Ukrainian-European Policy and Legal Advice Centre (UEPLAC)

Methodological note on special features of RIA within EU Legal Harmonization

Prepared by:
Dr. Péter Futó, International Short Term Expert

Kyiv, 19 February 2008

Ukrainian-European Policy and Legal Advice Centre (UEPLAC) is a project funded by the European Union, EuropeAid/122038/C/SV/UA. The overall objective of the Project is to strengthen understanding, implementation and ownership by the Ukrainian authorities of the whole process of legal approximation to the EU *acquis.* The views expressed in this assessment do not necessarily represent those of the official positions of the European Commission or the Governments of the European Union Member States.

Contents

Methodological note on special features of RIA within EU Legal Harmonization 1
Conceptual framework 3
Fields of RIA applications 4
Sources of templates used in this methodological note 6
How to use the recommended RIA Template 6
The recommended RIA Template 7
Methodological note on RIA scalability: best practices of simplified impact assessments 14
Information sources and the depth of analysis 14
United Kingdom: the three stages of RIA 16
UK Case Study: Initial RIA of raising the minimum age of leaving education or training 17
Options 17
UK Case Study: Initial RIA of the introduction of the EU Food Law 19
Italy: Preliminary vs. Final RIA 20
Poland: Summary vs. Extended Impact Assessment 21
European Commission: Roadmaps vs. Impact Assessments 21
European Commission Case Study: Roadmap to Impact Assessment of Safety of Toys Regulation 22
A. Initial impact assessment screening 23
B. Planning of further impact assessment work 24
Conclusions 24

Conceptual framework

Regulatory Impact Assessment (RIA) is an information-based analytical approach to assess probable costs, benefits, risks, consequences, and side effects of planned policy instruments (laws, regulations, etc.). The results are used to improve the quality of policy instruments, such as laws, regulations.

Regulatory Impact Assessment (RIA) has been practiced by the developed countries[1] and in particular by the EU[2] for the last two decades as a useful tool of regulatory policies. This method has been applied for facilitating a wide range of aims of regulatory policy, such as

- For ongoing quality check of planned regulations in view of improving the relationship between the Government on the one side and businesses, citizens and consumers on the other side
- For deregulation and administrative simplification purposes
- For legal harmonization purposes.

There are many excellent available and tested methodologies for preparing Regulatory Impact Assessments. Most of them can be downloaded from the Internet. The titles of some of these methodologies are cited in the footnotes of this Methodological Note. For this reason, in the general case there is no need to invent a method for preparing RIAs. However, in special cases – such as in case of RIA applied for facilitating a legal harmonization process – there is no widely known methodology.

[1] See for example the following OECD publications: (a) OECD: „From Red Tape to Smart Tape. Administrative Simplification in OECD Countries" OECD Publishing. Paris, 2003, 261 p. (b) "OECD Guiding Principles for Regulatory Quality and Performance" Paris, April 2005. (c) OECD: „Regulatory Impact Analysis in OECD Countries. Challenges for developing countries" Editor: Delia Rodrigo, p. 33, Dhaka, Bangladesh, June 2005.

[2] "A comparative analysis of regulatory impact assessment in ten EU countries". A report prepared for the EU Directors of Better Regulation Group. Council of the European Union. Dublin, May 2004.

Fields of RIA applications

The aim of this methodological note is to explain how RIA in the legal approximation context is different from conventional‘ RIAs.

RIA has been used for a wide range of purposes. The most relevant three fields of application have been as follows:

- *Better Regulation Programmes.* Many countries apply RIA as an integral part of long term programmes for checking the quality of planned regulations. In most of these cases the main purpose of preparing RIAs is to improve the regulatory environment for businesses, citizens and consumers, to use RIAs in the consultation process. An example of this type of RIA activity is the one performed under the guidance of SCURPE for implementing the Law of Ukraine on Principles of State Regulatory Policy in the Area of Economic Activity (No. 1160-IV, 11.09.2003)
- *Deregulation campaigns.* Many countries have launched deregulation programmes and administrative simplification campaigns. In these cases the overriding aim of the activity is to phase out a wide set of unnecessary, outdated regulations. Ukraine has embarked in 2005 in such activity by applying the so-called “Guillotine Principle” to several thousands of regulations issued by the central and local governments.[3] Deregulation is another activity where RIA can be successfully applied. If there are doubts about phasing out a regulation or not, a simplified RIA procedure can help in decision making.
- *Legal harmonization*. Several potential member countries of the European Union have been embarking on extensive or sporadic RIA programmes for facilitating the harmonization process between European laws and the respective national legislations. In these cases the aim of the RIA activity was to decrease the costs of legal approximation for Government, businesses, citizens, and to facilitate the negotiation process.

In case of legal harmonization, the methodology of RIA has some specific features, which can be summarized as follows.

Impacts of legal harmonization – and only of that. When analyzing the impacts of legal harmonization, one has to compare the measures of the previously existing national legislation with the measures of the piece of European legislation to be introduced. The legal and institutional differences are to be found between existing regulation and harmonized regulation. These legal and institutional differences are to be found in terms of the requirements, the measures, the enforcement mechanisms and procedures, and institutional / organizational arrangement that is necessary for the enforcement. In the RIA those (and only those) impacts have to be highlighted, which are attributable to the above mentioned difference. If a certain impact is found, but it was already attributable to the previously existing regulation in force, the RIA may mention it, but it has to qualify this impact as not directly a consequence of legal harmonization.

