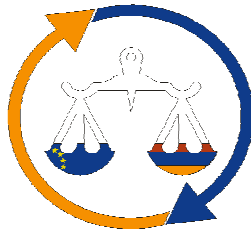


**CENTER FOR EUROPEAN LAW AND
INTEGRATION**



Research Paper

**The Regulatory Impact Analysis in the EU
and Its Member States**

**Yerevan
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The Practices of Regulatory Impact Assessment in EU and its Member States: General features and Possible Experience for Incorporating RIA in Armenia

Introduction

The present research briefly sets the experiences of the Regulatory Impact Assessment (hereinafter referred to as RIA) in European countries: The paper outlines the general features and highlights the main components of the assessment based on the Impact Assessment Guidelines of the European Commission¹, as well as an earlier EU document prepared Mandelkern Group on Better Regulation²: The second half of the paper presents the experiences of two EU member states with regard to incorporating RIA, which can potentially serve as a best practice for the application of RIA in Armenia.

The Importance of RIA

Under the conditions of the current economic progress, RIA is one of the main features of an efficient and competitive regulatory system both in EU member states and other countries. RIA has been applied in Anglo-Saxon countries, in particular in the USA, the Great Britain, Australia and others for a long time now.

RIA is a method of systematically and consistently examining selected potential impacts (such as e.g. environmental, economic and social) arising from government action or non-action, and of communicating the information to decision-makers and the public³: The aim of conducting impact assessment is to ensure that the most efficient and effective measure is selected. In other words RIA is the main mechanism which reveals the costs and benefits of the suggested regulatory option⁴: As a result of a successful RIA, the policy options are formed on credible basis, in the meantime providing the policy decision makers with information which is necessary to take the decision on the relevant option.

Unlike the expertise on draft laws currently provided in the CIS countries⁵, which predominantly focuses on the legality of the suggested legal act and its impact on the state budget as regards the costs, RIA emphasizes the impact that

¹ Impact Assessment Guidelines, European Commission, Sec(2005) 791, 15 June 2005

² Mandelkern Group on Better Regulation, Final Report, 13 November 2001

³ Regulatory Governance in South East European Countries: Progress and Challenges, July 2004, OECD, p. 35-37.

⁴ Edward Donelan and Diane de Pompignan, Better Regulation Practices in New European Member States: Context for Better Regulation, Edward Donelan and Diane de Pompignan

⁵ Similar options of undergoing expertise on draft laws, used to be applicable in the Countries of Central and Eastern Europe before the recent accession processes which brought to the enlargement.

the private sector will potentially bear, in particular the businesses, along with the impact on the society.

There is no uniform or common model for RIA, since in every single country the incorporation of such measures is preconditioned by the institutional, social and cultural differences in each country and the specifics of its legal system. However, it is possible to highlight some RIA features which are typical of those countries that are considered to have the best practices of RIA. It is advisable to adopt impact assessment as a component of a general regulatory policy, which is intended to improve the quality of regulation through the adoption of various other measures. There should be a developed methodology on impact assessment in place, which will require the assessment of the impact to be implemented at the earliest stage of drafting and will define the type or the list of the regulations subject to the assessment.

It will be necessary to ensure that the general oversight on the policy is embedded with a centralized government body, which will be coordinating the activities of the ministries in order to provide for a coherent and systematic approach. This centralized body will also ensure that the various ministries do not use the impact assessment in order to justify the decisions that have already been taken, as well as to promote an active cooperation among the ministries and resolve possible disputes.

Based on a couple of best practices, some researches⁶ highlight that the following components of the RIA are advised to be adopted in order to get the maximum benefit from it:

1. Maximize political commitment to RIA
2. Allocate responsibilities for RIA
3. Train the regulators
4. Use a consistent but flexible analytical method
5. Develop and implement data collection strategies
6. Target RIA efforts
7. Integrate RIA with the policy-making process, beginning as early as possible
8. Communicate the results
9. Involve the public extensively
10. Apply RIA to existing as well as new regulation

From among the EU countries UK, Denmark, the Netherlands, which were the forerunners of RIA, are regarded as those countries whose practices are the best and these can serve as a benchmark for other countries. In countries such as Sweden, or Finland RIA is also at a rather advanced level. In these countries RIA

⁶ Objectives for RIA OECD,1996; Regulatory Policies in OECD Countries (OECD 2002); also Cordova Jacobs (2004) *Seven quick strategies to improve the business environment in Bosnia and Herzegovina*, Prepared by Jacobs and Associates.

is compulsory for all regulatory measures with some impact (defined according to general pre-established criteria) and is actually and systematically applied.

