Israel Regulatory Authority

Regulatory Impact Assessment Guidelines

Guidelines for Developing Optimal Regulation and Assessing Its Impacts

December 2023

The Governmental Regulatory Impact Assessment (RIA) Guidelines

Guidelines for Designing Optimal Regulation and Assessing its Impacts

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We would like to thank the staff of the Israel Regulatory Authority, the network of regulatory policy leaders, and everyone who commented and contributed to developing these RIA Guidelines.

The Guidelines instruct regulators, when enacting regulation, on how to conduct the analysis to design optimal regulation and assess its impacts in proportion to the issue, the regulation, and its impacts, inter alia, according to the provisions of Section 2 of the Principles of Regulation Law, 2021 (hereinafter—"The Law" or "The Principles of Regulation Law").

The Israel Regulatory Authority publishes the Guidelines in a digital and accessible manner. They are based on the provisions of Section 3 of Cabinet Resolution No. 2118, dated October 22, 2014, concerning "Reducing the Regulatory Burden," as amended by Cabinet Resolution No. 218, dated August 1, 2021, concerning the "National Plan for Improving Regulation and Amending Cabinet Resolutions" (hereinafter – "Cabinet Resolution 2118", "Cabinet Resolution 218", and together – the "Cabinet Resolutions").

The Guidelines will come into effect on January 1, 2024.

The Guidelines are published digitally and accessible on the Israel Regulatory Authority website: https://www.gov.il/he/departments/regulatory-authority

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Message from the Chairman of the Israel Regulatory Authority

> *"There is nothing more important to the progress of our economies and societies than good regulation. By "good" regulation, it means the sort that attains legitimate ends for public policy in cost-effective ways; regulation that serves to enhance the wellbeing of the community at large."*
> OECD, Regulatory Policy Outlook 2015, p. 3 (2015).

Dear Readers,

You are either holding in your hands or viewing on your screen a mandatory professional guide designed to assist you – the regulators and decision-makers – in crafting the best possible regulation for the Israeli public.

Regulation is an essential policy tool in improving the country's citizens' and residents' quality of life. The significance of regulation and its impact on residents' lives necessitate the creation of optimal regulation: one that effectively achieves its objectives while minimizing undesirable effects.

In developing regulation, we must be vigilant and avoid transforming it from an asset into a burden. Excessive regulation can hinder and restrict free market activity. It is crucial to balance essential government intervention with the necessary space for the market to function, which is essential for creating optimal regulation.

These Guidelines outline the process for designing optimal regulation. They implement the provisions of the Principles of Regulation Law, 2021, and Cabinet Resolutions 2118 and 218. This edition of the Guidelines is published following the enactment of the Principles of Regulation Law and aims to provide clear and practical guidance for applying the Law's provisions.

The Israel Regulatory Authority is dedicated to enhancing and developing the capabilities of government regulators in the pursuit of optimal regulation. Integrating processes and practices is a gradual and challenging endeavor. The network of regulatory policy leaders within the ministries and the Israel Regulatory Authority is available to support and assist you in this process, aiming to achieve the shared goal

of developing and promoting optimal regulation with maximum positive impacts and minimal negative effects.

The central message of these Guidelines is clear – protect the public interest for which you are responsible while considering the broader economy and the general interest of society. Therefore, focus on refining and streamlining regulation wherever possible. If regulation is necessary, risks must be managed thoughtfully, and effective tools must be used to achieve the objectives. This is our commitment as a government, driven by our concern for advancing society in Israel.

Finally, special thanks to everyone involved in this effort and to Guy Mor, who oversaw the work and contributed his knowledge, experience, and wisdom to benefit everyone and the public.

I hope these Guidelines will serve as a valuable tool in your process of designing high-quality regulations.

Joel Baris
Chairman of the Israel Regulatory Authority

Introduction

Goals of The Guidelines

To achieve optimal regulation, regulations must be developed through a structured preparatory work process, the RIA process. The principles guiding this process were established in the Principles of Regulation Law, with its core components outlined in cabinet resolutions.

These Guidelines outline the RIA process expected from regulators today, which aligns with the Law and cabinet resolutions. They replace the Draft Guidelines published in 2015 and earlier directives on the subject.

The Process of Designing Optimal Regulation

Designing regulation requires a deep and comprehensive analysis of the issue. This involves examining multiple alternatives and selecting the most effective one. The analysis must be based on data, public consultation, and the expertise of professionals in the relevant fields to arrive at accurate conclusions.

Adopting globally accepted practices is a key tool for creating high-quality regulation. International benchmarking allows Israel's regulations to align with established frameworks and accumulated experience. Drawing on the experience of international organizations and other countries helps reduce trade barriers while also bringing Israel's regulations up to date and ensuring they are both effective and efficient.

The RIA process you conduct should be documented in a report. Presenting this process to the public through the report demonstrates professionalism, transparency, fairness, and accountability. Transparency allows for public scrutiny and builds trust. Documenting the process, data, and reasoning in real time sharpens insights, refines conclusions, and serves as a crucial tool for recording and preserving institutional knowledge.

Structure of the Guidelines and how to use them

The Guidelines begin with the General Provisions Chapter, addressing critical questions related to the process required from regulators.

Next, the Principle of Proportionality is introduced. This principle allows regulators to adjust the scope and depth of their process based on the specific issue. It enables you to tailor your work process and resource allocation to the particulars of the problem, avoiding unnecessary stages.

Following this, five cross-cutting principles are presented, applicable throughout the process as needed: data and evidence-based approach, public consultation, examination of policy instruments beyond regulation, risk management, and public transparency.

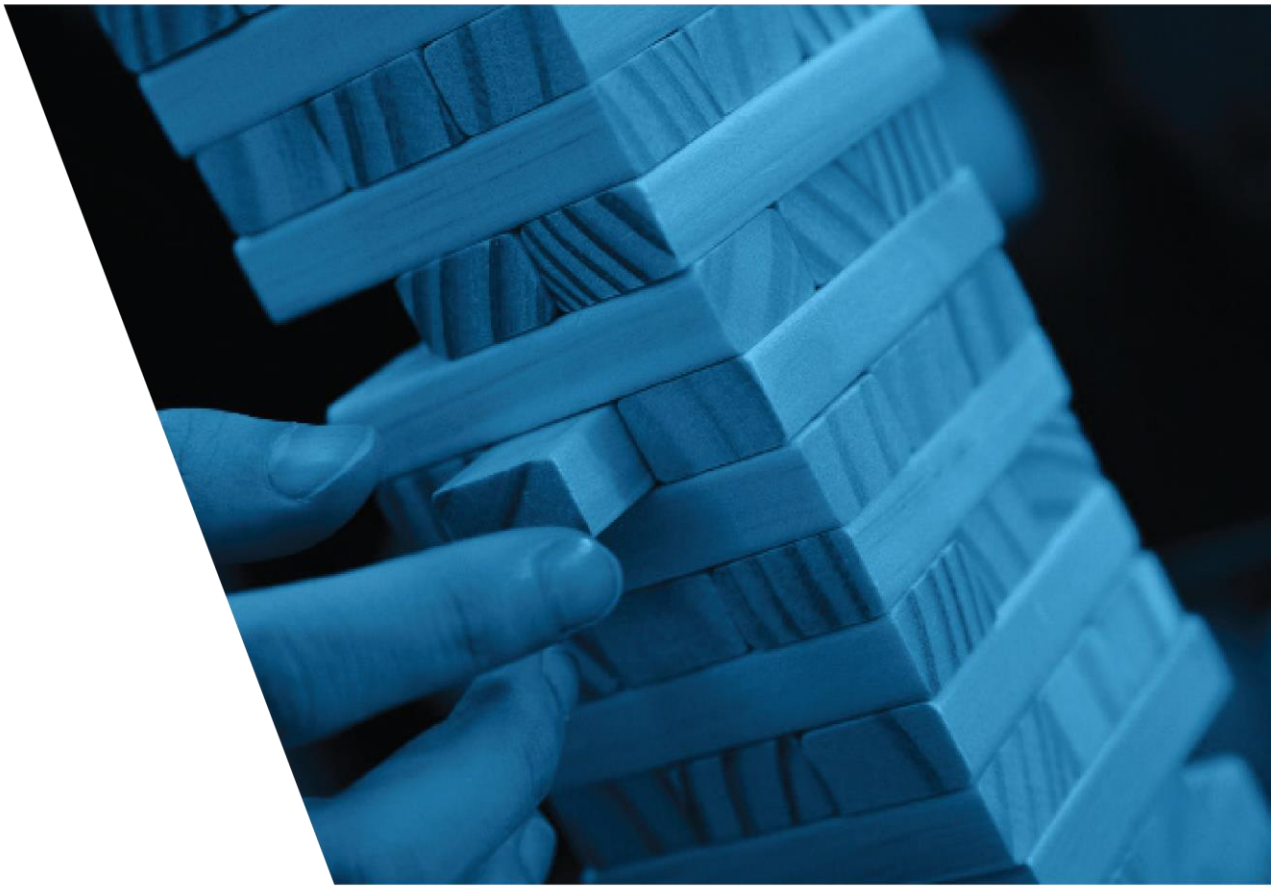
The core of the Guidelines is dedicated to the seven stages of the work process:

