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# REGULATORY QUALITY AND INNOVATION - THE BEST APPROACHES AND PRACTICES FROM THE EUROPEAN UNION AND THE WORLD AND REGULATORY POLICY IN BULGARIA

Sofia, 2021

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Analytical document

# REGULATORY QUALITY AND INNOVATION - THE BEST APPROACHES AND PRACTICES FROM THE EUROPEAN UNION AND THE WORLD AND REGULATORY POLICY IN BULGARIA

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**ANALYTICAL DOCUMENT**

# REGULATORY QUALITY AND INNOVATION - THE BEST APPROACHES AND PRACTICES FROM THE EUROPEAN UNION AND THE WORLD AND REGULATORY POLICY IN BULGARIA

**Abstract:** Both the European Union and the Organisation for Economic Co-operation and Development consider that today the member states need to strengthen their regulatory processes. In a time of fiscal restrictions and increased global uncertainty, the regulatory policy remains the key government instrument for ensuring the safety and well-being of citizens, while stimulating innovation, which also means economic prosperity. Despite what has been achieved so far, much work is yet to be done to reap the benefits from voluntary regulation. This is due to the fact that very often regulating as in "normal times" in the current situation of a global pandemic and its challenges can be a discouraging task.

Regulatory policy is critical for creating a favourable environment for investment, which again means the same: more innovation and, of course, additional economic growth. With the ever-increasing pace of transformative technological changes, governments are facing higher and higher complexity and uncertainty in more and more areas of regulation.

This analysis, for the first time in modern history, examines if the regulatory policy in Bulgaria has contributed to the economic growth and whether the regulatory management system has improved after the launch of the regulatory reform in 2016. It also presents recommendations for the introduction at the national level of the most efficient approaches and practices from the European Union and the world.

**Keywords:** regulatory policy, regulatory reform, better regulation, regulatory quality, regulatory management tools, innovation.

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**List of abbreviations used**

| | |
|---|---|
| **ACM** | Administration of the Council of Ministers |
| **EC** | European Commission |
| **EU** | European Union |
| **RA** | Regulations Act |
| ICT | Information and Communications Technology |
| **RCC** | Regulatory Control Committee |
| **CM** | Council of Ministers |
| **SME** | Small and medium-sized enterprises |
| **R&D** | Research and development |
| **NA** | National Assembly |
| **IA** | Impact assessment |
| **OECD** | Organization for Economic Co-operation and Development |
| **CMD** | Council of Ministers Decree |

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# I. INTRODUCTION

## 1. Relevance and importance of the chosen topic

In mid-2015, the European Commission announced its most ambitious and far-reaching programme since the beginning of the new millennium, concerning the standard-setting process at the level of the European Union and the Member States, called the Better Regulation Agenda. It includes the adoption of a comprehensive Better Regulation package including new and comprehensive Guidelines and a Better Regulation Toolkit. These impose a completely new and methodologically complete approach to the definitive integration of regulatory governance tools into the process of policy formulation and legislation. They bring together, for the first time, all the approaches, practices, and guidelines known to date that should be applied by officials in policy-making administrations at Union level and in individual Member States in order to achieve better regulation, which is the concept adopted in the EU, or quality regulation, which is the term imposed within the OECD.

Almost at the same time in Bulgaria the first modern concept for the practical implementation of the impact assessment of legislation was developed and adopted by the Council of Ministers. It does not simply envisage replicating some of the EU's better regulation mechanisms in Bulgaria. It prescribes the preparation and submission of a comprehensive package of amendments to the national statute law, called the Regulations Act. Through these, ex-ante regulatory impact assessment, structured public consultation, and ex-post legislative impact assessment are planned to be introduced as an integral part of the national standard-setting process. These are established and perceived as the most important tools for regulatory governance, both by the EU and its Member States and by organizations such as the OECD, which have a long tradition of monitoring regulatory policies and regulatory reforms globally.

The Bulgarian government's 2015 concept paper also envisages a change in the principles of standard-setting. This means a complete change of the philosophy of the Regulations Act, which should lead to a change of priorities and to a qualitatively new model of legislative decision-making in Bulgaria in line with the best standards and practices in the EU and the world. In 2016, the main package of changes is a fact. Thus, exactly 5 years ago, albeit with a delay of more than 16 years after the democratic changes of 1989 and more than 8 years after joining the EU, our country embarked on the path of better regulation.