Germany, Poland as well as Austria, with some qualifications, are ranked lower than the ones mentioned above. Here RIA is prescribed for all regulatory measures with some impact, but its application has begun recently. The cases in which it has been actually applied are only a few. Hungary and Italy fall below Germany and Poland, since RIA is applied only to some selected measures, in an experimental fashion⁷.

The requirement to conduct RIA as a part of the drafting processes has been vastly extended to new countries in the past decade. This is due to the fact that in the current world of economic development the countries need to boost the competitiveness in the economic field, which presupposes having a better regulatory system⁸. Another stimulus for incorporating RIA can be the European integration. The impact assessment, even if does not constitute a supranational requirement for EU member states, the EU Institutions strongly recommend and encourage the application of impact assessment in its MS⁹.

As for the countries of Central and Eastern Europe, then the application of impact assessment in these countries is determined by at least two circumstances: first, the regulatory reforms were and continue to form a precondition for accession to the European Union, second the newly formed governmental bodies were more capable to realize the importance of regulatory impact assessment¹⁰: Apart from Poland and Hungary, the Baltic States, Czech Republic, Romania, Bulgaria as well as other East European countries give a great significance to improving their regulatory mechanisms, including through RIA, and show significant progress in these terms.

The required components (aspects) of RIA

The components of RIA are not applied identically or in the same volume in all Member State of the EU. As with any newly incorporated mechanisms, the notion of impact assessment is often perceived differently by different persons, who give very diverse interpretations and connotation to it. Thus, it is strongly necessary to clarify the content of regulatory impact assessment at the very outset

⁷ A Comparative Analysis of Regulatory Impact Assessment in Ten EU Countries, A Report Prepared for the EU Directors of Better Regulation Group, DUBLIN, MAY 2004.

⁸ This need is often being emphasized in various reports by Organization for Economic Cooperation and Development, e.g. *OECD Guiding Principles for Regulatory Quality and Performance*.

⁹ Mandelkern Group on Better Regulation, Final Report, 13 November 2001; Commission AP on Simplifying and Improving the Regulatory Environment, Inter-institutional Agreement on Better Lawmaking

¹⁰ The use of impact assessment has been particularly relevant and continues to be for the countries of Eastern Europe, since it has served as a tool to avoid the automatic approximation of the third country's enormous amount of legislation to that of the EU.

and to distinguish its core (often required) aspects. Incorporation of RIA into the political system of a country requires a lot of efforts, and when as a result RIA does not include one of its core aspects, those efforts can be partially or completely in vain.

In order to determine the most important aspects of RIA, we will first turn to the “Mandelkern Report”, a documents whose recommendations are considered by the EU Member States. The report allows identifying those measures which are required to conduct an exhaustive impact assessment.

The first and most crucial step of RIA is the appropriate *problem definition*, which is expected to be resolved through regulation. The problem definition involves the identification of specific policy objectives. The definition of the problem shall be clear and shall avoid ambiguities, vagueness and contradiction. This implies that the results expected from the regulation, should be expressed in quantitative and physical terms. It is also necessary for the specific policy objectives to be defined in hierarchical order.

The next important step is the *consideration of multiple regulatory options*. Such options may include, for example, the assessment of leaving the status quo unaltered (“do nothing”) and alternatives to command and control regulations, (such as other options of regulations, self-regulation, adoption of new legislation, or improvement of the current regulation)¹¹:

The expected impact of each of the relevant options considered should be submitted to assessment through an *explicit and consistently used method*.

“This assessment should be based on coherent guidelines across all policy areas within the administration and should include the following elements: a clear statement of the risk or problem being addressed and of a) why action is necessary and b) why action at that level of government is appropriate ...; a description and justification of different options considered ...; for each relevant option, identification of affected parties (private and public) and a quantitative (if possible) or qualitative (as a minimum) assessment of impact on them - both advantages and disadvantages; a summary of who has been consulted, when and how, plus the results of such consultation ...; the estimated lifetime of the policy or options, plus a justification of why no review clause is proposed if that is the case; particular reference to the impact on small business or any other disproportionately affected group; ... an indication of what account has been taken of the practicalities of implementation ...”.

According to the Mandelkern report “.. the most rigorous framework in which the impacts – both positive and negative – of various policy options are assessed is Cost Benefit Analysis (CBA)”, since it gives the possibility to draw comparisons between “quantifiable advantages and disadvantages of any number of implementation options, over any policy lifetime and regardless of the timing of the benefits and costs”. Other, less precise methods are for example: Cost

¹¹ Mandelkern Group on Better Regulation, Final Report, 13 November 2001, p. 19.