1. Problem Analysis
2. Setting Goals
3. International Benchmarking
4. Developing Alternatives
5. Analysis and Comparison of Alternatives
6. Designing the Chosen Alternative
7. Defining Objectives and Criteria

The Guidelines outline the essence of each stage, its value to the regulator, the required output, the work process needed to achieve the output, and a glossary. The focus is on the essential outcome that must be produced at each stage.

Finally, procedural rules are presented, covering consultation with the Israel Regulatory Authority, publication of drafts for public comment, preparation of the accompanying report, and circumstances where exemptions may be granted.

We recommend reading the Guidelines in their entirety to gain a comprehensive understanding of the process and its underlying logic. Then, you can refer to them as needed.



Additional tools and resources

Alongside these mandatory Guidelines, we provide a Best Practices Document that elaborates each stage of the process and offers practical advice.

While the Guidelines specify what needs to be done, the Best Practices Document explains how to execute the process best. If you have questions or wish to explore a specific stage in detail, we encourage you to refer to the relevant chapter in the Document. The structure of the Best Practices Document mirrors that of the Guidelines for easy navigation.

Additionally, we offer other practical tools, including a recommended template for the regulation design report and resources to assist with various process stages. All these resources are available online at the Israel Regulatory Authority's website.

Future development

Just as regulations are periodically reviewed and updated, we will also periodically review and update the Guidelines. The Israel Regulatory Authority intends to learn from the experience of implementing the Guidelines and publish an updated edition within two years. Please do not hesitate to provide feedback and suggestions so we can incorporate your insights and experiences into the Guidelines.

General Provisions

As regulators, it is essential that our decisions are based on professional processes. RIA is mandatory. These Guidelines outline the provisions for conducting this process and assist you in your daily work.

The Guidelines are designed to facilitate a high-quality process tailored to your specific issue, allowing you to implement regulation more effectively and efficiently.

What is regulation?

Principles of Regulation Law, 2021, Section 3
For the complete and accurate definition, please refer to the Law and the cabinet resolutions

"Regulation" refers to general, binding provisions that govern economic or social activities and are enforceable through criminal or administrative measures, including the revocation of regulatory approvals (permits, licenses, etc.). It covers all rules established and enforced by the government, detailing what actions are prohibited, required, and under what conditions. Regulations are established through laws, regulations, procedures, licenses, and other binding documents applicable to the public.

The legal definition of "regulation" is established by The Law and provided here. Please contact us if you need assistance interpreting the term "regulation" or determining whether a specific regulation requires a RIA process. The Israel Regulatory Authority is available to help provide a consistent and informed response to these questions.

> **"**Regulation – A provision that establishes a general rule of conduct and meets all the following criteria:
> 1. It is intended to regulate economic or social activities.
> 2. It is enforceable through criminal or administrative measures by a public authority or a public corporation.
> 3. It is established by legislation or authorized under law through directives, procedures, circulars, opinions, or similar provisions, even if referred to by a different name. This includes provisions that become binding when incorporated as a condition in a regulatory approval. However, it excludes provisions detailed below: [...]
>
> For the purposes of this definition, "administrative measure" includes the withholding of regulatory approval."

The Principles of Regulation Law, Section 3.

Like all public policy, the goal of regulation is to enhance and improve the quality of life for residents. Regulation achieves this by fulfilling fundamental rights and public interests (collectively referred to as “protected interests”). Successful regulation is one where the benefits outweigh the costs. It is also important to note that the government can address public issues and influence individual, business, and group behavior through non-regulatory tools, such as incentives, public awareness campaigns, behavioral economics, and more. For further details, see Appendix D of the Best Practices Document.

What are the duties of a regulator when designing regulation?

Regulators must design regulation through a structured process called Regulatory Impact Assessment (RIA), as detailed in these Guidelines.

The Principles of Regulation Law, Cabinet Resolution 2118, and Cabinet Resolution 4398 (dated December 23, 2018), regarding "Smart Regulation – Implementing OECD Recommendations and Amending Cabinet Resolution" (hereinafter referred to as "Resolution 4398"), set forth the principles and mandatory work process for regulators involved in designing regulation.

These Guidelines are published under the authority of Cabinet Resolutions 218 and 2118, which mandate that regulators conduct a regulation design and impact assessment process in line with the principles established in these resolutions when enacting regulation. Additionally, these resolutions instruct the Israel Regulatory Authority to publish the RIA Official Guidelines, which regulators must follow when implementing the cabinet resolutions.

The Guidelines outline the rules for the RIA process and the preparation of the accompanying report, as specified in the cabinet resolutions. They replace the 2015 Draft Guidelines and nullify previous provisions on the subject, including documents such as "Recommendations for a 'Basic' Regulatory Impact Assessment Process," "Regulatory Changes Requiring Brief Justification," and "A Guide to the RIA Requirement."

These Guidelines are concise. We also publish the Best Practices Document and Recommendations for Regulation Development, which provide expanded recommendations, explanations, and examples in greater detail.

What is the RIA process?

An orderly process aids in analyzing the issue or problem, developing quality solutions, and selecting the best alternative. This process involves stages common to any good decision-making approach: problem analysis or risk assessment, setting goals, using data, examining multiple alternatives, assessing and understanding the impact of each alternative, and comparing the alternatives to choose the best one.

Using this process will help you to:

- Identify the root causes of the problem
- Leverage global experience to choose a solution that has been successfully tested elsewhere
- Minimize unintended effects of regulation (e.g., impacts on other protected interests)
- Select a viable alternative that effectively addresses the problem

Orderly work also helps streamline and expedite subsequent stages, such as inter-ministerial coordination or interactions with Knesset committees.

This process has been implemented in many countries worldwide for decades and is codified in Israel's Principles of Regulation Law.

When should the RIA process be used?

The RIA process should be applied whenever any regulation is being developed, whether it involves creating new regulations, adding to, reducing, amending, or repealing existing ones.

This process must be used for regulation at all normative levels, regardless of its form:

- Laws
- Regulations
- Procedures
- Guidelines
- Circulars
- Letters
- Opinions
- Any similar provision, even if referred to by a different name

Even easing regulation or making a simple change can alter processes, create uncertainty, or harm other protected interests. Therefore, preparatory work should also be conducted in these cases. The scope of the process can be adjusted according to the Principle of Proportionality, avoiding stages that do not add value.