In 2017, the Commission updated its Better Regulation Guidelines and Toolkit[1] and raises two very serious points concerning future approaches to regulation in the EU and its countries. First, the implementation of the key tools of better regulation, such as ex-ante impact assessments, stakeholder consultations, and ex-post evaluations, should be an inter-ministerial effort with the active involvement of all administrations and institutions with specific expertise, especially in areas such as competitiveness and innovation, impacts on SMEs, economic, social and environmental impacts, etc. Second, the impact assessment should analyze each public policy option or regulatory measure in terms of:

- ✓ expected impacts on research and innovation;
- ✓ the potential to reduce negative impacts on research and innovation, and
- ✓ ways to encourage investment and provide incentives for research and innovation.

[1] „Better Regulation Guidelines“, „Better Regulation Toolbox“ SWD(2017) 350.



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That is why these Better Regulation Guidelines and Toolkit, still in force today, require extremely careful and rigorous assessment of the potential impacts of future regulatory interventions that could affect R&D and innovation. This is secured through the approaches of:

1. conducting broad consultations capturing the perspective of R&D and innovation;
2. conducting a thorough assessment of potential impacts on R&D and innovation; and
3. addressing any considerations relating to the choice and design of regulatory measures that would be introduced.

In its latest and currently relevant Global Regulatory Policy Review 2018, the OECD points out that the prevailing pace of technological change and the unprecedented interconnectedness of economies confront governments with uncertainty and complexity about what and how to regulate. The validity of existing national legislation and the ability of governments in practice to adapt to challenges, including those related to the global pandemic, are called into question. This requires an increasingly agile public sector, able to exploit the many opportunities offered by the technological change to improve rule-making that is adapted to new realities and risks[2].

As for the better regulation programmes of the EU countries and the EU itself, the OECD considers that they need constant attention. The "set and forget" model[3] no longer works. Countries need to strengthen their regulatory processes and the institutions involved. At a time of fiscal austerity and heightened global uncertainty, regulatory policy remains a key government tool to ensure the safety and well-being of citizens, while stimulating innovation, which means economic prosperity. Despite what has been achieved so far, much work remains to reap the benefits of better regulation[4]. This is due to the fact that very often regulating as in "normal times" in the current situation of a global pandemic can be a daunting task. Regulatory policy is critical to creating a favourable environment for investment, which again means the same thing: more innovation and naturally more economic growth. With the ever-increasing pace of transformative technological change, governments face increasing complexity and uncertainty in more and more areas of regulation.

Within all this complex supranational context, this analysis "Quality Regulation and Innovation - Best Approaches and Practices from the European Union and the World and Regulatory Policy in Bulgaria" aims to examine where Bulgaria stands. Its theme is particularly relevant and timely at this moment in time because it is intended for the first time in the past 5 years since the start of regulatory policy reform in Bulgaria to examine in depth the question of whether our country has started to regulate with new technologies, R&D and innovation in mind, and whether it is capable of adopting legislation that is "fit for the future" according to the European Commission's new concept[5].

[2]OECD Regulatory Policy Outlook 2018, OECD Publishing, Paris, 2018.

[3] From Eng. 'set and forget'.

[4] Better Regulation Practices across the European Union, OECD 2019.

[5] This concept was launched by Commission Decision C (2020) 2977 final dated 11.5.2020 on the creation of the Future Ready Platform, from Eng. FitForFuture - F4F.



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**2. General and specific objectives of the analysis**

*The general objectives* of the analysis are to seek and find an answer to the question of whether and to what extent the new regulatory policy in Bulgaria has contributed to the effective implementation of the instruments of better regulation in Bulgaria and in particular whether they contribute to the promotion and development of innovation and economic growth.

*The specific objectives* of the analysis foresee the identification and selection of best practices and approaches to quality regulation from the EU and the world, which reflect and stimulate new technological solutions and development, a comparison between them and the instruments of better regulation applied in Bulgaria, and the formulation of recommendations for the adapted implementation of the most relevant of them at national level.

**3. Analysis scope**

The conduct of the study goes through the sequential implementation of the following activities and sub-activities presented below.

Activity 1. Defining the scope and structure of the analysis includes:

*Sub-activity 1.1. Carry out a rapid screening of current practices and approaches in the EU and individual Member States in the field of better regulation;*

*Sub-activity 1.2. A step-by-step approach with the following key points - "5Ps: practices, approaches, recommendations, achievements and selection";*

*Sub-Activity 1.3. Draft content of the analysis report*.