[3] See Decree of the President of Ukraine from 12 May 2005 № 779/2005 “Про лібералізацію підприємницької діяльності та державну підтримку підприємництва” (‘On liberalization of enerpreneurial activity and state support of entrepreneurship’)

The missing "Doing nothing" option. In the general case of RIA - when "better regulation" is the overriding aim of the exercise – it is expected from each RIA to list a wide portfolio of other relevant scenarios, besides issuing the assessed regulation. In these cases there is a wide possibility for regulatory and non-regulatory solutions, including the so-called "Doing nothing" option, i.e. abstaining from any interference. "However, in case of RIA done on behalf of the legal harmonization process, the option of "Doing nothing" is often not open, due to international obligations and agreements in force. In most of the cases only the following variations of potential options are open, feasible and meaningful: (a) "Partial harmonization"[4] or (b) "Full harmonization with a substantial delay and preparatory activity". These options, alternatives should be carefully examined in the RIA, in order to facilitate the adaptation process of all stakeholders, including the Government, the companies and various groups of the society.

Ukraine-Europe relations. When preparing RIAs for facilitating European legal harmonization in Ukraine, special attention should be paid to all aspects of European-Ukrainian relations, with special respect to trade, competition, tourism, investment and other economic flows. This can be a significant difference if compared with the general case of RIA. In RIAs facilitating EU-related legal harmonization special efforts have to be made (a) to collect Europe-specific statistical data about the affected Ukrainian economic sectors, social groups and activities[5] and (b) to consult those stakeholders that are dependent on the EU-Ukraine trade, competition, tourism, investment and other economic flows. However, depending on the particular acquis act under consideration, involvement of those Ukrainian stakeholders is also important, which do not trade or interact with the EU, but are affected directly or indirectly by the regulation.

Dealing with families of regulations. In many cases the impact of the introduction of individual European regulations cannot be readily measured. Instead, European regulations can be grouped into logically built-up families of inter-dependent regulations. Examples for such families of regulations: New Approach technical regulations, waste management regulations, etc. RIAs should possibly point out the impacts of the individual regulation. However, if this is not feasible, then as a good compromise, the impacts of the introduction of the full corresponding family of the analyzed regulation should be forecasted. The Ukrainian legal framework for regulatory impact assessment foresees the creation of RIAs only for individual draft regulatory acts. However, in several cases of legal harmonization, the measurement of impacts becomes feasible only at the level of 'family' RIAs. Moreover, legal harmonization could be effectively facilitated by (a) impact assessments measuring jointly the whole portfolio of harmonized legal acts affecting an economic sector, such as road transport or by (b) impact assessments measuring jointly the whole portfolio of harmonized legal acts affecting an individual company.[6]

---

[4] Art. 3 Chapter IX of the law of Ukraine «On the National Programme on Approximation of Ukrainian Legislation to the legislation of the European Union» (Відомості Верховної Ради (ВВР), 2004, N 29, p.367), indirectly hints that partial harmonization for an indefinite period of time is not possible, by saying that normative acts which contradict acquis communautaire, can be adopted only based on sufficient justification of the necessity of their adoption and for a clearly defined term.

[5] An example: if the target group of the planned regulation is a class of companies, than such data could be the export and import of these companies in the relation of the European Union, moreover, European investment in these companies.

[6] Methodological Guideline of Company-level Regulatory Impact Assessment with special respect to measuring the preparedness of companies for EU Accession. Peter Futo Vilnius 2000. Source: www.euro.lt/old/upl_images/20020212112232.doc

Use of analogous RIAs. For certain policy areas there is a wide portfolio of materials available from the legal harmonization practice of accession countries. RIAs analyzing the introduction of certain pieces European legislation should rely on the findings of the equivalent RIAs produced previously in other countries being in similar situations. By using these RIAs as benchmarks, previously hidden details of the regulatory environment can be revealed.

Aid from Ukrainian, European and other sources. Improving enforcement mechanisms, raising awareness may need additional resources. RIAs should point out, what kind of help should be requested, can be relied on from (a) the Government of Ukraine (b) other donors such as the EU.

Sources of templates used in this methodological note

This recommended methodology relies on three sources:

- The basic structure and the majority of the template questions are taken exactly (i.e. copied) from the following source: "RIA Manual for Ukraine" prepared by USAID-DAI[7]. The reason why this methodology has been recommended in depth is the following. There is an ongoing RIA activity in Ukraine under the guidance of the State Committee for Regulatory Policy and Entrepreneurship (SCURPE). This RIA activity has produced several thousands (!) of RIAs up to the end of 2007. It is desirable that RIAs prepared under the guidance of SDLA should be comparable with RIAs prepared in the framework of the process managed by SCURPE.
- The "RIA Manual for Ukraine" has been compared with the RIA methodology recommended by the Better Regulation Unit of the UK[8]. It has been found that there are no major differences between the methodologies. The referred UK methodology has outlined a gradual process of developing RIAs of individual draft regulations, whereby first an "Initial RIA", than a "Partial RIA" and finally a "Full RIA" is prepared. Some useful hints about preparing initial, partial and full RIAs and some template questions that have been explicitly recommended by the referred UK methodology have been included in this text.
- During the year 2007 the Ukrainian-European Policy and Legal Advice Centre (UEPLAC) has elaborated two RIA methodologies that are specific to the legal harmonization process. One of these working documents of UEPLAC[9] has been used to specify scales and indices for the RIAs, with the help of a set of tables.

How to use the recommended RIA Template

Each RIA must contain some information for each of the numbered subtitles of the Template (1,2,3,…10 - see the next section).

However, it is not mandatory to respond to all of the Template Questions under the numbered subtitles. Similarly, it is not mandatory to fill in all Tables. These Template Questions and Tables serve as methodological help on how to elaborate the chapter under the particular numbered subtitle (1,2,3,..10)

---

[7] "Regulatory Impact Analysis for Ukraine. RIA Manual for Ukraine". Manuscript prepared by DAI Europe with support from Ukraine's State Committee for Regulatory Policy and Entrepreneurship. Publication supported by the U.S. Agency for International Development (USAID).

[8] "Better Policy Making: A Guide to Regulatory Impact Assessment". Regulatory Impact Unit, Cabinet Office of the Government of Great Britain. Publication date: January 2003.