Effectiveness Analysis, Compliance Costs Analysis, and techniques that “weight and score” the different policy impacts, which “can suffer from subjectivity and where the importance of the timing of the costs and benefits may be lost”. The report also outlines, that the financial costs and expenditures of a given option can often be rather easy to determine, however with options involving non-monetary values a precise assessment becomes very difficult (such as the impact on the human life, on the forests etc.).

The impact assessment shall largely involve third persons and interested groups. Thus, one crucial element of a proper RIA is *consultation*, aimed mainly at information gathering through participation of all affected parties, economic entities and civil society. This should begin before assessment (“as early as possible”), when the choice is still open, should be very practical and should last throughout the whole assessment. The consultation too shall follow its objective, which means that the specific outcome of the consultation shall also be defines. An example of a consultation objective can serve, e.g. gathering of new ideas, obtaining a specific piece of information, confirmation of an existing hypothesis and etc. Depending on the objective pursued and the issue at stake, consultation can be carried out on different elements of the impact assessment (nature of the problem, objectives and policy options, impacts, comparison of policy options). It may also concern the whole draft proposal¹²:

The RIA process might be officially divided into various *phases*. Some of them must be compulsory, while some other can be optional. The Report specifies a possible distinction between a preliminary assessment (which should be produced as soon as possible, also to form the object of early, informal consultations) and a detailed assessment containing all the relevant items. If a preliminary assessment is foreseen, a detailed assessment is normally followed as well, with the exception when the first has clearly demonstrated that the proposal has no significant impact. The detailed assessment must be also revised so to reflect possible changes in policy design and the results of consultation.

A core and one of final components of RIA is the estimation of *expected compliance* by the target group for each relevant option. It must be analyzed to what extent are the members of the target group capable of complying to the policy with their behavior. Also the administrative preconditions for effectiveness of the various options, as well as the critical points which, at certain conditions, could diminish the effectiveness of the new measure should be taken into account. The possible positive and negative aspects of compliance shall be estimated along with defining a certain period of time during which the implementation of a specific measure is expected and prescribing most efficient sanctions (administrative or criminal) which will guarantee the compliance with that measure¹³.

¹² Impact Assessment Guidelines, European Commission, Sec(2005) 791, 15 June 2005, p. 10.

¹³ Impact Assessment Guidelines, European Commission, Sec(2005) 791, 15 June 2005, p. 35.

It is strongly advisable that impact assessment should be compulsory and actually applied at least for high impact measures. At the final state of RIA undesirable options should be excluded, and the preferable option should be eventually recommended.

The abovementioned 'core aspects' of impact assessment can be summarized as follows.

1. RIA shall be required and shall be actually applied at least for high impact measures at the pilot stage, and normally for all of them afterwards;
2. Shall include appropriate problem definition;
3. Identification of policy objectives in order to avoid ambiguities, vagueness and contradictions (which means expected results expressed in quantitative, physical terms; and that the hierarchy between objectives is made explicit);
4. Beginning of assessment and consultation at the earliest stage, when the choice is still open;
5. Includes publicized, wide ranging and not ritualistic consultation;
6. Relevant stakeholders and interests consulted or represented in the process;
7. RIA adopts a proper consultation technique;
8. Actual use of the results of consultation;
9. Impact assessment process officially divided into different phases (compulsory and optional);
10. Multiple regulatory options actually considered;
11. *Ex ante* impact assessment of each relevant option, through some explicit and consistently used method;
12. Description and most of the time quantification of effects;
13. Expected compliance estimated for each relevant option;
14. Impact on implementing entities;
15. Recommendation of one preferable option (or more), or at least the exclusion of undesirable ones.

The experience of certain Member States of EU in incorporating impact assessment

In this section the research sets the experience of two EU Member States, the Netherlands and Poland, related to integrating impact assessment into their regulatory systems. The choice of the countries is determined by the following factors: in case of Netherlands, the impact assessment practice is considered as one of the longest and most successful experience among the continental European states, whereas Poland's experience as a former socialist country can be of interest, since it has also incorporated RIA on its stages of European integration.

NETHERLANDS

The Netherlands has practiced impact assessments since 1985 and as noted above the experience of this country is very successful.

At the outset of RIA implementation, the political responsibility for the quality of legislation was assigned to the Minister of Justice, thus in 1989 a directorate general for regulatory policy was established within this department with the duty to review all the legislative bills. Following the recommendations of the Minister for Justice the Dutch government issued new guidelines on regulation in 1992. They were mainly concerned with the quality of the legislative drafting and consultation procedure and the most important innovation of those guidelines introduction of a compulsory regulatory impact assessment.