Under Sub-Activity 1.1, an initial mapping of the main relevant data and information sources on quality regulation practices and approaches was carried out to clearly outline the scope of the study.

Sub-Activity 1.2 involved the application of the "5P" step-by-step approach, whereby a preliminary selection of practices, approaches, recommendations, achievements, etc. was made based on a more detailed review of data from the identified sources of information and desk research.

Sub-activity 1.3 foresees the drafting of the content of the analysis report, which has been submitted for discussion and received the approval of the study sponsor, the Institute of Public Administration of the Bulgarian Government.

Activity 2. Conducting a benchmarking study for the selection of good practices and approaches with potential for successful implementation in Bulgaria includes the implementation of:

*Sub-activity 2.1. Selecting best practices and approaches in better regulation in the EU and Member States with a particular focus on R&D and innovation;*

*Sub-activity 2.2. Selection of key recommendations and outlining key trends from OECD research and development in the area of better regulation with a focus on R&D and innovation.*

Sub-Activity 2.1 resulted in the creation of a "Long list" of best practices and approaches to better regulation from the EU and individual Member States, from which the most relevant and applicable for Bulgaria will be selected.

Within Sub-Activity 2.2, an expert filtering of key findings and recommendations made by the OECD in its recent studies, analyses, and guidelines concerning regulation, in particular in areas such as R&D and innovation, was carried out.



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Activity 3. Report preparation includes sub-activities for structuring and preparing a report in the following segments:

1. Presentation of the final selection of best practices and approaches "Shortlist" with the most relevant and suitable for replication in Bulgaria;

2. Key findings and conclusions from the research and analytical activities carried out and suggestions for expert adaptation of the selected practices, approaches and recommendations to integrate them most fully and smoothly into the current Bulgarian legislation;

3. Preparation of a final report structuring, summarizing and analyzing the results of the implementation of activities 1 and 2 to be submitted for final approval by the contracting authority, the Institute of Public Administration.

**4. Opportunities to use the results of the analysis for the development of public administration**

The results of the study can serve as a solid basis and starting point for future broader and deeper analytical and practical developments in the same field. Based on them, new methodological guidelines and tools can be created, aiming at regulation of the highest quality in the country and containing guarantees for its maximum focus on creating favourable conditions for research and development and stimulating innovation as key factors for accelerating economic growth and improving the well-being of society.

To facilitate as much as possible, the use of the results of the study by the public administration and other stakeholders in the field, specific means of labeling the data, findings, and conclusions of the report have been used. The results of the mapping (benchmarking) and selection are presented in separate sections (boxes), presenting the selection of practices, approaches, recommendations, and achievements in the different sections of the report. Outside of these, where practices, approaches, and recommendations relevant to the objectives of the study have been identified, the text has been placed in **bold.** Where the selected practices, approaches, and recommendations are from specific countries, organizations (such as the EU and OECD) or institutions (such as the EC), or comparative and comparative legal effect is sought, their names are placed in ***bold and italic***.

## II. STEPWISE APPROACH "5P"

In the broadest sense, the stepwise approach [6] is used to refer to a phenomenon that occurs or changes gradually, as a series of regular, sequential and planned stages. In a slightly narrower sense, the stepwise approach finds application in some of the main management tools for regulation. This is the case of ex-ante impact assessment, which is in practice a logically complete mechanism of key analytical steps and procedural stages, strictly defined in terms of content and sequence. The stepwise approach is also widely used by the EU and the OECD in structuring the various instruments aimed at better and quality regulation. This is most clearly demonstrated in this study in the section on recommendations,

[6] Eng. „Stepwise approach“.



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which presents Research and Innovation Impact Assessment Tool 21 from the European Commission's 2017 Better Regulation Toolkit, which has been developed as a sequence of concrete steps[7].

In the context of the present study, the 5P step approach is an original creation of its authors used as a model for conceptualization and analysis. The 5 steps included in it: practices, approaches, recommendations, achievements, and selection are applied as a way to disintegrate, for the purpose of the analysis, the established EU and OECD methodology for presenting regulatory policy as a set of tools (for managing regulation), the most important of which are stakeholder engagement in regulatory processes, ex-ante impact assessment, and ex-post regulatory impact assessment. Through the 5P approach, these tools are examined in terms of their practical value, utility, and applicability. This is the reason why EU and OECD regulatory policy is presented in the study with its practical aspects and the key tools for regulatory governance are outlined through a benchmark study. The ultimate aim is to make an evidence-based selection of good practices, approaches, and recommendations with a view to their actual implementation in Bulgaria.