[9] Ukrainian regulatory impact assessment methodological guide in the context of legal approximation . Draft December 2007. Manuscript prepared by Ukraine-Europe Policy and Legal Advice Centre (UEPLAC),.

A RIA evolves through various drafts and working documents. The stages of this evolution are called Initial RIA, Partial RIA and Full RIA. Initial RIAs may include many open questions, its judgments, statements and recommendations may be associated with low level of certainty. Consultation and data gathering serve the aims of improving the knowledge about the regulated field, to get acquainted deeper with the regulatory environment and the regulated social and entrepreneurial groups. Later stages of RIA are characterized by deeper and more detailed knowledge, refined impact estimation and improved certainty.

For the above reasons, if more Template Questions can be responded to, and if all Tables can be filled in, then the resulting RIA will be a Full RIA. On the other hand, if the results are only of indicative nature and very qualitative, (i.e. no quantitative responses are available) then the RIA is called an initial RIA.

If more help is needed to respond to a particular Template Question, the referred methodological material should be consulted.

The recommended RIA Template

1 Title of RIA

Title or titles of EU legislation (e.g. directive, regulation etc) that the proposed measure will be transposing (implementing)

And / or: Name of Ukrainian draft regulatory act.

2 Identify the Goal

State the intended outcome of the regulation.
State the purpose of the intervention.
If feasible, explain the nature of the European regulation to be introduced: its relation to other European regulations, its membership in a family of European regulations. What is the relation of this regulation to corresponding European horizontal / vertical regulations, if any?
If feasible, explain, whether and why the introduction of this European regulation represents a big change, a substantial reform of (a) existing Ukrainian regulatory environment (b) existing Ukrainian enforcement agencies? Or, on the contrary, is it only a formality, which has to be done according to Ukraine's international obligations?
Which Ukrainian regulations are to be abolished due to the introduction of this European regulation? Why?
Which Ukrainian regulations are to be amended / modified due to the introduction of this European regulation? Why? If feasible, explain, what is the relevance and the direction of these amendments?

3 Define the Problem

Identify and analyze the problem. Evaluate the importance of the problem. (E.g. those specific risks of product safety, environment protection, etc. which call for this regulation).
Explain, why the defined problem cannot be dealt with via economic mechanisms and requires state regulation.
If the problem is to be solved with the help of a new regulation, explain, why the defined problem cannot be dealt with via existing regulatory acts or amendments to them.

4 Identify Alternative Options

Identify all acceptable alternative methods of achieving the set goals, including those that do not foresee direct state regulation.

Is a partial harmonization in this case possible? What would be a meaningful partial introduction of the European regulation? What are the arguments in favor of a partial introduction?
If the proposed Ukrainian regulation is adopted, will the transposition of the above mentioned EU legislation be full or partial? If harmonization is partial, for what time?
Is a delayed implementation of the harmonization in this case possible? What would be a meaningful schedule of the introduction of the European regulation? What are the arguments in favor of a slower introduction?

What is the relationship between the possible options and Ukraine's obligations under international agreements with international organizations other than the EU? (E.g. WTO membership, international agreements under the UN, CIS, etc.)

5 Assessing the Options –Impact Analysis

Evaluate all acceptable alternative methods of achieving the set goals, including those that do not foresee direct state regulation. Determine the expected results from the adoption of the proposed regulatory act, including estimates of expected expenses and advantages for business entities, citizens, and the state in consequence of the operation of the regulatory act.

Explain, what are the legal and institutional differences between the existing regulation and the harmonized regulation. Find legal and institutional differences in terms of the measures, the enforcement mechanisms and procedures, and institutional / organizational arrangement that is necessary for the enforcement. Try to highlight those (and only those) impacts which are attributable to the above mentioned differences. If a certain impact was already attributable to the previous regulation, you may mention it, but highlight this impact as not directly a consequence of legal harmonization.

The impacts of each option (alternative, scenario) should be recorded here.

There should be a quantitative analysis of each option,in particular, costs of the impact, both negative and positive, for each of the following stakeholders:

- The State (institutional impacts and impacts on Government budgetary revenues and expenditures),
- The Citizens (impacts on consumers, social impacts),
- Business Entities (What will be the impact on Small and Medium Sized Enterprises?)

This chapter of the RIA should also identify any distributional impacts in each of the stakeholders above. For instance if a particular business sector will be impacted on more than another or if there is a disproportionate impact to a part of society. This will assist the decision making process by showing where the impacts of each option will be. In some cases quantitative information may be not available and in these cases qualitative analysis should be used.

Name and describe the markets that are affected by this regulation. What will be the impact on competition of these markets?

What kind of conflicts are likely to arise as a consequence of introducing this regulation? If there will be interest groups negatively affected by the proposed regulation, please recommend measures that are aimed at alleviating the negative effects.

Highlight those impacts which are connected with the economic and political relations between Ukraine and the European Union. Pay special attention to impacts upon EU-Ukraine trade relations.

Moreover, the general economic impact should be highlighted if there is any.

Use the above questions for evaluating the impacts of each option (i.e. alternative, scenario).

For illustrating and demonstrating the impacts, use under this sub-title the results of fact-finding research and of consultation. In particular, use here information about

- the present regulatory environment of the planned regulation, i.e. what are the regulations in force, how are they enforced today and what is the institutional structure like that is responsible for the enforcement;
- the statistical size of the group of the affected stakeholders, their affected activities and the markets that are affected;
- existing and potential compliance behaviour of the affected stakeholders under the various regulatory options;
- the size of the associated regulatory burden under the various regulatory options.

If there is no quantitative information available, evaluate the impacts with a qualitative approach.