The obligation to follow the RIA process applies to any enactment of regulation or any changes to its content. Examples include:

- Enacting regulation for the first time
- Amending existing regulation
- Reducing or easing regulation
- Changing enforcement methods: setting sanctions or adjusting their severity
- Amending regulation based on recommendations from public committees
- Temporary regulation: enacting or extending regulation set by a temporary order
- Amending regulation as part of a regulatory burden reduction program
- Minor changes to regulation

There is no need to follow the process for purely formal changes (e.g., correcting typographical errors or adding page numbers) or when applying a mathematical formula already established in legislation (e.g., indexation adjustments).

Since different changes require varying levels of effort, the scope of the RIA process work can be adjusted according to the issue at hand. For guidance, refer to the "**Managing the Process: Proportion in Scope and Depth of the Process**" chapter.

In case of uncertainty regarding the need to follow the process or its scope, **consult with your regulatory policy leader**.

Who is responsible for this duty?

The responsibility for conducting the RIA process lies with the regulator who enacts or proposes the regulation.

The obligation to follow the RIA process applies to any public authority legally authorized to propose regulation to another body, enact regulation, publish guidelines for implementing regulation, or issue regulatory approvals (unless a specific exemption is provided in the Principles of Regulation Law or cabinet resolutions).

This obligation applies to the government, government ministries and their units, auxiliary units, and the Israel Police.

When should the RIA process begin?

The process should begin as early as possible, ideally when a new issue or problem is first identified. The process starts with the initiation of preparatory work, before a final decision has been made. Experience shows that the earlier the process begins, the more beneficial it is for the regulator.

If the process begins when the outcome is already predetermined, following the process holds no value, as the decision has already been made. It is important to note that decisions made in advance, without following an orderly process, may be flawed: they may fail to resolve the problem and could create additional issues.

Even when a preferred direction is established from the outset, the RIA process can still be valuable. This work can refine the approach or lead to a better solution. The RIA process is a tool that helps you make better decisions to solve the problem effectively and advance the public good.

Conducting and documenting the RIA process

The RIA process is a decision-making tool for enacting regulation. Its outputs are crucial: understanding the problem, evaluating the impact of different alternatives, identifying the preferred alternative, and more. Alongside this substantive decision-making process, **every regulator is required to document their analysis, considerations, and decisions in an accompanying report (the RIA Report).**

The report must document the reasoning behind the decision-making process, including the information, analysis, considerations, and conclusions. It must also include data and references to information sources. The regulator is responsible for preparing and signing this report.

The report is intended to reflect the process itself, so **its length and scope will depend on the scope of the work undertaken**. For example, the report can be brief and concise in cases where the process was relatively simple.

It is recommended to document the RIA process as you go, rather than waiting until the end. This approach aids in the thought process, simplifies the preparation of the final report, and ensures complete documentation.

Who can you consult with?

Whenever you have doubts, it is recommended that you consult with the regulatory policy leaders within your ministry. These regulatory policy leaders are professional experts in the RIA process and possess the tools and knowledge to help you maximize its effectiveness—whether it is analyzing the problem's components, conducting effective public consultation, identifying relevant alternatives, or comparing them. **They should be your first point of contact for planning the process and seeking advice throughout its duration**. Additionally, you may consult with the Israel Regulatory Authority.

While you may engage external consultants, the responsibility and authority to exercise

discretion during the design and enactment of regulation remain with you—the regulators.

Managing the process: proportion in scope and depth of the process

Deciding the appropriate depth and level of investment required for each process stage.

The Essence of the Principle of Proportionality

The Principle of Proportionality allows you to adjust the work process and the level of investment according to the specific issue at hand.

The Value of the Principle of Proportionality

This principle enables a process tailored to the appropriate scope and depth, allowing you to invest where necessary and avoid inefficient stages.

General: Structure of the process

The RIA process consists of seven stages:

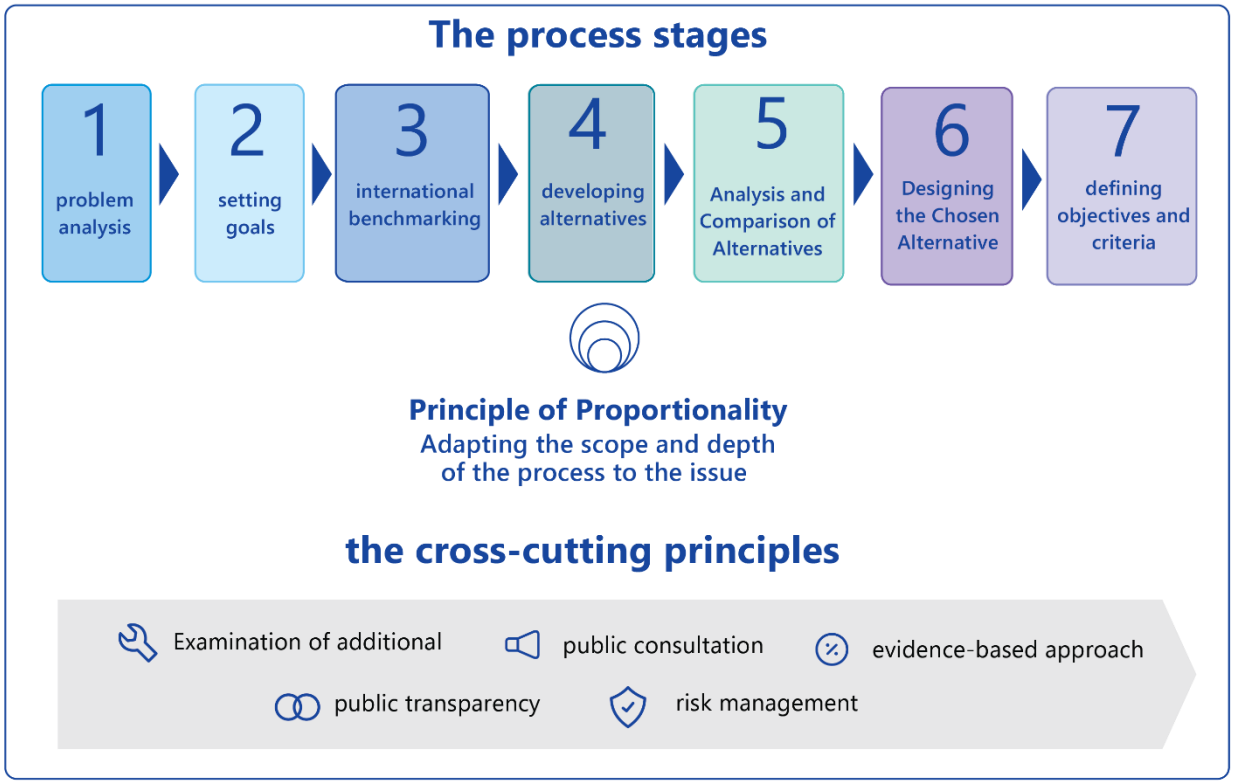
1. Problem Analysis
2. Setting goals
3. International Benchmarking
4. Developing Alternatives
5. Analysis and Comparison of Alternatives
6. Designing the Chosen Alternative
7. Defining objectives and Criteria

In addition, throughout the process, five cross-cutting principles should be applied:

1. Evidence-based approach
2. Public consultation
3. Examination of additional policy instruments other than regulation
4. Risk management
5. Public transparency

Flexibility in the structure of the process

- The process can be linear or iterative.
- It may involve addressing multiple separate issues, each analyzed individually.
- Use your discretion when defining the scope of the process—whether to address the issue in its entirety or focus on a particular.



The Principle of Proportionality

Aligning the level of investment with the process

The process is designed to serve you, allowing you to exercise discretion regarding the level of investment. This is the **Principle of Proportionality**—each stage of the process should be proportional to the benefits it provides, ensuring that the investment does not exceed the value gained from it.

Investment in the various stages, such as problem analysis, international benchmarking, and alternative development, should be proportional to the scope and depth of the process. A smaller-scale process may suffice for more simple or limited issues. Conversely, for more complex issues, severe problems, or innovative fields, the process should be expanded and deepened accordingly.