1994 was the crucial year for the re-launch of the Impact Assessment initiative. The new government program “Competitiveness, deregulation, and legislative quality”¹⁴, set as the main goal of the new government on its political agenda, and was formulated with the aim of reducing the administrative costs of business.

The focus on efficiency of economic regulation and competitiveness produced two main innovations. Firstly, the Ministry of economic affairs began to take responsibility for the new ‘better regulation’ policy. And secondly, the definition of regulatory quality was extended to cover explicitly the economic impact of regulation.

In Netherlands the impact assessments are implemented for both primary and secondary legislation, however it still does not cover the third level of regulation, i.e. it does not extent to the by-laws. Of this primary and secondary legislation only the ones expected to show a significant impact are reviewed, however there are no clear standards to decide what is “expected as significant”.

Three main features can describe the Dutch approach to applying RIA: some questions cover the economic and business impact; other questions concern the environmental impact of proposed regulations; the last set of questions deal with feasibility and enforcement.

The general oversight on the impact assessment activities is shared between three departments, specifically the Department for Economic Affairs, the Department of Environment, and the Department for Justice. The checklists are applied on a set of primary and secondary regulations. The set is identified by a specific working group, nominated by a commission for regulatory reform chaired by the Prime Minister. The assessment is divided between a first Phase, called quick scan, before drafting starts, and a second phase called extended impact assessment, during the drafting process.

This process is followed with a compulsory consultation, the specific timeframe for which is not defined. The draft of the proposed regulatory measure

¹⁴ Known as MDW programme

is accompanied by a memorandum which includes the answers to the checklist. In Netherlands RIA is public, but not at the consultation stage. It is made public when draft legislation is sent to the Parliament.

The impact assessment is conducted by specialists working in various governmental departments with the use of external consultation resources. The “quality oversight” on the impact assessment is endorsed with two government bodies: the Proposed Legislation Desk, a unit within the three responsible ministries (justice, economic affairs, environmental affairs); and the Advisory Board on Administrative Burdens¹⁵, an independent organization. There is no systematic training in the use of the assessment methods and other checklists; only some occasional ad-hoc training.

During the last few years, the overall responsibility for RIA has moved to the Department of Economic Affairs. Consultation has been strengthened.¹⁶

¹⁵ Advisory Board on Administrative Burdens – Actal: www.actal.nl

¹⁶ A Comparative Analysis of Regulatory Impact Assessment in Ten EU Countries, A Report Prepared for the EU Directors of Better Regulation Group, DUBLIN, MAY 2004.

POLAND

At the end of the 1990s, the government of Poland launched and engaged in the implementation of an economic development short-term strategy, which was planned to be completed by 2002. The plan identified regulatory reform activities as a high priority.

In 2000 the Government takes the decision to submit Poland to an OECD regulatory review¹⁷, which as a result provided for reform guidelines. In the same year a Regulatory Quality Team was created, to serve as an advisory body to the Prime Minister and the Council of Ministers, to co-operate with the OECD team during the review, to prepare draft documents on regulatory reform, to give opinions on the actions undertaken by administrative organs, and finally to promote the establishment of RIA. The Regulatory Quality Team is chaired today by the Deputy Secretary of State, in the Ministry of the Economy, Labor and Social Affairs and it comprises of 15 representatives of the various governmental bodies.

Already at the end of 2001 impact assessment became compulsory for all the legislative drafts adopted by the Council of Ministers, according to the Resolutions adopted by the same Council on the regulation of its work. In order to ensure general and quality supervision over the implementation of the impact assessments a Department for impact assessment is being established at the Government Legislation Centre, which is also responsible for the co-ordination of activities and social consultation. There is no formal distinction between summary and extended impact assessment, but the responsible ministry can decide if an extended impact assessment should be prepared, according to the subject and scope of proposed legislation, however that decision is not binding. If the Council of Ministers does not consider the RIA satisfactory, it can also ask the responsible minister to extend impact assessment. In practice, it is normally up to the body proposing the draft legislation to decide on the depth of the impact assessment. Here too, an account shall be taken of the extent of the possible economic and social aspects of the impact.

Summary of RIA is an integral part of the explanatory report annexed to each draft, which is published with the draft on the Internet site of the responsible ministry.