Tabular representation of the impacts

Table 1. Groups affected by the regulation

Please define groups which will be most affected by adoption of this measure proposed (please mark negative impact by '-', and positive one by '+'):

Subject	**Duration of the impact**		**Intensity of the Impact**	
	Short term	**Medium/long term**	**Strong**	**Weak**
A Business groups				
[name]				
B Social groups				
[name]				
C Public institutions				
[name]				

Table 2. Major winners and losers due to the introduction of the regulation

Please rank the groups (subjects) according to the intensity of negative as well as positive impact:

Negative impact	**Positive impact**
1.	1.
2.	2.
3.	3.
4.	4.
5.	5.

Table 3.

Impact Scores

Please fill in the following form**. Impact scores: -2 = strong negative impact; -1 = some negative impact; 0 = no impact expected; 1 = some positive impact; 2 = strong positive impact**. Please mark only impact associated with this measure proposed and based on the assessment of the difference between the present regulatory situation and the situation when the measure proposed is fully implemented:

Element	Topic	Score
A National economy	Changes in the output level	-2...-1...0...+1...+2
	1. Impact on price level (inflation rates)	-2...-1...0...+1...+2
	2. Number of employees	-2...-1...0...+1...+2
	3. Changes in export level	-2...-1...0...+1...+2
	4. Opportunities to import	-2...-1...0...+1...+2
	5. Innovations in economic sector	-2...-1...0...+1...+2
	6. Investment level	-2...-1...0...+1...+2
B Enter-prises	7. Additional non-recurring costs	-2...-1...0...+1...+2
	8. Changes in current expenses (costs)	-2...-1...0...+1...+2
	9. Need for non-recurring and current expenses for SMEs	-2...-1...0...+1...+2
	10. Need for non-recurring and current expenses for individual/separate region	-2...-1...0...+1...+2
	11. Impact on production quality	-2...-1...0...+1...+2
	12. Impact on the level of competitiveness	-2...-1...0...+1...+2
	13. Opportunities to export	-2...-1...0...+1...+2
	14. Opportunities to invest	-2...-1...0...+1...+2
	15. Opportunities for modernization	-2...-1...0...+1...+2
	16. Impact unknown, research needs to be carried out	-2...-1...0...+1...+2
C Society	17. General level of life quality	-2...-1...0...+1...+2
	18. Social differentiation	-2...-1...0...+1...+2
	19. Uneven cost (benefits) for specific groups	-2...-1...0...+1...+2
	20. Uneven cost (benefits) for specific regions	-2...-1...0...+1...+2
	21. Public perceptions of the effect of implementation of requirements provided in draft legal act	-2...-1...0...+1...+2
	22. Impact on environment	-2...-1...0...+1...+2
	23. Impact on cultural environment	-2...-1...0...+1...+2
	24. Impact on consumers' rights, health and protection	-2...-1...0...+1...+2
D Institutio-nal structure	25. Need to establish new institutions	-2...-1...0...+1...+2
	26. Need to reorganize institutional structure	-2...-1...0...+1...+2
	27. Need for training of public servants	-2...-1...0...+1...+2
	28. Need for granted expenditures at public institutions	-2...-1...0...+1...+2
	29. Need for current expenses at public institutions	-2...-1...0...+1...+2

6 Engaging with Stakeholders

Consult with the relevant types of stakeholders, affected directly or indirectly by the planned regulation. Among them consult with those economic operators that are (a) actively or (b) potentially trading with the EU or (c) their success on Ukrainain or European markets is dependent on their European competitors.

State the consultation and promulgation methods used in developing the draft regulatory act and RIA.

Document the responses, both in favor and against, the adoption of the proposed regulatory act and any relevant evidence presented or uncovered.

State how the feedback from stakeholders has been addressed in the draft regulatory act and RIA.

7 Implementation and Compliance

Is the regulation enforceable? If yes, at what costs?

Do bodies of state authority, bodies of local self-government have the necessary resources for enforcement?

How will those affected comply with the proposed regulation?

Individuals and legal entities that must comply by this regulation and meet its requirements: do they have the necessary resources?

Evaluate the risk of the effect of external factors on the operation of the proposed regulatory act.

Improving enforcement mechanisms, raising awareness may need additional resources. What kind of help should be requested, can be relied on from (a) the Government of Ukraine (b) other donors such as the EU?

For illustrating and demonstrating the impacts, use readily available and collected information about enforcement and compliance.

8 Monitoring and Evaluation

Determine the indicators of the regulatory act's effectuality.

Determine the actions that will have to be taken to track the effectuality of a regulatory act in case it is adopted.

9 Summary and Recommendations

Present arguments in favor of the advantages of the chosen method of achieving the set goals.

Describe mechanisms and actions that will ensure dealing with the identified problem by adopting the proposed regulatory act.

Convince the readers of the RIA that the regulatory goals can be achieved if the proposed regulatory act is adopted.

Prove that the achievement of the set goals via the proposed regulatory act is possible at the least costs for business entities, citizens and the state.

Prove substantially that the advantages gained by operation of the proposed regulatory act justify the respective costs in case if the costs and/or advantages cannot be determined quantitatively.

10 RIA prepared by:

Name, surname	
Telephone number	
E-mail address	
Position	
Division	
Institution	

Date:

Methodological note on RIA scalability: best practices of simplified impact assessments

Information sources and the depth of analysis

This methodological note is about the scalability of the RIA exercise and its outcome. In other words, this is an overview of best practices applied by researchers when addressing the issues of scope and depth of RIA studies.

The aim of this methodological note is to offer methodological knowledge and some practical examples about basic forms of RIA. The following questions are addressed: in what cases and why does this distinction arise, and how is initial RIA different from other stages of assessment (partial / extended and full).

Since RIA should be part of the policy development process, it should begin as early as possible. Therefore the regulatory process often cannot wait until the full range of the above information is collected. Therefore administrations have learnt to build existing or easily accessible information into RIAs that are helpful but not yet complete. In other words, RIA activities are **scalable**, depending on the efforts invested into research and consultation.

Depending on the depth of the above information basis we can speak about Initial RIA, Partial RIA and Full RIA. An Initial RIA is often called “basic” or “preliminary” or “summary” RIA, and an alternative name of a full RIA is “in-depth” or “extended” RIA Study.