## 1. Practices

### 1.1. Practical aspects of modern regulatory policy

EU regulatory policy is designed under the banner of better regulation. The introduction of the EU Better Regulation agenda in its current form dates back to the beginning of the new millennium. In the early stages, the European Commission's Better Regulation agenda was based primarily on an **approach to simplifying and improving the quality** of EU legislation, as well as **strengthening the competitiveness** of European economies. As early as 2005, the European Commission recommended that EU Member States set up national Better Regulation Strategies and, in particular, integrated impact assessment systems that examine the economic, social and environmental effects of policies and regulatory measures.

The main pillars of the EU's Better Regulation agenda include:

1. a standardised process for consultation with external stakeholders and the public during the development of the Commission's regulatory proposals, with a clear understanding that transparency and open participation in the regulatory process are fundamental to the adoption and compliance of legislation by its addressees;

2. a mandatory ex-ante impact assessment during the development of all major EU regulatory proposals, which is the central mechanism to ensure the building of a solid evidence base on the expected economic, social, environmental and other impacts of regulatory proposals;

3. the systematic use of ex-post impact assessments to review existing legislation, ensuring that it remains fit for purpose over time, and the pursuit of a comprehensive regulatory simplification programme [8].

[7] Tool #21. Research & Innovation, Better Regulation Toolbox SWD (2017) 350.

[8] Regulatory Fitness and Effectiveness Programme, known as the REFIT programme. See Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "EU Regulatory Fitness", Strasbourg, 12.12.2012, COM(2012) 746. The full title of the programme is 'A Regulatory Fitness and Performance Programme'. The short title of the programme is 'EU Regulatory Fitness'. In this case,



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With its 2015 Better Regulation Package, further refined in 2017, the Commission is renewing its political commitment to the central elements and tools of better regulation, while introducing significant changes to its regulatory policy. The package includes new **Guidelines and Toolkit** for consultation, ex-ante impact assessments and ex-post evaluations. Other changes include reforms to the Commission's supervisory oversight mechanism for IA and ex-post impact assessments.

While the European Commission is the sole institution responsible for initiating EU legislation, the co-legislators, i.e., the Council of the EU (composed of representatives of the Member States) and the European Parliament, negotiate and adopt final proposals through the legislative procedures provided for in the Treaties. All three institutions are increasingly seeking to introduce a common approach to better regulation. This has led to **interinstitutional agreements** recognising the importance of public consultation of stakeholders, ex-ante and ex-post impact assessment in improving the quality of Union legislation. The most recent of these is the 2016 Interinstitutional Agreement on Better Lawmaking between the European Parliament, the Council of the European Union and the European Commission.[9]

In all EU Member States, both in the past and today, better regulation is a concept that is recognised as an important part of effective public governance. However, the drivers for initiating better regulation management strategies vary from country to country. For example, economic growth, competitiveness and the needs of business are the main reasons for engaging in better regulation policies for some countries, while for others they are related to achieving public objectives such as maintaining quality public services and reducing the burden of regulation.

Today, EU Member States show, at least in principle, a strong political commitment to better regulatory policy. They have all adopted strategies promoting regulatory reform or encouraging higher quality regulation across Whole-of-Government [10]. Each Member State has in place a mechanism for ex-ante impact assessment. Almost all EU countries have stakeholder engagement (consultation) systems in place for regulatory policies, ensuring transparency and consistency of decisions with their addressees. However, ex-post impact assessment is less common in only 22 out of 28 Member States, indicating that not all EU countries have yet developed and implemented effective models for reviewing existing legislation.

**Regulatory oversight** is a critical element of effective frameworks for improving regulation. It provides important incentives to put regulatory policy into practice. Already in 2012, in its Recommendation on regulatory policy and governance[11] OECD recognizes the important role of regulatory oversight. It outlines a wide range of institutional functions and tasks to promote high-quality, evidence-based decision-making and enhance the effects of regulatory policy. These tasks and functions include:

1. quality control;

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the acronym REFIT is used in two ways, as an abbreviation of 'Regulatory Fitness' and as a word in its own right 'refit', which in English means to repair, fix, renovate, rebuild, refurbish, etc.

