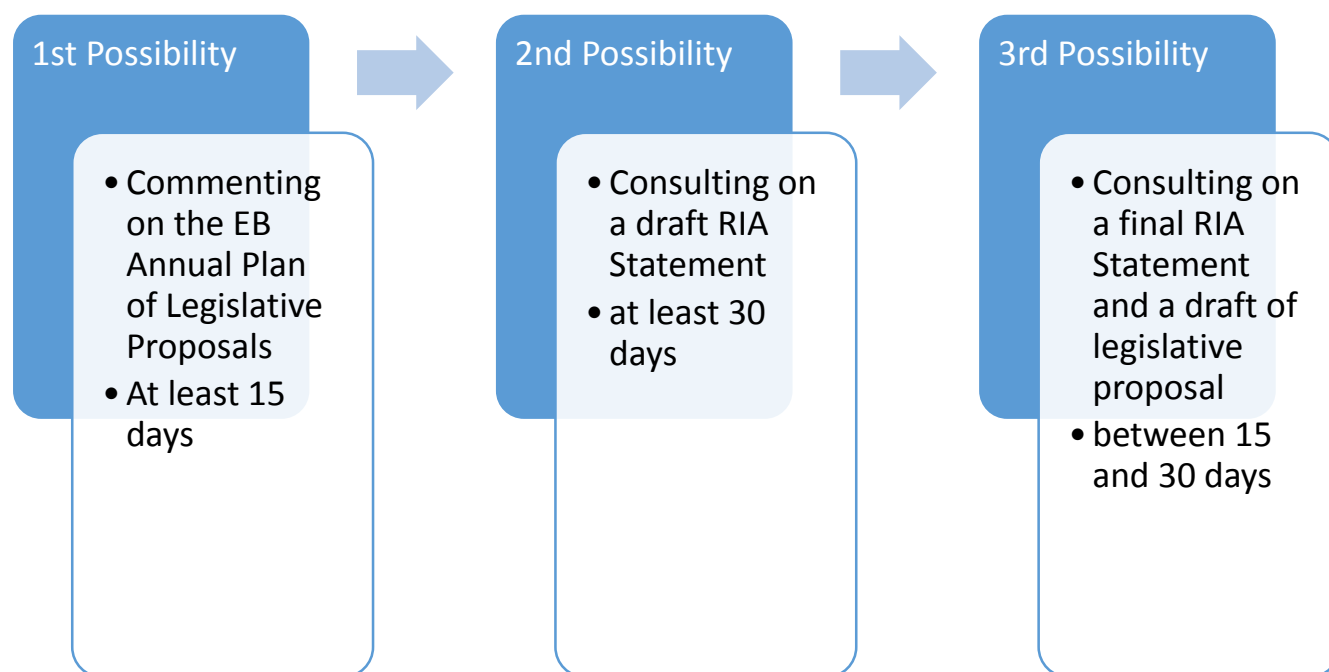
- In the process of preparing PIAs:
 - initiates the PIA process for legislative proposals within the scope of the EB;
 - participates in the Working Group of the EB or Commission that drafts the PIA, if it is established;
 - directs and supervises the RIA process and provides expert advice to officers from the EB regarding the drafting process of the PIA
- In the process of drafting the draft Annual Plan of Legislative Proposal:
 - drafts the Plan based on the delivered legislative proposals of the organisational units within the EB and submits it to the relevant head of the EB for consideration;
 - on receiving confirmation from the head of the EB, drafts the Plan and publishes it on the EB's website for at least 15 working days in order to inform the public and interested stakeholders;
 - after the deadline for informing the public, updates the Plan and delivers it to the relevant head of the EB for further process in accordance with the RIA Act.
- In the RIA process:
 - coordinates and monitors the drafting process of the RIA Statement on all conducted consultations with stakeholders;
 - actively participates in the RIA process for drafting the draft RIA Statement and the final RIA Statement
 - provides expert advice, which is related to the application of the RIA Guidelines to officers from the EB that are drafting the draft RIA Statement, the final RIA Statement and the legislative proposal
 - responsible for the correct implementation of the RIA process, including being a member of Working Groups established by the EB to develop individual legislative proposals.

Annex 3: Stakeholder involvement in the RIA process

One of the goals of an RIA is to **increase transparency by opening the RIA process up to stakeholders, including business and trade interests and associations, public, consumer and community groups and the public in general.**

Parties that are not in the state administration and that are affected by regulations have the right to take part in the process of the adoption of new regulations. In this way stakeholders have the opportunity to express your opinions, to comment and to influence both the content of any recommended regulation and how it is implemented.

During the RIA Process, there are three main opportunities for external stakeholders' input as shown below.



