

THE GOVERNMENT OF THE REPUBLIC OF CROATIA

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Pursuant to Article 24 of the Act on Regulatory Impact Assessment (Official Gazette, No. 90/2011), the Government of the Republic of Croatia, at its session on 14 June 2012, adopted the following

REGULATION ON THE IMPLEMENTATION OF THE REGULATORY IMPACT ASSESSMENT PROCESS

I. GENERAL PROVISIONS

Article 1

This Regulation stipulates the conditions for an Initial Regulatory Impact Assessment, the form for drafting the Initial Assessment, the mode and method of implementation of the Regulatory Impact Assessment process, the form for the Regulatory Impact Assessment Report, the mode of implementing consultation and public discussions in the Regulatory Impact Assessment process, and other issues in this respect.

II. DETAILED CRITERIA FOR THE IMPLEMENTATION OF INITIAL REGULATORY IMPACT ASSESSMENT

Article 2

(1) The Initial Regulatory Impact Assessment (hereinafter: Initial Assessment) is conducted in accordance with criteria prescribed by the law regulating Regulatory Impact Assessment (hereinafter: RIA Law) and the criteria listed in the Initial Assessment form, which is prescribed in Annex 1 of this Regulation.

(2) In addition to the criteria in paragraph 1 of this article, the Initial Assessment shall be conducted according to the contents of the regulatory proposal.

*1. Appropriate financial threshold related to the
most significant regulatory impact*

Article 3

- (1) The financial threshold as a criterion in the Initial Assessment process is determined for the area that shall be regulated – sector within an area for which the most significant regulatory impact is expected.
- (2) The financial threshold, as the criteria, shall be considered fulfilled if financial impacts have been identified for the sector mentioned in paragraph 1 of this article.
- (3) The estimate of the financial impact on the sector is determined as a minimum for a future three-year period, taking into account the significant imposition of additional costs or a significant reduction of existing costs, or their significant reallocation within the sector.
- (4) If the Initial Assessment determines the financial threshold from paragraph 1 of this article, the qualified authority responsible for drafting regulation (hereinafter: qualified authorities) is obliged to conduct a regulatory impact assessment.

2. Expected impacts on a specific economic area and the economy as a whole

Article 4

- (1) Expected regulatory impacts on a specific economic area are assessed through impacts on the small business sector according to the following criteria:
 - Employment in business entities,
 - Requirements for investments related to the operations of small and medium businesses,
 - Operating expenses and operations of small and medium businesses,
 - New administrative costs for small and medium business entities,
 - 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 qualified authorities.
- (2) The business entities referred to in paragraph 1 of this article refer to:
 - Micro economic entities - with less than 10 employees
 - Small business - from 10 to 49 employees
 - Medium business - from 50 to 250 employees and
 - Major corporations - more than 250 employees.
- (3) Expected impacts on the economy as a whole are assessed in relation to economic objectives that are pursued by regulation, particularly related to the following criteria:
 - Competitiveness of economy and inflow of investments,
 - Economic growth,

- Environmental sustainability,
- The achievement of social goals and regional development,
- 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.

(4) The expected impact on market competition must be assessed according to the Form contained in the Guidelines under Article 20 of this Regulation.

(5) The criteria referred to in paragraph 1 and 3 of this Article are determined by an estimate of the expected impacts according to following measures: probably small, significant and highly significant.

(6) Measures from paragraph 5 of this article, Article 5 paragraph 2 and Article 6 paragraph 2 of this Regulation, the qualified authorities will assess with discretion, which will be based on collected data and evidence, with a professional and scientific approach to the determined problem and practice related to the objectives that shall be achieved in order to solve the problem.

3. Expected impacts on socially vulnerable groups and other groups

Article 5

(1) The 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 the quality of the job,
- Social inclusion and protection of special groups of people,
- Achieving social goals related to gender equality,
- Protection / exposure of personal data of individuals,
- Public health,
- Crime and Terrorism
- 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 qualified authorities.

(2) The expected impacts from paragraph 1 of this Article are determined in accordance with the following criteria: probably small, significant and highly significant.

4. Expected impacts on the environment and sustainable development

Article 6

(1) For the expected impacts on the environment the relevant assessment of likely impacts are related to 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.

(2) The estimate of the expected impacts from paragraph 1 of this Article shall be conducted so that for each area in which the expected regulatory impact will take place, the expected probability of the impact shall be established according to the following measures: probably small, significant and highly significant.

(3) Impact assessment on sustainable development includes a considered accumulation of mutual impacts from Articles 3 to 7 of this Regulation.

5. Risk Assessment

Article 7

In determining the impacts according to Articles 3 to 6 of this Regulation, the qualified authorities shall provide an assessment of the associated risks along with the Initial Assessment form.

Sources of data

Article 8

(1) Qualified authorities are responsible for determining the facts and data that will serve as a baseline and basis for Regulatory Impact Assessment according to Articles 3 to 7 of this Regulation and use the relevant sources of data that are available through the appropriate competent authorities in the Republic of Croatia, as well as from relevant public accessible sources such as research, studies, academic and NGO reports.