[9] Interinstitutional agreement between the European Parliament, the Council of the European Union and the European Commission on better law-making. OJ L 123, 12.5.2016.

[10] Eng. Whole-of-Government.

[11] Recommendation of the Council on Regulatory Policy and Governance 2012, OECD Publishing, Paris, 2012.



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2. exploring the potential for more effective regulation;
3. contributing to the systematic improvement of regulatory policy implementation;
4. coordination between institutions and
5. training and implementation guidelines.

Supervision and quality control of regulation is the least developed aspect of EU Member States' regulatory policies. For example, less than a third have judicial or supervisory oversight to ensure that comments received during stakeholder consultations are taken into account in finalising a regulatory proposal. The supervisors responsible for overseeing stakeholder engagement are often, but not always, the same bodies responsible for quality control of the IA. Systematic quality control of ex-post evaluations is rare among EU countries, as it is rare among OECD members. Nine EU countries currently have a quality control system for ex-post impact assessments. Responsibility for quality control of ex-post IAs is in almost all cases assigned to the same body responsible for quality control of ex-post IAs.

However, each Member State has built up some capacity for regulatory oversight, in particular establishing at least one body responsible for promoting regulatory policy, for monitoring and reporting on regulatory reform, for regulatory quality, and for quality control of IA. Most of the countries have a body responsible for the quality of the law in general, for administrative simplification and reduction of regulatory burdens, and for stakeholder engagement. Bodies responsible for overseeing and promoting ex-post impact assessment and those mandated to engage in international regulatory cooperation are much less common across the EU.

**Practices 1. EU Member States**

In 2015, **Denmark** set up a **new oversight mechanism** to ensure a systematic and uniform approach to the implementation of EU law across government and to avoid imposing additional burdens on business by transposing EU directives. The **Inter-Ministerial Committee** on the Implementation of EU Law examines all national legislative proposals arising from business-oriented EU legislation to ensure that new legislation follows the five principles of implementation. These principles include, amongst others, requirements to avoid burdens on businesses arising from the transposition and implementation of EU directives going beyond the minimum requirements set out in Union law. The Committee consists of eight ministers and is based in the Ministry of Employment. As part of the development of legislation to implement business-oriented EU legislation, all Danish ministries must submit an implementation schedule to the Committee secretariat explaining whether the five principles have been complied with. If a bill does not comply with the five principles, the matter is referred to the **Inter-Ministerial Committee**, which can approve or reject measures that go beyond what is necessary as part of the implementation of EU legislation.

Alongside the Committee, an external **EU Enforcement Board** has been set up in Denmark to advise the Committee in its efforts to prevent unnecessary costs for business in implementing new EU legislation. The Council consists of 11 members, representing business, consumer,



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employers and trade union organisations. It is supported by a secretariat located at the Danish Labour Market Agency and recruitment, which is a unit of the Ministry of Employment. The Council performs three tasks:

1. in the event that it identifies a risk of burdensome future EU legislation, it could advise the Government, through the Inter-Ministerial Committee on EU Implementation, to lobby proactively at the EU legislation development stage;

2.The Council advises ministries on the transposition of new EU legislation. As part of this task, all ministries must submit an implementation plan for the relevant directive to the Council within 4 weeks of adoption in Brussels, indicating the planned process and method of implementation. On this basis, the Council sends recommendations to the ministries, which are then also discussed in the Committee;

3. The Council may propose to the Inter-Ministerial Committee to carry out a so-called **"Neighbour Check"**[12] . This means that the competent ministry should examine best practice in other EU Member States and check the state of existing implementation against the methods used by them to identify opportunities to simplify regulation for business. For example, as a result of such a 'neighbour check', the Danish Maritime Administration decided in 2016 to abolish 33 shipping rules in order to reduce the regulatory burden for Danish businesses.

In mid-2018, **Portugal** carried out a comprehensive reform of its regulatory policy through a new resolution of its Council of Ministers. The resolution obliges ministries to assess the impact on citizens as well as businesses of all laws and regulations. According to it, subsequent reviews and evaluations of EU legislation can also be carried out upon request. As part of the reform, Portugal is also improving its regulatory management tools, including the IA guidelines and training on them.