Every September, each Ministry consults for at least 15 calendar days on its draft Annual Plan of legislative proposals. The next opportunity to make comments arises when the Ministry consults on the draft RIA for an individual legislative proposal. This must be for at least 30 calendar days and can be longer. The third opportunity arises when the Ministry consults on its final draft legislation and RIA Statement concerning an individual legislative proposal. This is for a period of between at least 15 and no more than 30 calendar days.

1st opportunity - proposal of the EB Annual Plan of Legislative Proposals

The purpose of consultation is to open legislative planning up to the public so that external stakeholders have the opportunity to be informed about the expected legislative activities of the concerned EB.

This first opportunity for involvement in the RIA process enables stakeholders to get a clear view of the likely legislative changes that are going to take place. Stakeholders can send constructive comments, opinions and suggestions on the proposed list of legislative proposals. In this way, stakeholders are able to inform the EB if they are in favour of the proposed two lists of legislative proposals and whether the proposals require a full RIA to accompany them, or not having regard to the expected impacts.

If a stakeholder holds a view that a legislative proposal needs to go through the RIA process, the stakeholder needs to inform the EB explaining why they think this.

How to approach the EB and explain views on a Legislative proposal:

- Study the EB Annual Plan of Legislative Proposals;
- Find a legislative proposal which interests you from the lists set out in the Annual Plan;
- If it isn't on the RIA list, consider whether it has significant impacts;
- If so, tell the Ministry what these significant impacts are by email, memo or fax.

2nd opportunity – consultation on the draft RIA Statement

Consultation on a draft RIA Statement has to be for at least 30 calendar days and it should be published on the government e-consultation platform. The consultation will give information on how stakeholders can be involved in the consultation process.

During the consultation, the EB is obliged to conduct at least one public presentation of a draft RIA Statement. A variety of different methods can be used such as public discussions in the form of the round tables, or public meetings on the subject generally or for focused group meetings of interested stakeholders. The EB must state what methods will be used during consultation by timely publication of all relevant information alongside the draft RIA Statement.

Stakeholders may suggest alternative to legislation options based on their knowledge and expertise.

After the consultation is complete, the EB has to inform the public and interested parties regarding the opinions, proposals and remarks received in the consultation and public discussion processes by preparing a summary report. The report will be published on the e-consultation platform or on the EB's website.

How to participate in consultation on a draft RIA Statement:

- On the basis of the adopted Annual Plan, highlight the deadline for adoption of the legislative proposal your calendar;
- Regularly monitor the Government e-consultation platform for consulting activities as it may be the case that an EB starts consultation earlier;
- Ensure you know how consultation will be conducted through additional information about the deadlines;
- Engage thorough respective stakeholder's organisations if you are a member of the business community or civil society organisations;
- Contribute to public presentations, forums, round tables and actively participate in the discussions;
- Send any available information, data, research or analysis that could help the EB in its analysis and send comments, opinions etc. no later than the closing date given.

3rd opportunity – Consultation on the final RIA Statement and a legislative proposal

In the second round of consultation, an EB consults on two documents in the same manner as in the 2nd opportunity for at least 15, but no more than 30 calendar days. This period cannot be extended.

Take into consideration cooperation with other stakeholders who will potentially be affected by a legislative proposal and try to work together with the representatives of the EB to explore possible options

Comments, suggestions and opinions should be presented in a form stakeholders are most comfortable with. However, these should be constructive and aimed to be improved the legislative proposal. Stakeholders may have information and facts related to the matter that will help the EB in its cost-benefit analysis.

Further recommendations⁸ to the GLO RIA Unit and EBs on more active stakeholders' involvement:

- continuous raising awareness about RIA benefits of political officials;
- providing continuous RIA trainings to EBs and external stakeholders;
- publishing more of RIA documents (PIAs, RIAs, GLO opinions) on the internet so to raise government transparency and openness;
- ensuring more resources to RIA development across government.

LEGAL FRAMEWORK FOR CONSULTATION

Legislation

- The Law on the Right of Access to Information (OG 25/13, 85/15)
- The Code of Good Practice for Civil Participation in the Decision-Making Process (OG 140/09)

Guidelines

- Guidelines for Implementation of the Code of Good Practice for Civil Participation in the Decision-Making Process (2010)

RIA

Legislation

- RIA Law (OG 90/11);
- RIA Regulation (OG 66/12);
- Government Rules of Conduct (OG 154/11, 121/12, 7/13, 61/15);
- Parliament Rules of Conduct (OG 81/13).

Guidelines

- RIA Guidelines for Civil Servants (2012);
- RIA Guidelines for GLO (2012);
- RIA Guidelines for Stakeholders, Public and Interested Parties (2012);
- RIA Guidelines (2015)

EIA for SMEs

Guidelines

- Manual of EIA for SMEs (2014)

⁸ These recommendations were agreed at the round table discussion that was held on Wednesday, October 28, 2015 at the Croatian Government premises, as a public event under the IPA 2011 TWL project „Strengthening capacity for the implementation of RIA Strategy 2013 – 2015.