The regulator decides on the scope and depth of the process. Because this decision impacts the quality of the RIA process and outputs, it is recommended that you **consult with your ministry's regulatory policy leader.**

Adapting each stage of the process to the issue

There is no one-size-fits-all approach to the process or the depth of investment in its stages—some stages may require a comprehensive approach, while others may be more limited. For example, the problem analysis stage might be extensive and involve gathering substantial data, while the development of alternatives could be more concise due to a lack of viable options.

As part of defining the scope and depth of the process, the regulator is responsible for determining how many countries to examine during international benchmarking, how many public consultation processes to conduct and their depth, how deeply to analyze the root causes of the problem, and more.

In the Best Practices Document, you will find examples of frameworks and suggestions for structuring smaller-scale processes, such as:

- Pure regulatory relief.
- Adopting a foreign regulation that is mandatory and implementation without changes.

Continuously applying the Principle of Proportionality throughout the process

At the end of each stage, assess how the information and decisions influence the process's scope and depth.

Criteria for Proportionality in the Process

1. **Complexity of the Issue** – Assess the complexity of the issue, including the number of stakeholders involved (both inside and outside the government), the amount of information needed to analyze it, and the variety of impacts, among other factors.

2. **Severity of the Problem** – Consider the severity of the damage and harm to the public and protected interests from a broad perspective.

3. **Is this a Fundamental or Substantial Regulation?** – Evaluate whether the process might lead to a fundamental or substantial regulation in the field, or to significant changes to the current situation. Conversely, some processes may result in minor changes without altering the foundations of the existing framework.

4. **Novelty and Innovation in the Field** – Greater uncertainty exists in unfamiliar or new fields, where there is often a lack of information and experience. Additionally, regulating a new field for the first time may dictate its development and significantly influence future innovation and progress.

5. **The Regulator's Scope of Discretion** – Consider whether a smaller-scale process is appropriate when implementing a binding norm. Evaluate whether a binding norm limits or narrows discretion, such as legislation, court rulings, cabinet resolutions, or an international treaty to which Israel is a party.
   If the process aims to implement a binding norm, consider a more limited process depending on how constrained discretion is (for example, some

cabinet resolutions are broad, while others prescribe detailed frameworks). If the decision is made to reassess the binding norm, this may require a more comprehensive process.

6. **Extent and Weight of the Expected Impact of the Policy, Emphasizing Costs and Unintended Consequences** – Once the policy or regulation can be estimated (typically not at the early stages of the process), consider its impact. A more comprehensive and in-depth process will be necessary if the policy or regulation may have a broad and significant impact. If the regulation meets the definition of Economically Significant Regulation (as defined by The Law or that can be anticipated), a broader and deeper process is required.

7. **Urgency** – An urgent and unexpected need may require a rapid process. However, even urgent issues can be complex or innovative, requiring thorough analysis. When an issue is unforeseen and requires immediate action to prevent severe and significant harm, a more limited process can be performed, provided that the regulation is temporary and will remain in effect for no more than one year. Urgency may also influence the content of the process, such as prioritizing a partial solution focused on quick impact.

Outputs of the Principle of Proportionality

1. **Decision on the Level of Investment in Executing Each of the Seven Stages**
    - **Scope of Work for Each Stage:** Determine how many root causes will be analyzed, how many countries will be examined, how many alternatives will be developed, and similar considerations.
    - **Depth of Work for Each Stage:** Decide how deeply you will analyze the problem and its systemic nature, the extent of the international review, the thoroughness of the impact analysis for each key alternative, the level of detail in comparing alternative regulatory measures, and so on.

2. **Decision on When and to What Extent to Apply the Cross-Cutting Principles**
    - **Data and Evidence-Based Approach:** Determine how much data to collect, the effort required to refine and analyze the data, the rigor needed to ensure the data is up-to-date and complete, the number of separate sources to collect data from, and so on.
    - **Public consultation:** Decide when to conduct public consultation processes, the level of investment in each process, the effort to diversify stakeholders, how many stakeholders to engage, and so forth.
    - **Examination of Additional Policy Instruments Beyond Regulation:** Identify which stages should consider alternative policy instruments as a basis for analysis.
    - **Risk Management:** Determine in which stages to apply risk management tools and the depth of risk assessments and mitigation efforts.
    - **Public Transparency:** Decide at which stages and to what extent to invest in making the process and its interim outputs transparent to the public, and how much to invest in the final process and outcomes transparency.

3. **Decision on Stages That Cannot Be Skipped**
    - **Exceptional Situations:** In some cases, it may be apparent from the outset that the investment in a particular stage would significantly

outweigh its benefits. If so, it may be decided that the stage does not justify the investment and should not be carried out.

- **Justification:** Any decision to skip a stage must be justified in writing in the RIA report, based on the specific characteristics of the process and the criteria for proportionality in the process.
- **Mandatory Stages:** It is not permissible to skip the problem analysis stage, the alternatives development stage, or the analysis and comparison of alternatives stage.
- **Smaller Scale Completion:** Even when the value of a particular stage seems low, it is generally advisable to complete the stage on a smaller scale rather than skip it altogether.

Note: An incorrect decision on the scope and depth of the process may severely impact the quality of the process and its outcomes. Therefore, consulting with your ministry's regulatory policy leader, who serves as the methodological expert for formulating regulation is recommended. You may also consult with the Israel Regulatory Authority.

For explanations, advice, and examples, see the "Managing the Process: Proportionality in Scope and Depth of the Process" chapter in the Best Practices Document.

It is not permissible to skip the problem analysis stage, the alternatives development stage, or the analysis and comparison of alternatives stage

Cross-cutting principles for RIA

Tools to Help Conduct RIA and Assess Its Impacts Effectively

The cross-cutting principles should be applied throughout all stages of the process.

Summary of the Value of Using Cross-Cutting Principles

These principles assist in making well-reasoned decisions that form the basis for effective and efficient regulation.

Evidence-Based Approach

Regulation and public policy must be grounded in data and evidence. Often, we begin the RIA process with assumptions about the problem or a possible solution. However, decisions should be based on reliable data and evidence, not merely on assumptions. International reviews can be used to gather insights and data at different stages of the process. This data can come from domestic and international sources, including government publications, academic research, and private-sector reports.

We rarely have perfect information, so the data relied on must be up-to-date, relevant, and accurate. Estimates and assumptions may be used when collecting or analyzing data proves challenging.

Therefore, data should be collected and examined throughout all stages of the RIA process to support the analysis. High-quality data should focus on trends rather than anecdotes (individual cases or fleeting events).

For more detailed information, recommendations, and tools, it is recommended to review Appendices C and G of the Best Practices Document.

Public Consultation

Engage with the Public and Stakeholders: Try to connect with various stakeholders during the thought process to gather information and ideas, ensuring that their opinions and needs are considered. Public consultation

does not always have to involve the broad public—it may include discussions with those directly affected by the problem, people who the regulation may impact, experts in the field, civil society, government representatives (either from your ministry or another one), and other relevant stakeholders.

Public consultation can occur at any stage of the RIA process and has the potential to improve it. A discussion qualifies as public consultation if it takes place before a decision is made, distinguishing the public consultation process (which happens before a decision is reached) from the publication of a draft regulation for public comment.

Generally, RIA should include at least one public consultation process with those impacted by the problem and those affected or expected to be affected by the regulation. If you choose not to conduct any engagement, you must justify the accompanying report. The goal is to uncover new perspectives or obtain information that otherwise would not have been available.

In addition to public consultation, interministerial coordination is highly valuable. If a relevant government entity has been identified regarding the issue, you should contact them and involve them in the process.

For more detailed information, recommendations, and tools, it is recommended to review Appendix F of the Best Practices Document and the Governmental Guidelines for Public Consultation.

Examination of additional policy instruments other than regulation

Consider non-regulatory alternatives, such as incentives, taxation, public awareness campaigns, behavioral economics, infrastructure development, etc. Various policy tools can address the problem; sometimes, regulation alone may not suffice. In most cases, solving complex problems requires a combination of several tools.