According to international experience, the difference between initial and later stages of RIA lies mainly in the fact that the deeper is the RIA, the more detailed is the analysis and the more quantitative is the description of the impacts. Initial RIAs are often made in order to determine, whether the potential impacts forecasted by the initial RIA are high. According to the principle of proportionality, in this case a deeper version of RIA might become necessary.

For each of the addressed various regulatory options, RIAs should generally cover the following dimensions of impacts:

- policy area specific impact
- (general) economic impact;
- business (enterprise) impact;
- social impact (including environmental);
- institutional impact
- budgetary expenditures impact.

A RIA can only be prepared if sufficient information is collected about the following issues:

- Type 1 Information: What is the present regulatory environment of the planned regulation, i.e. what are the regulations in force, how are they enforced today and what is the institutional structure like that is responsible for the enforcement?
- Type 2 Information: What is the statistical size of the group of the affected stakeholders and what is the statistical size of their affected activities? Market research type information about the markets that are affected.

Moreover, in most cases it is necessary to receive feedback from the affected interest groups about the following issues:

- Type 3 Information: What is the existing and potential compliance behavior of the affected stakeholders under the various regulatory options like, (i.e. in case no regulatory intervention is planned, and in the case of implementing the planned regulation)?
- Type 4 Information: What is the size of the associated regulatory burden under the various regulatory options.

Often it is not easy and not straightforward to collect the above information. In public administration organizations such as ministries and subordinated Government agencies there is ample knowledge about Type 1 Information, but the other Types of information are not immediately available and their collection needs some research and consultation efforts.

A recent survey[10] among 10 EU member states has formulated the following question to public administrations: “In your country is there a distinction between a summary and an extended, in depth impact assessment?” Out of the 10 responding countries, only 2 countries, Finland and Holland have responded with “yes”. However, the notion of “analysis depth” appears in the British, the Italian and the Polish RIA practice as well.

[10] „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. Italian, Irish and Dutch presidencies of the Council of the European Union.

United Kingdom: the three stages of RIA

The referred UK methodology[11] clearly specifies the various stages of RIA preparation. The stages are called "initial", "partial", and "full / final" RIA. They show significant differences in terms of

- the reliability of impact estimations,
- the extent of consultation on which the statements are based,
- and the specific nature of the recommendations.

The characteristic features of these three stages are as follows:

- *The initial RIA* should inform and ideally accompany the draft regulation to the particular Line Ministry. An initial RIA should inform requests for departmental ministerial agreement to a proposal. It should be proportionate to the impact of a proposal and can consist of a rough and ready analysis based on what is already known. The initial RIA should be based on existing institutional knowledge and on early/informal consultation. An initial RIA can consist of a rough and ready analysis based on what the drafters already know. It should include the drafter's best estimates of the possible risks, benefits and costs, and should identify areas where more information is needed. The contents of an initial RIA are as follows: Provide a clear statement of the policy objectives and the issue. Describe and, where possible, quantify the scale of the risk (ie the problem to be addressed). Identify regulatory and non-regulatory alternative options, including do nothing/base case. Consider the pros and cons of each option and the fit with existing requirements on the relevant sector. Identify who is affected, including business sectors affected. Identify any issues of equity and fairness. Examine what is already known about the costs and benefits. Identify any potential unintended consequences. Identify distributional impacts. Try to identify markets that may be affected and flag up any potential competition issues. Consider how to secure compliance and whether a review of how it is working is required.

- *The partial RIA* builds on the initial RIA. The partial RIA must be submitted with any proposal needing collective agreement from the Prime Minister's Office, the Cabinet of Ministers or the associated committees. It must also accompany the formal consultation process with the stakeholders. It should be informed by more discussions, data gathering and informal consultations. It should include refined policy options on regulation, compliance, monitoring, cost and benefit estimates and risk analysis. A Competition Assessment and a Small Firms' Impact Test is also needed.

- *The full/final* RIA builds upon the analysis in the partial RIA which should be updated in the light of consultation and further information and analysis. It should be submitted with clear recommendations to the Ministers and should accompany legislation when it is presented to Parliament. It should also be placed on the website of the responsible Ministry. It must include a signed declaration from the relevant minister that he/she is satisfied that the benefits of a proposal outweigh the costs. The full/final RIA differs from the partial RIA in the first place not in its template but in the depth and reliability of the information that it is based on, and in the explicit nature of its recommendations. In particular, wherever possible, the impact estimates in terms of cost, benefit and risk should be accompanied by sensitivity analyses. Full RIAs often use some economic / econometric model to forecast the impacts of the planned regulation. Full RIAs are often the products of a research and consultancy effort that has been outsourced to some organization outside the public administration.

[11] "Better Policy Making: A Guide to Regulatory Impact Assessment". Regulatory Impact Unit, Cabinet Office of the Government of Great Britain. Publication date: January 2003.

It follows from the above description that in the British RIA tradition there are no significant differences in terms of the template required for each of these three stages.

UK Case Study: Initial RIA of raising the minimum age of leaving education or training[12]

This Initial RIA was issued in 2007 by the Department of Education and Skills of the United Kingdom. The name of the regulatory initiative is "Raising Expectations". The document can be downloaded from the Internet. Length of the document: 17 pages. Level of quantification for describing the groups under the impact of the regulation: high. Level of quantification of assessing the impacts themselves: low.

The structure of the document is as follows.

Objective
To raise to 18 the minimum age at which a young person could leave education or training. This will be done in two stages: to 17 from September 2013; and to 18 from September 2015.

Background
Current relevant legal requirements and measures.
Overall number of people affected by the proposal.
Participation in education or training at 16 and 17 years in the UK, as compared with other OECD countries.
Government's existing aspirations and policies.
Statistics of employment prospects by sectors, depending on the level of education and training of workforce.
Young people not being in education or training: its costs to economy and its negative social side effects.