(2) In addition to sources of data mentioned in paragraphs 1 this Article, the qualified authorities shall, in order to determine facts and data that will serve as a baseline and basis for Regulatory Impact Assessment, use other relevant sources of data from the relevant EU institutions and relevant international organizations and institutions.

III. DUTIES AND RESPONSIBILITIES OF THE RIA COORDINATOR

Article 9

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

1. In the process of the Initial Assessment:
 - initiates the Initial Assessment process for regulations within the scope of the qualified authority;
 - participates in the work of the qualified body or commission that drafts the Initial Assessment, if it is established;
 - directs and supervises the drafting process and provides expert advice to officers from the qualified authorities regarding the drafting process of the Initial Assessment.

2. In the process of drafting the Regulation Plan Proposal:
 - drafts the Regulation Plan Draft Proposal based on the delivered proposals of the organisational units of the qualified authority and submits it to the head of the qualified authority for consideration;
 - upon the confirmation of the head of the qualified authority, drafts the Regulation Plan Proposal and publishes it on the website of the qualified authority for the duration of at least 15 days in order to inform the public and interested public;
 - after the deadline for informing the public, updates the Regulation Plan Proposal and delivers it to the head for further process in accordance to the Law.

3. In the Regulatory Impact Assessment process:
 - coordinates and monitors the drafting process of the complete report that is drafted by the qualified authority on all conducted consultation with stakeholders and submits it as documentation along with the RIA Report Draft;
 - actively participates in the regulatory impact assessment process in regards to drafting the RIA Report Draft Proposal (hereinafter: Draft Report) and RIA Report Proposal (hereinafter: Report Proposal);
 - provides expert advice, which is related to the application of the Guidelines from Article 20 of this Regulation, to officers from the qualified authority that are drafting the Draft Report, regulation and Report Proposal;
 - responsible for the correct implementation of the process

IV. REGULATORY PROPOSAL ON THE CONTENT OF REGULATIONS AND THE INITIAL ASSESSMENT PROCESS

Mandatory contents of the Regulatory Proposal

Article 10

- (1) The Regulatory Proposal shall include the title of the Regulation, indications and substance of the subject that is being regulated, and a short explanation of the problem that will be solved with the regulation and the objective that will be achieved.
- (2) The subject matter that will be included in the future regulation shall be presented in the Regulatory Proposal in points, which will be listed as headings for the future regulation, while listing the general themes that will be organised under each heading.
- (3) The provisions of this Article shall be appropriately applied when, in accordance to the Law, the recommended impact assessment is related to the regulation that is in the drafting process.

Drafting the Initial Assessment

Article 11

- (1) Qualified authorities shall draft the Initial Assessment after the Regulatory Proposal has been drafted.
- (2) Qualified authorities shall draft the Initial Assessment according to the criteria determined by this Regulation, in a way that gives answers to the requirements from the "Initial Assessment" form, which is contained in Annex 1 this Regulation.

Development of the Proposal of the Regulation Plan

Article 12

- (1) Qualified authority, after drafting the Initial Assessment for all regulations that are intended to be drafted in the following year, shall develop the Proposal of the Regulation Plan.
- (2) The Proposal of the Regulation Plan shall contain the following provisions:
 - Proposal of normative activities in the field of Croatian legislation (which do not in the function of harmonizing with EU legislation) and
 - Proposal of normative activities related to the Regulatory Impact Assessment process (impact assessment will be conducted for legislative measures which will be based on the results of Initial Assessment).
- (3) The proposal of normative activities related to the Regulatory Impact Assessment process based on the results of the Initial Assessment, must include:

- A list of regulations (legislative measures) from the area of Croatian legislation that are not part of harmonization with EU legislation and
- A list of regulations (legislative measures) which harmonize the Croatian legislation with EU legislation, and that are proposed / incorporated in the act that the Croatian Parliament passes the same year.

Preparation of Annual Plan of Normative Activities

Article 13

- (1) Government Legislation Office shall prepare the Annual Plan of Normative Activities based on the submitted Proposal of the Regulation Plan from all qualified authorities.
- (2) Annual Plan of Normative Activities shall be prepared according to the form contained in Appendix 2 of this Regulation.

V. IMPLEMENTATION OF THE REGULATORY IMPACT ASSESSMENT PROCESS

Obligations of Implementation

Article 14

- (1) Qualified authorities shall implement the Regulatory Impact Assessment process according to the obligations set forth in the Annual Plan of the Normative Activities, or according to the obligations in accordance with the Law.
- (2) Qualified authorities is obliged to access the Regulatory Impact Assessment as early as possible once the Annual Plan of Normative Activities has been adopted, taking into consideration all determined phases of the process in accordance with the Law and this Regulation

The procedure for implementation of an outstanding commitment for Regulatory Impact Assessment

Article 15

- (1) Regulatory Impact Assessment carried out by the Conclusion of the Croatian Parliament or the Conclusion or Decision of the Croatian Government in accordance with the provisions of the Law, shall be implemented by the appropriate application of the provisions of this Regulation.
- (2) When Regulatory Impact Assessment is conducted for a law, regulation or ordinance that are in force, the baseline will be the period from when the law, regulation or ordinance enters into force until the Conclusion or Decision is adopted, which determines the obligation of the implementation of the impact assessment for that regulation.