Considering additional policy instruments can be relevant throughout the entire process. For example, the problem definition is often influenced by the types of solutions we typically implement, so expanding the range of tools considered can lead to a more precise problem definition. Additionally, international benchmarking can involve reviewing both regulations and other policy instruments.

For more detailed information, recommendations, and tools, it is recommended to review Appendix D of the Best Practices Document.

Risk Management

When assessing a problem or risk, the severity of the damage caused by the risk and the likelihood of it occurring must be considered. Additionally, the level of uncertainty—both regarding the risk itself and the success of the different alternatives—must be considered. Furthermore, remember that a zero-risk scenario does not exist. Therefore, the goal of intervention should be to mitigate the risk, not to eliminate it.

For more detailed information, recommendations, and tools, it is recommended to review the Governmental Guidelines to Risk Management in Regulation and Public Policy.

Public Transparency

Promote transparency of the process to the public and stakeholders—both in real-time and after completion. Document your thought process and the results of your analysis. In the report published at the end of the process, present the study, rationale, and data that underpin the regulation you designed.

The Cross-cutting principles

- Evidence-Based Approach
- Public Consultation
- Examination of additional policy instruments other than regulation
- Risk Management
- Public Transparency

Stage 1: Problem Analys is

Analyzing the characteristics of the problem as the foundation for RIA

The Essence of this stage

Analyze the problem, its root causes, and the harm or damage it causes. This stage forms the foundation of the entire process and will dictate the issues that need to be addressed.

The Principal Value of this Stage

Without a thorough analysis of the problem and its root causes, it cannot be effectively solved.

Required Output

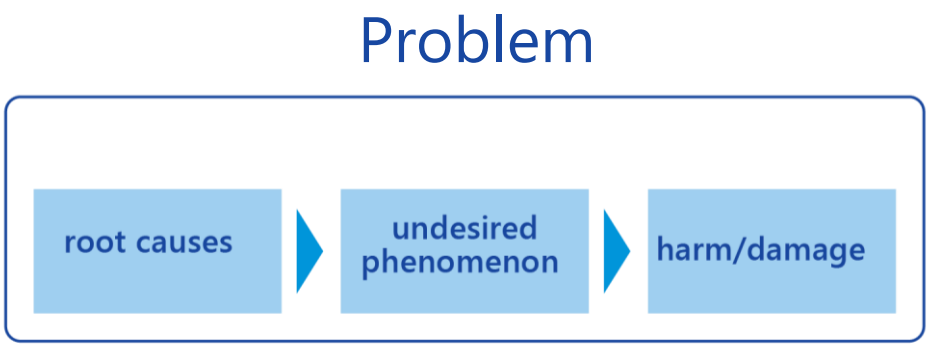
1. A clear definition of the problem, including:
    - A description of the undesired phenomenon and its characteristics.
    - A description of the root causes of the undesired phenomenon.
    - A description of the primary harm or damage caused by the undesired phenomenon.
2. Justification for whether government intervention is needed to address the undesired phenomenon:

- Does the extent of the harm or damage nationally justify government intervention?
- Will the problem resolve or diminish on its own without government intervention?
- Does the public, in addition to the regulator, perceive a need for government intervention?

3. Mapping of key stakeholders involved in the problem.
4. Mapping the current situation, including relevant regulation, regulators, and policies that intersect with or are relevant to the problem.
5. A conclusion that this is a systematic problem that recurs due to the root causes.

The work process required to achieve the output

1. Defining the undesired phenomenon and the damage it causes.
2. Verifying that the phenomenon and damage justify government intervention.
3. Defining the main actors and the current factual and regulatory situation.
4. Identifying the root causes of the undesired phenomenon and verifying that they systematically cause the problem.



Glossary

Undesired Phenomenon: A negative occurrence or conduct that causes harm or damage or poses a risk of causing harm or damage, which the regulation seeks to mitigate. The undesired phenomenon may also exist within the regulation itself, such as conflicting or unworkable provisions or unnecessary bureaucracy. The undesired phenomenon exists in the real world, so a "lack of legislation" cannot be considered an undesired phenomenon.

Harm or Damage: The harm to social welfare or a protected interest (such as economic damage or other deterioration) caused or potentially caused by the undesired phenomenon.

Root Causes: The actions, events, or incentives that create the undesired phenomenon.

Systematic Problem: A problem that recurs due to a built-in mechanism, cause, or failure that consistently generates it (as opposed to anecdotes or a group of cases without a common root cause).

For explanations, advice, and examples, see the "Problem Analysis" chapter in the Best Practices Document.

Stage 2: Setting Goals

Setting the outcomes the regulation aims to achieve

The Essence of this stage

Setting the Goals of government intervention clearly and broadly.

The Principal value of this stage

Setting the Goals will determine the desired outcome of the regulation.

Required Output

1. clearly setting the intervention's goals provides a vision of successful regulation
    - A concrete definition that addresses improvements in the current situation or the mitigation of the problem (such as reducing the undesired phenomenon or the harm and damage it causes).
    - The goal should focus on the final outcomes you aim to achieve, not the means or actions to be taken.
    - The goal should not predefine a specific alternative or solution.
    - It is possible to define multiple goals.
    - At this stage, there is no need to set specific measurable objectives.

The Work Process Required to Achieve the Output

1. Identifying the government intervention's goal as a derivative of the problem definition.
2. Defining the goal at an appropriate level—not too broad and vague, but not too narrow either.
3. Phrasing the goal in a way that allows it to be used to evaluate the alternatives.

For explanations, advice, and examples, see the "Goals Setting" chapter in the Best Practices Document.

The Cross-cutting principles

- Evidence-Based Approach
- Public Consultation
- Examination of additional policy instruments other than regulation
- Risk Management
- Public Transparency

Stage 3: International benchmarking

Review of relevant global regulations as the foundation for developing alternatives

The Essence of this stage

Conduct a review of relevant regulations from international organizations and leading countries. This will form the basis for developing regulatory alternatives for Israel.

The Principal value of this stage

International benchmarking allows us to learn from the experiences of others, providing a strong foundation for developing effective regulation.

Required Output

1. A review of the prevailing global regulations or policies related to the issue at hand, including:
    - The problem the regulation is intended to solve.
    - The context and circumstances surrounding the problem.
    - The regulation itself.
    - The regulation's outcomes—both in resolving the problem and any additional impacts, where available.
2. A review of foreign regulations previously relied upon by the ministry, or relevant regulations from the relevant field.

3. Definition of a foreign regulation to serve as the foundation for Israel's domestic regulation, including a rationale for why this regulation was chosen as the foundation.

4. Further explanations:

    - If a global regulation was not chosen as the foundation for the Israeli regulation, explain the reasoning.
    - If a different regulation was chosen from the one previously relied upon by the ministry, explain the reasoning.
    - If a regulation that is not the prevailing global standard is chosen, explain the reasoning.
    - If multiple regulations from various countries are selected as the basis for developing local regulation, explain the reasoning.

Cases with strong international affiliations

These provisions apply when international affiliations significantly outweigh local ones. For example, in industries with predominantly international interfaces (e.g., the tech industry, international aviation). In such cases:

1. This stage cannot be skipped.
2. A comprehensive review of prevailing global regulations must be conducted.
3. A justification for the exceptional circumstances that warrant this must be provided if the decision is made not to rely on the leading and prevailing global regulation.

The work process required to achieve the output

1. Reviewing international regulations from developed countries with significant markets, leading countries in the relevant field, countries with relevant similarities to Israel, and international organizations.
2. Reviewing foreign regulations previously adopted by the ministry or in the relevant sector.
3. Choosing the global regulation that will serve as the foundation for the domestic regulation.

Glossary

Developed countries with significant markets: See the recommended list in Appendix B of the Best Practices Document.

For explanations, advice, and examples, see the “International Benchmarking” chapter in the Best Practices Document.