Rationale for government intervention
Impacts of skill levels on economic performance, productivity growth, employment, living standards, crime rates, competitiveness UK vs. EU member countries, India and China.
Statistics: Impacts of existing qualifications on wage returns and promotions by gender.
Quantified forecast: there will be a sharp decline in low-skilled jobs up to 2020 whilst the importance of high-tech jobs will increase.
Indicator: what percentage of 17 year old population should participate in education and training by 2015.

Consultation
Declaration: the Ministry will fully consult on this proposal with all key stakeholder groups.
Fora and channels of planned consultation.
List of Government agencies that have been already consulted.

Options
Option 1 - Do nothing.

[12] This Methodological Note offers only case studies of Initial RIAs. A wide selection of final (in-depth) RIA case studies is available in the Appendix of the following document: „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. Italian, Irish and Dutch presidencies of the Council of the European Union.

Option 2 - Legislation to raise to 18 the minimum age at which a young person could leave education or training including a minimum duty on the employer.
Local authorities could be required to operate a registration system.
Employers should require young people to bring proof that they are participating before appointing them.

Benefits and costs
List of economic sectors and social groups affected.
List of social groups and stakeholders affected by these proposals.

Benefits

- Option 1 - Do nothing. Impacts of existing actions and measures.
- Option 2 - Legislation to raise to 18 the minimum age at which a young person could leave education or training. Initial estimated additional benefit to the economy of around £1,400m for a single cohort of young people (discounted over their lifetime) once a steady state scenario has been reached. This figure is arrived at by taking into account the increased wage returns and better job prospects from higher levels of qualifications and skills.

Costs

- Option 1 - Do nothing. No additional costs to the Budget but the economy as a whole will have to face the (not quantified) costs of a significant proportion of young people not having the skills needed by employers in the future. UK to be left behind on the OECD list. UK to become a less attractive place to do business than it otherwise would be.
- Option 2 - Legislation to raise to 18 the minimum age at which a young person could leave education or training. Costs are additional to those under the 'Do Nothing' alternative are estimated in a semi-quantitative way. The following elements of cost are considered: (a) Costs to employers (costs associated with training; adjusting work patterns; other costs) ; Potential costs of an incentive to encourage young people who wish to work to participate in education or training; (b) Costs to Government (participation costs, cost of the registration and enforcement system, financial support costs, capacity building costs; and other costs).

Small Firms Impact Test
The costs associated with these proposals will have an impact on micro, small and medium sized enterprises (SME's). In comparison to large business SME's will incur a slightly higher cost.
Number of young employers working at large firms vs. at SMEs.

Competition assessment
All sectors would be affected by the proposed changes. Little or no effect on competition, besides slightly negatively affecting the competitiveness of SMEs. This is an expert estimation without numbers.

Enforcement, sanctions and monitoring
Short description of the enforcement process.

Implementation and delivery plan
Proposal: to implement these changes from September 2013. Legislative tasks during the next Parliamentary session.

Summary costs and benefits table
Estimated annual costs and benefits on top of 'Do Nothing' Alternative are tabulated.
Cell content of the table: additional annual earning per cohort, in terms of Millions of UK Pounds.

Table headings:
- Breakdown of Options: Option 1 (Do nothing) vs. Option 2 (Acceptance of the Proposition).
- Breakdown of benefits: one-off and recurring benefits.
- Breakdown of costs: one-off and recurring costs.

Declaration and publication
"I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs."
Signed by the Secretary of State for Education and Skills
Date 22 March 2007

UK Case Study: Initial RIA of the introduction of the EU Food Law[13]

This Initial RIA was issued in 2001 by the responsible Line Ministry of the United Kingdom. The document can be downloaded from the Internet. Length of the document: 6 pages. Level of quantification for describing the groups under the impact of the regulation: low. Level of quantification of assessing the impacts themselves: very low.

The structure of the document is as follows.

Title of Regulatory Proposal
Proposed Council/EP Regulation laying down the General Principles of Food Law, establishing the European Food Authority, and laying down Procedures in Matters of Food Safety.

Purpose and Intended Effect
- to establish and define the functions of a European Food Authority (EFA); and
- to harmonise general food law requirements in the Community.

Main EU documents in which these objectives appear.
Key functions and rights of the planned European Food Authority, its role in food safety, trade policy

Identify Options
Only one option: as a Regulation the proposal, once adopted, would be directly applicable in the UK, but the draft text will be the subject of discussions in the EU Council Working Group before adoption.

Issues of Equity or Fairness
New responsibilities on food and animal feed businesses in relation to traceability, and product recall and withdrawal. Special burden on smaller businesses.

Identify Benefits
Increased consumer benefits from safer food, rapid notification of emerging risks.
Food and feed businesses may benefit from a more level playing field in Europe. Because existing anomalies in national legislation will be ironed out will facilitate trade.

[13] This Methodological Note offers only case studies of Initial RIAs. A wide selection of final (in-depth) RIA case studies is available in the Appendix of the following document: „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. Italian, Irish and Dutch presidencies of the Council of the European Union.

Quantify and Value Benefits
No quantification given.

Compliance Costs for Business, Charities and Voluntary Organisations

Business Sectors affected

Summary listing of stakeholders: primary producers, processors, wholesalers, retailers and importers/ exporters, charities and voluntary organisations. Estimates of the numbers of businesses affected in the UK: Farm animal feed producers (405) , Importers and agricultural merchants (70) , Farmers (63,000) , Food business establishments (Total number 612,203) Primary producers (8,876) , · Manufacturers/packers (17,657)·, Importers/exporters (1,069) ,· Distributors/transporters (11,926) , Retailers (191,026), Restaurants and other caterers (381,649).

Compliance Costs for a Typical Business

Qualitative assessment: compliance costs will be minimal, except in relation to administrative systems necessary to meet traceability and product recall/withdrawal requirements.