REFERENCES

In the RIA process it is necessary to list the relevant data sources that are related to analyses, studies, facts and information that are used in the cost-benefit analysis. These usually include national or international statistical data or instructions on the implementation of regulatory impact assessment.

Some of the relevant sources of data:

CROATIAN DATA SOURCES

- A central Government platform: <https://gov.hr/>
- A list of state administration bodies: <https://gov.hr/ministarstva-i-drzavna-tijela/58>
- The GLO's website: <https://zakonodavstvo.gov.hr/>
- A list of RIA Coordinators: <https://zakonodavstvo.gov.hr/default.aspx?id=227>
- A list of RIA Statements: <https://zakonodavstvo.gov.hr/procjena-ucinaka-propisa/iskazi-o-procjeni-ucinaka-propisa/228>
- Statistical data of Ministry of Finance: <http://www.mfin.hr/hr/statistika-i-izvjesca>
- Statistical data of Croatian National Bank: <http://www.hnb.hr/statistika/hstatistika.htm>
- Statistical data of National Bureau of Statistics: http://www.dzs.hr/Hrv/system/stat_databases.htm
- Statistical data of the Croatian Parliament: <https://infodok.sabor.hr/>
- Financial Agency: <http://www.fina.hr/Default.aspx>
- The Institute of Economics Zagreb: <http://www.eizg.hr/>
- The Institute for Public Finance: <http://www.ijf.hr/>
- Government Information-Documentation Office: <http://www.digured.hr/>
- Croatian Chamber of Economy: www.hgk.hr
- Croatian Banking Association: <http://www.hub.hr/Default.aspx>
- Croatian Employers Association: <http://www.hup.hr/>
- Croatian Chamber of Trades and Crafts: <http://www.hok.hr/>
- Independent Croatian Unions: <http://www.nhs.hr/>
- BIZImpact II project: http://www.bizimpact.hr/english/documents-and-publications_7/

INTERNATIONAL DATA SOURCES:

- EUROSTAT: <http://ec.europa.eu/eurostat/data/database>
- OECD: <https://data.oecd.org/>
- SIGMA: <http://www.sigmaweb.org/publications/>
- UN: <http://data.un.org/>
- WORLD TRADE ORGANISATION: <http://stat.wto.org/Home/WSDBHome.aspx?Language>
- WORLD HEALTH ORGANISATION: <http://www.who.int/gho/database/en/>
- INTERNATIONAL LABOUR ORGANISATION: <http://www.ilo.org/global/statistics-and-databases/lang--en/index.htm>
- WORLD BANK: <http://data.worldbank.org/>
- INTERNATIONAL MONETARY FUND: <http://www.imf.org/en/Data>
- CEFTA: <http://192.232.255.119/~ceftamab/3Dproject/Site/index.php>

IMPACT ASSESSMENT DATA SOURCES

OECD

- Regulatory policy data sources: <http://www.oecd.org/gov/regulatory-policy/ria.htm>

EUROPEAN COMMISSION:

- Better Regulation: http://ec.europa.eu/smart-regulation/index_en.htm
- Better Regulation Guidelines: http://ec.europa.eu/smart-regulation/guidelines/index_en.htm
- Better Regulation Package: http://ec.europa.eu/smart-regulation/better_regulation/key_docs_en.htm
- Better Regulation Toolbox: http://ec.europa.eu/smart-regulation/guidelines/toc_tool_en.htm
- Impact Assessment: http://ec.europa.eu/smart-regulation/impact/index_en.htm
- Inception Impact Assessments: http://ec.europa.eu/smart-regulation/roadmaps/index_en.htm
- Final Impact Assessments reports:
- http://ec.europa.eu/smart-regulation/impact/ia_carried_out/cia_2015_en.htm

UNITED KINGDOM:

- Impact Assessments: guidance for governmental departments: <https://www.gov.uk/government/collections/impact-assessments-guidance-for-government-departments>
- Publications: Impact Assessments: [https://www.gov.uk/government/publications?departments\[\]=department-for-business-innovation-skills&publication_type=impact-assessments](https://www.gov.uk/government/publications?departments[]=department-for-business-innovation-skills&publication_type=impact-assessments)
- Impact Assessment Calculator: <https://www.gov.uk/government/publications/impact-assessment-calculator--3>
- Impact Assessments: <http://www.legislation.gov.uk/ukia>
- Unit Cost Database: http://neweconomymanchester.com/stories/832-unit_cost_database
- Delivering High Quality Impact Assessments: <https://www.nao.org.uk/report/delivering-high-quality-impact-assessments/>
- Using alternatives to regulation to achieve policy objectives: <https://www.nao.org.uk/report/using-alternatives-to-regulation-to-achieve-policy-objectives/>
- The Green Book: appraisal and evaluation in central government: <https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-government>