The Cross-cutting principles

- Evidence-Based Approach
- Public Consultation
- Examination of additional policy instruments other than regulation
- Risk Management
- Public Transparency

Stage 4: Developing Alternatives

Identifying a range of possible solutions to the problem

The Essence of this stage

Identify and outline several practical and diverse alternatives that could help mitigate the problem.

The Principal Value of this Stage

Developing alternatives allows for identifying well-defined approaches to address the issue before selecting the preferred one.

Required Output

1. A list of at least three key alternatives:
    - The list will include the "Status Quo" alternative (no change in the current regulation) and additional alternatives.
    - If the previous stage relied on foreign regulation, one of the alternatives should be based on that regulation.
    - In exceptional cases of smaller processes, two key alternatives (including the Status Quo) may suffice.
2. Each key alternative will include:
    - The people, actions, or objects it affects.

- The policy tools included in the alternative.
- The core provisions.
- Supervision and enforcement mechanisms.
- How the alternative impacts the problem.
- The feasibility of the alternative.

Key points for the output

1. Identifying potential alternatives should focus, where possible, on alternatives that include:
    - Focus on the root causes of the problem.
    - Non-regulatory alternatives and those that include self-regulation.
    - Differentiated alternatives considering variations among regulated entities (e.g., size and risk level).
    - Alternatives where supervision occurs during activity rather than through pre-approvals.
    - Alternatives that adjust existing regulation rather than adding new provisions.
    - Alternatives that set performance standards rather than procedural standards.
2. The list of key alternatives should include those with high feasibility, significant impact on the problem, and optimal effects on the protected interest, society, the environment, and the economy.
3. Where possible, the key alternatives should reflect a variety of approaches—both in terms of policy instruments and the mechanisms that address the problem.
4. Non-viable alternatives should not be included in the list.
5. If the RIA involves multiple issues, a separate list of alternatives should be drafted for each issue.

The work process required to achieve the output

1. Identifying potential alternatives.
2. Focus and decide on the key alternatives.
3. Outline each of the key alternatives.

Glossary

Key Alternatives: Chosen alternatives from the range of possibilities selected for focused consideration.

Non-Regulatory Alternatives and Other Policy Tools: Public awareness campaigns, civil litigation rights, physical infrastructure, financial incentives, etc.

Self-Regulation: A system in which the regulated parties or another private entity set the rules (and sometimes also enforce them). In some cases, the government is not involved at all, and when it is, it plays a secondary role (usually by encouraging such a system or assisting with enforcement).

Ongoing Supervision: Supervision and enforcement carried out during the regulated activity.

Pre-Approval Supervision: Supervision activities carried out before the activity begins, where pre-approval, such as a license or permit, is required to perform the regulated activity.

Process Standards: Establish requirements related to work processes, materials, technologies, and inputs.

Performance Standards: Establish mandatory results that must be achieved.

Feasibility: The likelihood of successfully approving, implementing, and enforcing the alternative, including the timelines and resources involved.

Non-Viable Alternative: An alternative that is inferior to all the others.

For explanations, advice, and examples, see the “Developing Alternatives” chapter in the Best Practices Document.

The Cross-cutting principles

- Evidence-Based Approach
- Public Consultation
- Examination of additional policy instruments other than regulation
- Risk Management
- Public Transparency

Stage 5: Analysis and Comparison of Alternatives

Evaluating the impacts of each key alternative and comparing the alternatives

The Essence of this Stage

Identifying the various impacts of each key alternative and quantifying those impacts, comparing the alternatives, and selecting the preferred one.

The Principal Value of this Stage

Analyzing the expected impacts of each alternative allows for selecting the option that will benefit society and the economy the most.

Required Output

1. Identifying the impacts of each key alternative on:
    - The incentives of different stakeholders.
    - Benefits – including mitigating the harm and damage the problem causes.
    - Direct costs to the regulated parties – including compliance, bureaucracy, fixed, and one-time costs.
    - Additional impacts – on the protected interest, society, environment, economy, competition, innovation, government costs (including supervision and enforcement), and other effects.

2. Quantifying the impacts of each key alternative:
    - Real-world Quantification of all impacts.
    - Monetary Quantification of direct compliance costs.
    - Monetary Quantification of other impacts – as much as reasonably possible.
3. Comparison of the key alternatives based on a prevailing method:
    - Cost-Benefit Analysis (CBA); or
    - Cost-Effectiveness Analysis (CEA); or
    - Multi-Criteria Analysis (MCA).
        - If MCA is chosen:
            - The criterion reflecting the regulation's purpose will be concretely formulated based on the objective defined in Stage 2.
            - The decision on weight distribution for the various criteria should be explained.
            - When the comparison is conducted using qualitative variables, the method of determining each score should be explained.
4. Reasoned selection of the preferred alternative, considering its impact on the problem, benefits, costs, and chances of success:
    - If the preferred alternative is not based on foreign regulation, explain the reasoning.
    - If the preferred alternative is based on foreign regulation but deviates from it, explain the reasoning.
    - If the regulator is an elected official (minister) and decides to deviate from the professional recommendation, this should be noted separately. It is recommended that the minister’s decision be explained.
5. Determining whether the selected alternative constitutes an economic-impact regulation.

The work process required to achieve the output

1. Identifying the various impacts of each key alternative.
2. Quantifying the different impacts of each key alternative.
3. Comparing the key alternatives.
4. Selecting the preferred alternative.

Glossary

Bureaucratic Cost: The direct cost resulting from interactions with the regulator, such as reporting requirements, submitting applications and forms, obtaining approvals, waiting times, etc.

Compliance Cost: The direct cost of meeting the content requirements of the regulation, including financial expenditure, labor time, and waiting periods for government approvals.

Real-world Quantification: Quantifying factual impacts, such as the number of annual accidents, number of employees, or number of issued approvals.

Monetary Quantification: Financial quantification of the annual cost of various impacts.

Cost-Benefit Analysis (CBA): This method sums up all the economic impacts of the alternative to determine the net benefit (total benefits minus total costs). The preferred alternative is the one with the highest net benefit. This method is recommended because it is relatively objective and comprehensive. It is preferred when the impacts of the different alternatives can be quantified.

Cost-Effectiveness Analysis (CEA): This method includes a quantitative assessment of the costs and a qualitative assessment of the benefits. First, a specific goal is set—mitigating the problem—and the cost of each alternative to achieve that goal is examined. This method is quantitative at its core and produces consistent analysis, but it is less precise than CBA, as the benefits are not quantified. This method is appropriate when there is a qualitative evaluation of the benefits and most of the costs can be quantified.

Multi-Criteria Analysis (MCA): This method allows for analyzing various factors, including qualitative and quantitative aspects. MCA compares alternatives based on different criteria, assigning each criterion a "weight" and consolidating the comparison into a single final score. This method is appropriate when quantitative data on the benefits and costs are unavailable, as it allows for estimations and subjective scoring. Due to its reliance on estimations, this method is more complex and less precise. It is recommended for use when the two previous methods are not feasible.

Economically Significant Regulation: Regulation that meets one of the following criteria: (1) The annual compliance cost exceeds ILS 100 million; (2) It establishes a requirement for regulatory approval that was not previously required (as defined by The Law)

For explanations, advice, and examples, see the “Analysis and Comparison of Alternatives” chapter in the Best Practices Document.

The Cross-cutting principles

- Evidence-Based Approach
- Public Consultation
- Examination of additional policy instruments other than regulation
- Risk Management
- Public Transparency

Stage 6: Designing the Chosen Alternative

Defining the precise content of the regulation

The Essence of this Stage

To concretely define the general alternative chosen to establish the provisions' content. This involves determining the professional content rather than the legal drafting.

This stage is intended for cases where, in Stages 4-5, general or conceptual alternatives were examined without defining their precise content. The aim here is to delve deeper into the chosen alternative and to specify its detailed content.

The Principal Value of this Stage

Defining the detailed content of the chosen alternative as a basis for enacting effective and efficient regulation.