Total Compliance Costs

No readily available information on likely compliance costs, but information is being sought from industry and will be assessed once it is available.

Small Business Litmus Test

No such test made , but planned in the framework of consultation.

Other (Government) Costs
The cost of setting up and running the European Food Agency will be met from Community funds. UK enforcement authorities already have adequate control measures in place, due to existing obligations under the Food Safety Act and the Food and Feed Controls Directives.

Results of Consultation
Consultation with all interested parties both internal and external has begun, including the Small Business Unit of the Government.

Regulatory Impact Assessment
This is only an Initial RIA. After the consultation process a more complete RIA will be developed.

Financial Implications
Still unknown, depends on the results of the consultation process.

Timetable
Deadlines for communicating the decision to the EU Commission.

Italy: Preliminary vs. Final RIA

In Italy RIA was introduced experimentally by law n. 50/1999 and by the Prime Minister's directive 27-3-2000.[14] In 2003 new RIA guidelines were developed which have partly modified the contents of the Guide published in 2000. With regard to the methodology, the main difference relates to the shift towards a more flexible approach to the evaluation technique to be followed.

[14] Quoted from the following document: „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. Italian, Irish and Dutch presidencies of the Council of the European Union.

The impact assessment process is divided into two different phases. The difference between the *preliminary RIA* and the *final RIA* has to do with the depth of the analysis. In fact, in the first phase a comparison of the pros and cons of multiple option is made and a preferred option is selected. In the second phase the preferred option is subjected to a deeper analysis keeping in mind the possibility that, in the light of new and more detailed information, other options (initially rejected in the first phase) could eventually be judged as being better.

Poland: Summary vs. Extended Impact Assessment

In Poland In 2000 a Regulatory Quality Team was established which has promoted the establishment of RIA.[15] At the end of 2001 RIA became compulsory for all the bills adopted by the Council of Ministers. RIA covers primary as well as secondary regulations.

The scope of RIA depends on the subject and scope of proposed regulation. 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 and on the magnitude of the expected impact. In-depth analysis is applied only to drafts which are expected to generate some remarkable social and economic impact. The RIA unit can propose to perform an extended impact assessment. The Council of Ministers can also ask the responsible minister to extend impact assessment, when it considers that RIA is not satisfactory.

European Commission: Roadmaps vs. Impact Assessments

According to a Decision of the European Commission taken in 2005[16], a formal Impact Assessment is required for items on the European Commission's Work Programme. All regulatory proposals, White Papers, expenditure programmes and negotiating guidelines for international agreements put on the Work Programme are concerned. In addition, the Commission may, on a case-by case basis, decide to carry out an impact assessment of a proposal which does not appear on the Work Programme. Besides this provision, each Directorate General of the EC is free to choose how to organise its Impact assessment work.

Proportional analysis. The impact assessment's depth and scope will be determined by the likely impacts of the proposed action (principle of 'proportionate analysis'). The more significant an action is likely to be, the greater the effort of quantification and monetisation that will generally be expected. The EU methodology advises to perform the analysis of impacts in the following three steps, that are characterized with increasing depth and detail.

- Step 1: Identification of impacts
- Step 2: Qualitative assessment of which impacts are the most significant
- Step 3: Advanced qualitative and/or quantitative analysis of impacts.

Some details about the methods applied in these steps of analysis:

---

[15] Quoted from the following document: „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. Italian, Irish and Dutch presidencies of the Council of the European Union.

[16] COM(2005)97.

- Step 1 identifies environmental, economic and social impacts of a policy, why they occur and who is affected. Intentional and unintended impacts are differentiated. Links between cause (the action, instrument, etc) and effects (the impacts) are highlighted. The extent by which the proposed action will contribute to reaching the (operational) objective(s) is high lighted, moreover who is affected by the identified impacts and over what timescale the impacts will occur, by carefully identifying 'winners' and 'losers'.
- Step 2 identifies the most important impacts by applying causal models, assigning likelihoods (e.g. low, medium or high probability) that the identified impact will occur (or conversely the risk that the impact will not occur). The irreversibility and the approximate magnitude of each impact is assessed (e.g. low, medium or high).
- Step 3 offers an advanced in-depth analysis of impacts. These can take a number of forms, building on the analysis and results of Step 2. In-depth qualitative analysis of selected impacts which focuses on selected impacts or chains of impacts about which both qualitative and quantitative data are collected and analysed qualitatively, typically using a case study/scenario approach. This type of analysis can be implemented on its own, though in reality it is generally used in conjunction with a quantitative analysis of impacts. Quantitative analysis of impacts uses techniques, varying from simple extrapolation - based for instance on previously derived coefficients - through to proper quantitative modelling. Essentially, the aim is to understand the extent of the impacts of the policy options and to estimate the costs and benefits in monetary form when this is feasible.

Roadmaps. Many key elements for a formal impact assessment are generally already available in early stages of the policy process. Therefore, to help plan the impact assessment work, the Commission has requested its own services to establish 'Roadmaps' for the initiatives they have put forward before these initiatives have been submitted to higher level for a of the administration. Roadmaps should ideally be circulated to other Directorates-General (DGs) sufficiently early. The Roadmaps are published in parallel with the working programme of the Commission, so external stakeholders can anticipate the timing of the policy preparatory work and be ready to provide input.[17]

Roadmaps provide the following types of information:
- What data are available, what complementary data are needed, and how they will be produced.
- What is the estimated time required for completing the IA
- Brief statement on the likely impacts of each policy option
- Who is likely to be affected
- Which impacts have to be analysed by further analysis
- Who has to be consulted and how (consultation plan)
- Is there a need for establishing a co-operation among various services of the Commission

European Commission Case Study: Roadmap to Impact Assessment of Safety of Toys Regulation

This Roadmap has been published as one of the 98 roadmaps in the publication cited above.

The full text of the published Roadmap follows.