In July 2003 the guidelines on RIA, containing recommendations to methods that can be used and their possible application to RIA procedure, were published. The methods such as cost and benefit analysis, cost analysis, multi-criteria analysis, are indicated in the guidelines. By that time Ad hoc training programs for central government officials were already underway, and are continuing to date.

¹⁷ Poland became a member of Organization for Economic Cooperation and Development in 1996. For further details see <http://www.oecd.org/countrieslist/>.

These Guidelines stipulate that the impact assessment shall be held at the earliest possible state of the drafting. Currently RIA is applicable to legislative bills only, whereas in the case of bylaws it is applied only as a formality. Continuous efforts are being applied in order to adverse such experiences. Even if the impact of a given secondary legislation is not a very grave one, it shall still be submitted to the relevant ministry. Impact assessment should show whether regulation is the best alternative, and that the benefits of the selected option are higher than the costs. However, multiple regulatory options are not considered and there is not a requirement to consider alternatives to command and control regulation.

As regards the quality oversight on the RIA, Poland adopts a two-level system. The RIA unit in the Government Legislation Centre gives advice (first level) on the scope of RIA and on the scope of public consultation both working with officials responsible for the draft in the competent ministry and in the form of formal opinion, which accompanies the draft during the following stages of the legislative process. If the ministry does not agree with the opinion given by that Centre, then it is obliged to prepare an official answer. The Center's opinion and the ministry's answer are part of the documentation attached to the draft during the following stages of the legislative process, until the adoption by the Council of Ministers. However, the Impact assessment unit has no competence to veto (ban) the draft. This can be done (second level) either by the advisory Committee of the Council of Ministers or by the Council of Ministers itself, since these bodies enjoy the power to refuse discussing a draft without RIA. In any case, only the advisory Committee or the Council of Ministers has the power to return the draft and the RIA to the responsible Minister in order to improve them. The Parliament, as well, may return the draft of the law to the Council of Ministers, when it considers the explanatory report incomplete, or there is no presentation of public consultation undertaken at the governmental stage of the legislative process

Public consultation of all the parties affected by the proposed legislation is compulsory. Consultation is recommended at the earliest stage possible; practice shows that usually public consultation takes place parallel to inter-ministerial consultation. A rich variety of private and public actors is usually being consulted, in particular there are ad hoc ways to take actors or groups deemed weak into account (charities, NGOs and minorities). A wide range of techniques is generally used to carry out consultations.

There is not a legal obligation for regulators to take account of the comments received as a result of the consultation.

It is particularly worth specifying in this research, that before the Impact assessment has been considered as a compulsory regulatory measure, it has been applied in Poland to assess the applicability of certain EU legislative acts. Those

assessments were being prepared by Polish government officials along with foreign experts involved¹⁸.

Summary

To sum the various experiences noted above, it is worth emphasizing that RIA is one of the preconditions to having competitive and efficient regulatory system. Countries willing to incorporate RIAs into their legal systems may like to consider the following suggestions:¹⁹

Each country should develop its own pragmatic strategy/program for including regulatory impact assessment in its system, which shall:

1. Adopt principles of good regulation, also adopted by other countries and the European Commission, to guide regulators and inform the public of government intentions.
2. Require an expanded justification statement for all new laws and regulations prepared by the ministries. The content of the justification statement depends on the capacities of ministries and availability of data.
3. Develop a training program for civil servants on the goals and methods of RIA.
4. Develop mechanisms to consult with the private sector on the RIA.
5. Invest in institutions. Put into place a quality control and oversight mechanism at the centre of government to assist and direct ministries in preparing high-quality regulations.

¹⁸ A Comparative Analysis of Regulatory Impact Assessment in Ten EU Countries, A Report Prepared for the EU Directors of Better Regulation Group, DUBLIN, MAY 2004.

¹⁹ Scott Jacobs, *Assisting Economic Transition: An RIA Strategy for Developing Countries*, Conference Paper Conference on REGULATORY IMPACT ASSESSMENT: STRENGTHENING REGULATION POLICY AND PRACTICE, Centre on Regulation and Competition, University of Manchester.

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- Develop a MA Program on European Studies

The research has been conducted by Center's Legal Expert Anna Hakobyan. Anna holds an LLM in European Law from University of London/University College London. Her previous professional experience involved legal policy work with various foreign organizations in Armenia. Anna's main research at the Center focuses on the legal aspects of EU external relations with specific focus on relations with EU neighbouring countries. She is also interested in the external dimension of the internal market and is currently writing on the Methodology of Legal Approximation. Anna will be teaching Freedom to provide services and establishment in EU and Methodology of Legal Approximation at the Master's Program in European Law at Yerevan State University as of September 2007.

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