Required Output

1. A detailed characterization of the content of the chosen alternative, including the following details:
    - Scope: Clear definitions of the regulated parties (people, objects, and actions) subject to the provisions.
    - The provisions for each regulated party – duties, prohibitions, conditions, and required approvals.
    - Exceptions and exemptions (if necessary).
    - Supervision and enforcement mechanisms.
    - Monitoring mechanisms.
    - Implementation framework (transition period, required budgets, arrangements for experimentation and modification of the alternative, etc.).
2. Decision regarding the detailed content of the chosen alternative:
    - For issues with significant impact – the decision should be based on comparing alternatives.
    - For issues with minor impact – the decision should be reasoned.

Key points for the output

Design the content of the alternative according to the following principles:

1. Focus the provisions on the problem and avoid over-regulation.
2. Consider factors such as differentiation, risk management, and digitalization (especially regarding regulatory approval); minimize pre-approvals; consider competition, economic, environmental, and social considerations; public accessibility; intergovernmental coordination; and prioritize performance standards over procedural standards.
3. Consider setting mechanisms for behavior change, such as persuasion and behavioral economics.

4. Consider using technology to improve compliance, reduce compliance costs, and simplify bureaucratic processes.

The work process required to achieve the output

Defining the content of the chosen alternative.

Glossary

Monitoring: The set of actions intended to create a factual picture of reality (compliance with the provisions, risk map, impact of the regulation, etc.). Monitoring includes the collection and analysis of information.

For explanations, advice, and examples, see the “Designing the Chosen Alternative” chapter in the Best Practices Document.

Stage 7: Defining Objectives and Criteria

Establishing objectives and criteria for future assessment of the regulation

The Essence of this Stage

Establishing measurable objectives and criteria for the future assessment of the current changes in the regulation.

The Principal Value of this Stage

Defining measurable objectives and criteria will ensure that the chosen alternative achieves its goals and remains necessary.

Required Output

1. A measurable objective to assess the regulation's effectiveness (i.e., did the alternative achieve its goal?), including:
    - Quantitative/qualitative metrics.
    - A success threshold.
    - Evaluation frequency.
    - The type of data to be collected.
    - Data sources.

2. Criteria to assess whether the regulation is still needed, based on problem analysis and setting.
3. A timeline for reviewing progress on objectives and criteria (within 5 or 10 years).

The work process required to achieve the output

1. Establishing measurable objectives for evaluating effectiveness.
2. Establishing criteria to assess the need for regulation.
3. Establishing the method for collecting and analyzing the data.

For explanations, advice, and examples, see the “Defining Objectives and Criteria” chapter in the Best Practices Document.

Procedural rules

Completing the process: consultation with the Israel Regulatory Authority and public comments

Receiving feedback from the Israel Regulatory Authority and the public

After completing RIA as outlined in the Guidelines, two steps must be taken before the regulation can be finalized:

1. Submit the regulation draft and the RIA report to the Israel Regulatory Authority for consultation under Section 21 of the Principles of Regulation Law via email: reg_report@pmo.gov.il. Wait to receive feedback or a decision from the Authority about its advisory. The Authority's feedback is publicly available.

2. Publish the regulation draft and the RIA report for public comment on Israel's Government Legislation Website.

For instructions on mandatory consultation with the Authority, see the Guidelines for Consultation Procedures with the Israel Regulatory Authority.

Once the consultation process is complete, the regulation can be enacted. As per Section 38 of the Principles of Regulation Law, all regulations and amendments must be published in the Regulation Registry.

In addition to the mandatory consultation requirements under the Principles of Regulation Law, it is advisable to seek assistance from the regulatory policy leaders and the Israel Regulatory Authority throughout the process.

Rules for preparing the accompanying report (RIA report)

How to document and reflect the work process?

Transparency and clarity

When dealing with complex issues, it is essential to provide clear explanations. Here are some principles for drafting the report:

1. Use clear and straightforward language. Write short, concise sentences. The report should be understandable to various audiences, including elected officials (in the Knesset and government), professional government staff, stakeholders affected by the regulation (civil society organizations, businesses), and the public.
2. Present your assumptions in the report.
3. Highlight information limitations. For example, indicate where data is missing or uncertain.
4. Include technical calculations, models, and discussions in appendices.
5. When required to provide reasons, they must be concrete and specific to the process and its particular circumstances.

Report structure

The report should include the following components:

1. **Cover Page:** Include the issue's title, name, drafting regulator, and date.
2. **Executive Summary:** Recommended length is up to two pages. The summary should include: Background on the issue (subject matter, the interest under the regulator's responsibility); The scope and depth of the process carried out; Definition of the issue and extent of its damage; Why government intervention is necessary; The purpose of the regulation; Foreign regulations examined, and the baseline regulation established; Key alternatives considered; The selected alternative and reasons for choosing it; A summary of the costs and benefits of the chosen alternative; An explanation of whether the chosen alternative constitutes an Economically Significant Regulation.

3. **Scope and Depth of the Process:** At the beginning of the report, describe the process's scope and depth as defined. Explain the choices and considerations considered.

4. **The Report's core:** Describe the analysis and reasoning according to the process stages. The description should include specific details on the problem, considerations, and impacts (avoid general statements like "market failure" or "public health"). While the structure is flexible, it must address the stages of analysis:

    - Problem Analysis
    - Setting Goals
    - International Benchmarking
    - Developing Alternatives
    - Analysis and Comparison of Alternatives
    - Designing the Chosen Alternative
    - Defining Objectives and Criteria

5. **Foundational Assumptions and Data:** The report should reflect all foundational assumptions, data, rationale, and explanations upon which the regulator relied.

6. **Data Presentation:** Present the data and reference the information sources (such as reports, research, statistics, and international regulations). Provide links when possible. Note any uncertainties or data gaps.

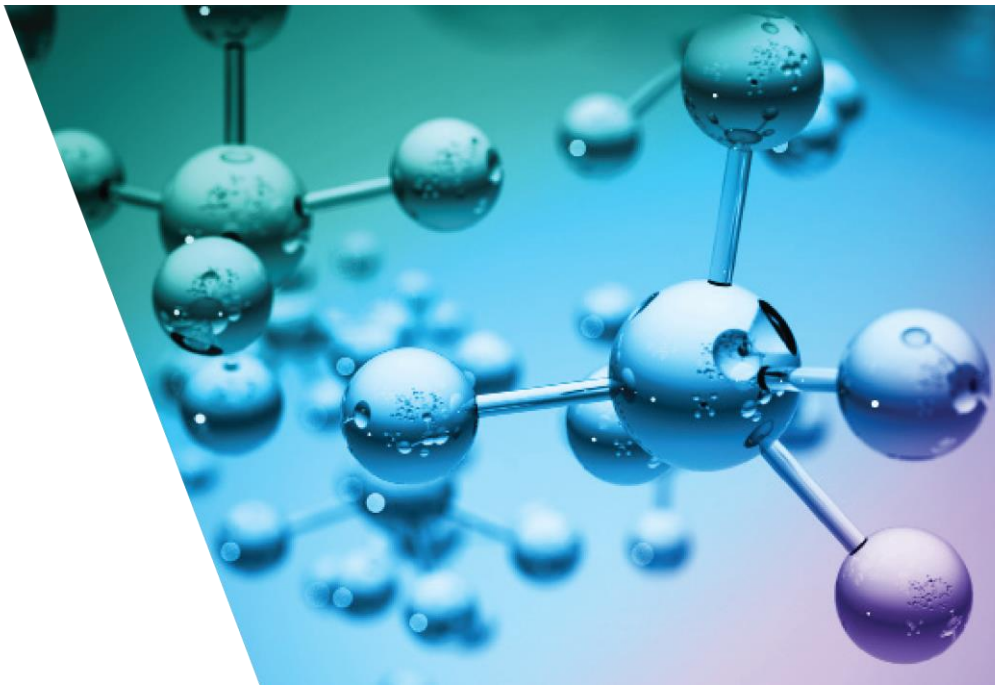
7. **Cost and Benefit Analysis:** Present the basis for calculating costs and benefits and comparing alternatives, including data, assumptions, and calculations. If calculation files (e.g., Excel files) were used to estimate benefits and costs, they should be attached as appendices.