[17] A list and the full text of all Roadmaps produced in 2006 are published in the following document: 'Commission Work Programme 2006, Roadmaps" Brussels 2005 p 209. Downloadable from the following Internet address: http://ec.europa.eu/governance/impact/practice_en.htm

Title of the proposal: Revision of Directive 88/378/EC on the safety of toys.
Expected date of adoption of the proposal: 3rd/4th quarter 2006.

A. Initial impact assessment screening

1. What are the main problems identified? Are they unlikely to be solved satisfactorily by the sole action of Member States? (principle of subsidiarity – necessity test)

- need to update certain essential safety requirements and introduce new ones to improve the safety of toys;
- need to clarify and enforce the obligations of the person who places the toy on the market, and in particular the importer;
- clarification of the relationship between the Directive on the Safety of toys and the General Product Safety Directive (RAPEX and safeguard clauses, administrative co-operation);
- improve the conditions for a more coherent approach in enforcement by Member States, in particular in the area of market surveillance;
- provide the Commission and the Member States with the appropriate organisation to address issues raised by the implementation of the Directive in an efficient manner;
- clarification on whether some specific new products are covered or not by the Safety of Toys Directive (for instance, video-games peripherals); Directive 88/378/EC is a total harmonisation Directive. There is no specific national legislation. Better enforcement of the legislation on the safety of toys can take place through co-operation. However, the other identified problems require changes in the current legislation.

2. What are the main policy objectives?

The main policy objectives are the simplification of the current legislation, the improvement on the safety of toys by clarifying essential safety requirements, the improvement in the functioning of the Internal Market by developing conditions for a better common approach by national market surveillance authorities in the implementation of the legislation in force.

3. What are the policy options? What regulatory or non-regulatory instruments could be considered?

Option 1: No changes in the current policy and in the current Directive.

Option 2: Improvement of the implementation of the current Directive by promoting joint initiatives by the market surveillance and customs authorities of different Member States.

Option 3: Revision of Directive 88/378/EC on the safety of toys.

4. What are the impacts likely to result from each policy option and who is affected? Which impacts are likely to warrant further analysis (cf. list of impacts in the impact assessment guidelines)?

Option 1: the problems identified under 1 will persist. In particular, grey zone areas involving essential safety requirements, namely related to chemicals and noise, will remain, legislative simplification will not take place, better organisation will not be available.

Option 2: Effective enforcement would be improved with positive results for the responsible toy manufacturers and consumers.

Option 3:

- Economic impact – many of the proposed modifications are considered to improve the efficiency of the directive thus contributing to benefit all involved parties. However, the impact of possible modifications on chemicals essential safety requirements will need to be examined. Furthermore, the impact assessment study concluded also that a positive impact on reducing the level of counterfeiting was to be expected.
- Social impact – consumers are likely to benefit most from legislative greater efficiency, clarification of safety provisions and transparency.
- No environmental impacts are expected from this proposal pending the possible

modifications in the area of chemicals.

Different possible modifications to the Directive were assessed by an impact assessment study carried out by an outside consultant (see http://europa.eu.int/comm/enterprise/toys/index_en.htm). It states that "the complexity of the structure of the toy market makes it impossible to develop meaningful aggregate estimates of the likely costs of the existing Toys Safety Directive, and proposed modifications to it, on the sector as a whole;…" The cost-benefit analysis was approached through case studies, available in the above mentioned web-address.

B. Planning of further impact assessment work

5. What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

An impact assessment study of the main changes to the Directive has been completed in 2004 by an outside consultant (see http://europa.eu.int/comm/enterprise/toys/index_en.htm).

A call for tender for a study on certain chemicals used in toys has been launched in order to obtain elements for the revision of the chemicals part of the directive. The study will be finalised by the Summer 2006. Progress in this study will allow to assess whether further work in the area of impact assessment is needed.

6. Which stakeholders & experts will be consulted, how and at what stage?

The revision is discussed with the Member States experts and stakeholders (industry/consumers) as well as with standardisation organisations within the Expert Group on Toys Safety. A public consultation on the revision will be organised once the chemicals study has been completed and enough elements for the impact assessment are available.

7. Will an inter-service steering group be set up for the IA?

The impact assessment study was followed by a steering group with the participation of other services of DG ENTR and DG SANCO. The chemicals study will be followed by a inter-service group with the participation of DG ENTR chemicals Unit and of DG SANCO.

Conclusions

Several RIA administrative cultures have successfully institutionalised the preparation of preliminary simplified regulatory impact assessments. The role of these documents is

- To formulate preliminary regulatory and non-regulatory options for tackling the problem
- To provide summary information about the legal and institutional background and about the likely impacts of the proposal
- To inform public administration instances, drafters and external stakeholders at the early stage of the policy process
- To highlight availability or lack of data for estimating the impacts
- To highlight if there is a need for conducting a deeper impact assessment, or, on the contrary, there is no such a need, because the likely impacts of the proposal will be negligible.
- To clarify the various stages of the ensuing policy process.

The production of these simplified RIA documents has evolved according to the administrative cultures. The content and length of these documents depends on the needs of the respective policy processes of the governments.

The best practices of simplified RIA guidelines show that for simplified RIAs it is sufficient to respond to a list of maximum 10 questions. The case studies in this Methodological Note offer some ideas about how to select these questions.

Regarding the content, scope and detail of preliminary or basic RIAs, public administrations have consciously abstained from setting too high standards, in order to facilitate the timely production of these documents.

- The depth of information about legal and procedural matters corresponds to the level of detail of an Executive Summary.
- These RIAs offer only some summary information about the size of groups affected by the proposal and about the impacts themselves. The level of measurement of this type of information is typically very low. In other words, in most cases the simplified or preliminary RIAs contain only robust and qualitative information about these matters, and it is rather an exception when statistical information is offered about the size of the groups affected or quantitative estimation is given about the forecasted likely impacts.