Preparation of the Draft Report and the Report Proposal

Article 16

- (1) Qualified authorities shall begin preparing the Draft Report by collecting relevant data and conducting consultation with interdisciplinary bodies and other stakeholders, depending on the administrative area in which the regulation is drafted.
- (2) Qualified authorities shall prepare a Draft Report according to the requirements determined in the form attached in Annex 3 of this Regulation.
- (3) Qualified authorities shall conduct a prescribed consultation on the Draft Report with the public and interested public for the length of 30 days. Upon the qualified authorities' assessment, and depending on the complexity of the subject matter, it may last longer. Consultation shall include one or more public presentations on the subject matter of the consultation.
- (4) Qualified authorities, following the consultation prescribed in paragraph 3, shall update the Draft Report with the Regulatory Proposal in accordance with the adopted opinions, suggestions and views from the consultation. Then, the Draft Report with the Regulatory Proposal shall be submitted for opinion to the competent authorities for the following areas: economy, health, welfare, environmental protection and finance.
- (5) The competent authorities are obliged to submit their opinion within the prescribed period of 15 days.
- (6) Once the qualified authorities obtain the opinion of competent authorities and harmonize them into the Draft Report, the qualified authorities shall draft the regulation and Report Proposal.
- (7) The Report Proposal contains updated information prescribed by the Law and by the form in Annex 3 of this Regulation.

Publication of regulation and the Report Proposal for public discussion

Article 17

- (1) Qualified authorities provide the regulation and Report Proposal for public discussion to the public and interested public on their website, within the prescribed period of 15-30 days.
- (2) After the public discussion from paragraph 1 of this Article, the qualified authorities shall update the regulation and Report Proposal with the adopted opinions, suggestions and comments from the public discussion and submit them for opinion to the competent authorities.
- (3) After receiving and including the opinions of the competent authority, the qualified authorities submit the regulation and Report Proposal for approval to Government Legislation Office.
- (4) Qualified authorities submit the regulation into Government procedure once the Regulatory Impact Assessment Report has been finalized in accordance with the Law.

VI. CONSULTATION WITH STAKEHOLDERS, CONSULTATION AND PUBLIC DISCUSSION

Consultation with stakeholders

Article 18

- (1) In the initial stages for preparing a Draft Report, the qualified authorities shall conduct consultations with competent authorities and other stakeholders, depending on the area problem that the regulation is trying to solve, in order to get a better scope and identify the problem, and identify the goals that will be achieved.
- (2) The consultation procedure under paragraph 1 this article should include as many relevant interested stakeholders.
- (3) The qualified authorities shall conduct consultations with stakeholders using active methods such as letters, e-mail, working meetings and round tables, and using a variety of passive methods such as placing the material on the website of the qualified authorities, etc.
- (4) Qualified authorities, after completion of the consultation process, are obliged to prepare the complete Report on all the consultations held with stakeholders that, in general, include:
 - Appropriate information (sector, activity area, etc.) of each stakeholder (body, or legal or natural person - businessman, citizen, scientist, scientific institutions, professional institutions, citizen associations, etc.) that is consulted or who participated in consultation,
 - Issues and goals that were discussed and
 - Allegations of significant impacts identified by stakeholders in the consultation process.

Consultation and public discussions

Article 19

- (1) Information on conducting consultations on the Draft Report and holding a public discussion on the regulation and the Report Proposal shall be conducted according to the form contained in Annex 4 this Regulation.
- (2) Consultation and public discussions are proceedings in which their comments, suggestions and opinions, according to their own interests, within the prescribed time limits and in the manner specified in Annex 4 on Information of this Regulation, in the role of the public and interested public, each stakeholders can participate and each individual (physical and legal persons, groups and interested citizen).
- (3) In order to inform the public and interested public with the substance that is the subject of consultation and the public discussion, the qualified authorities shall conduct a public presentation in accordance with the Law and this Regulation on the subject that shall be included in the record.
- (4) After the conducted consultation and public debate, including public presentations, the qualified authorities are obliged to consider all comments, suggestions and opinions of the public and interested public and consider accepting and not accepting the comments, suggestions and opinions, and shall make a statement that will be disclosed to the public and interested public on its website.

Article 20

(1) Qualified authorities are obliged to draft and implement the Initial Assessment and the RIA under this Regulation according to the Guidelines for RIA.

(2) Guidelines for RIA shall contain methodological and technical instructions for the preparation of an Initial Assessment and RIA, and instructions for the implementation of other procedures in this regard.

(3) The guidelines referred to in paragraph 1 of this Article shall be provided by the Government Legislation Office, and will be published on the GLO website.

Article 21

Appendices 1, 2, 3 and 4 are an integral part of this Regulation.

Article 22

This Regulation shall enter into force eight days after its publication in the "Official Gazette".

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Zagreb, 14 June 2012

PRESIDENT
Zoran Milanovic, v.r.