8. **Appendices:**

    - **First Appendix:** Describe the process, including when it started, who was involved (including stakeholders and external consultants), public consultation procedures, process stages completed, and decisions made throughout. List all parties involved and consulted during the process. If a consulting firm was engaged, mention it.

- **Second Appendix:** Detail the sources of information and data used in the process (if not detailed in the report's main body). Include legal sources, reports, research, quantitative data, international sources, expert opinions, etc. Include references and links to the sources where available.

- **Other Appendices:** Attach other appendices as needed, according to the information and analysis conducted throughout the process (such as further details on cost-benefit analysis, international review, terminology explanations, professional process descriptions, and so on).



Publishing the report

The report should be attached to the regulation draft and published for public comment on Israel's Government Legislation Website.

Updating the report

If additional preparatory work is done after the report is published, leading to changes in the draft regulation by the regulator (e.g., due to comments received from the public or the Israel Regulatory Authority), the report should be updated to reflect the revised RIA process. The updated report accompanying the revised draft regulation should accurately reflect the updated RIA process and conclusions for decision-makers and the public.

Rules for cases in which an exemption may be granted

The government's policy is that a thorough thought process must be conducted before deciding on regulation. According to the Principle of Proportionality, in the case of a narrow issue, a streamlined process should be conducted and documented in a concise report.

Accordingly, a closed list of three narrow exemptions has been established. These exemptions apply to cases where it is evident from the outset (without conducting the complete RIA process) that the case falls within the exemption, and there is no need for the RIA process before finalizing a decision.

Any decision to grant an exemption must be signed and justified, attached to the draft regulation as part of its distribution for public comments on Israel's Government Legislation Website, and sent to the Israel Regulatory Authority at reg_report@pmo.gov.il before the public comment period ends and before the regulation is enacted.

Exemption for a change with negligible impact

Section 3(19) of Cabinet Resolution 2118 states that the minister responsible for the regulation or the head of one of the regulators (as defined in the cabinet resolution) may exempt their ministry from the process if the regulation's impact is negligible. A similar provision applies to procedures under Cabinet Resolution 4398, and these rules apply to it as well.

What constitutes a negligible impact?

This exemption is intended for changes that are clearly minor (*de minimis*) and for which the benefit of the RIA process would be minimal compared to its cost.

A regulatory change is presumed to have a negligible impact if it meets all the following conditions:

1. The total costs and benefits (absolute value) are less than ILS 1 million annually nationwide.
2. The impact on any single entity (individual or corporation) does not exceed ILS 25,000 annually.
3. The change does not add or eliminate more than 1,000 waiting days annually nationwide.

4. The change does not create a new regulatory approval (license, permit, or any approval required beforehand).

If a change does not meet one or more of these conditions, a written justification explaining why it is considered to have a negligible impact must be provided. A copy of this justification must be sent to the Israel Regulatory Authority before the public comment period ends and before the regulation is enacted.

Exemption for changes due to the need for immediate action to prevent significant harm

Section 3(20) of Cabinet Resolution 2118 states that the minister responsible for the regulation or the head of one of the regulators (as defined in the cabinet resolution) may exempt their ministry from the process if an event occurs that requires immediate action to prevent significant harm to the public interest. A similar provision applies to procedures under Cabinet Resolution 4398, and these rules apply to it as well.

What constitutes a need for immediate action to prevent significant harm to a protected interest?

If an unexpected and unforeseen event endangers the protected interest, there may not be time to conduct an orderly RIA analysis. The following guidelines help determine if an event requires immediate action to prevent significant harm, which the Israel Regulatory Authority will use to assess whether the exemption was warranted:

1. The event was unexpected and unforeseen.
2. The harm to the protected interest would be significant:
    - The severity and extent of the harm to the public are high.
    - The likelihood of harm occurring is substantial (not a remote risk).
3. The harm would be immediate and, therefore, requires immediate action.
4. The proposed regulatory change would immediately impact the risk of significant harm.
5. Special reasons justify the regulatory change without conducting the RIA analysis (note that the measures taken may not adequately address the existing risk due to the lack of analysis).

6. The regulation is not a renewal of regulation previously enacted by a temporary order.

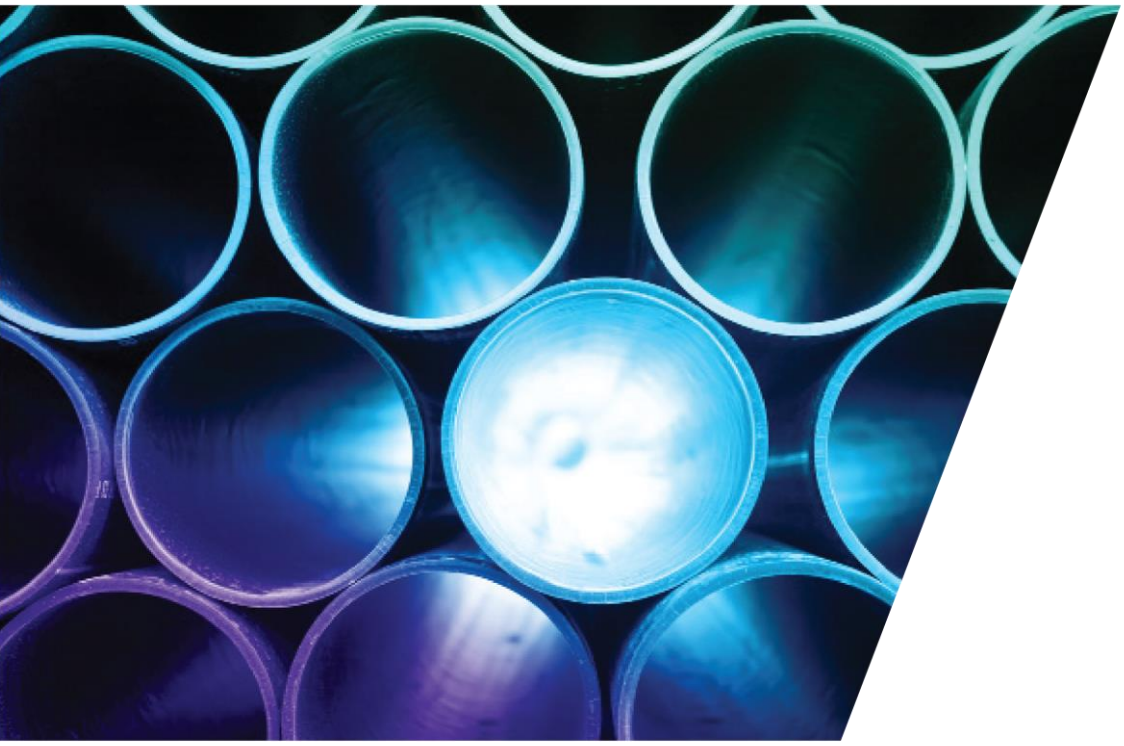
Establishing a "Sunset Clause"

If an exemption is granted due to the need for immediate action to prevent significant harm, the regulation must be enacted for a limited period, automatically expiring within a year at most.

Exemption for changes due to an exceptional national event requiring immediate actions

Section 3(21) of Cabinet Resolution 2118 states that after the government declares an exceptional national event requiring immediate actions, it may exempt all or part of the regulation related to the exceptional event from the RIA process. The exemption will be granted for a period not exceeding six months, and the government may extend it to an additional six-month period each time.

A regulator promoting regulation under this exemption must submit the draft regulation, citing the cabinet resolution and explaining why the regulation falls under the exemption, to the Israel Regulatory Authority at reg_report@pmo.gov.il by the public comment period or when the regulation is enacted—whichever comes first. The reason why the regulation is exempt will be published alongside the draft regulation on Israel's Government Legislation Website.



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