Evaluating regulatory governance tools is critical to understand whether the regulatory policy decisions and frameworks adopted are achieving their objectives and to identify areas that need improvement. These evaluations in practice measure the effectiveness of the regulatory management tools applied. They also provide an opportunity to carry out a so-called "**reality check**"[13] , which shows whether individual instruments are achieving their objectives and having their predicted impact on the quality of regulation. Evaluations of regulatory policies in general help to focus limited, by definition, reform resources where they are most needed and serve as a benchmark for ministries and agencies to improve their use of regulatory management tools. Finally, information on the effectiveness of a regulatory policy provides a means to obtain insight into the progress of ongoing regulatory reform and to gain political support for regulatory policy in general.

[12] Eng. “Neighbour check”
[13] Eng. “Reality check”



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Currently, EU Member States do not systematically evaluate the use of regulatory governance tools, i.e. they cannot benefit from the important results that such evaluations have. Reports on the effectiveness of regulatory management tools focus largely on ex-ante IA and are often produced ad hoc. Half of all EU countries have published at least one ad hoc report on the effectiveness of the IA system and how it has functioned in practice over the last ten years. Ten EU countries undertake regular evaluation efforts to assess the effectiveness of their IA systems. In contrast, only a few EU countries have published reports on the results of stakeholder consultation practices or subsequent impact assessments.

Institutional arrangements to mobilise greater capacity for regulatory oversight in EU countries are diverse and numerous. In OECD countries, responsibilities for different supervisory functions are often divided among several authorities. The picture for the European Union looks very similar. Most of its countries have more than one supervisor, and the authorities share responsibilities for different supervisory functions. The majority of regulatory oversight bodies in EU countries are units or departments within the executive branch, i.e. at the **centre of government**[14] or the relevant ministry. However, specialised bodies or authorities outside the executive, such as parliamentary bodies, national audit institutions or bodies that are part of the judiciary, also play an important role in regulatory oversight.

In EU countries, regulatory oversight capacity within the executive branch is most often built within the executive branch. More than three-quarters of them have assigned regulatory oversight powers to one or more bodies located specifically at the centre of government. In about half of all EU countries, these authorities share oversight responsibilities with one or more line ministries, drawing on the specific expertise of these ministries in economic or administrative matters.

**Practices 2. Regulatory oversight bodies**

Over the last 20 years, a new trend has emerged in Europe of establishing regulatory oversight bodies **"at arm's length"**[15]. Although they have the effect of building capacity for regulatory oversight within the executive, these bodies are not obliged to comply with the instructions or decisions of the executive. Although they may have their own staff, they may also be supported by officials or administration located within a ministry. The 'arm's length' bodies differ in their institutional structure and capacity, but share a number of management characteristics that distinguish them from more 'traditional' actors in regulatory oversight such as units at the centre of government or in line ministries. Their institutional structure and resources provide safeguards against external interference in their regulatory oversight activities. At the same time, these bodies remain linked to and accountable to state institutions or government because the latter provides their budget, appoints the members of their bodies or shares common secretariats with them.

[14] Eng. Centre of Government. A term for the institution or group of institutions that provide direct support to the head of the executive authority (prime minister or president).
[15] Eng. "Arm's length".



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In line with their mandate, these bodies are responsible for quality control of regulatory governance instruments, although the scope and focus of their supervision, particularly in relation to impact assessments, varies. For example, some of them only examine IA for selected proposals, often due to resource constraints, while others focus on examining the business impact or cost of regulation. In most cases, the 'arm's length' regulatory oversight bodies established in EU countries have advisory powers to control the quality of impact assessments and cannot refer them back for revision if they consider their quality to be insufficient. The exception is the Regulatory Control Committee[16] of the European Commission. If they issue a negative IA opinion, the assessment must be revised and resubmitted.

The emergence of regulatory supervisory authorities in Europe reflects the institutional dynamics in the field of regulatory supervision at the international level. Within the OECD, many countries have established oversight bodies with less traditional characteristics, such as "arm's length" or **joint regulatory oversight bodies** involving representatives from government, the legislature and/or civil society, academia, business or other.

**Practices 3. National parliaments as regulatory oversight bodies**

Parliaments have a crucial role to play in regulatory policy and oversight. As the ultimate body for approving legislation, they are by definition well placed to oversee the application of better regulation principles to new and amended laws. Parliaments are also one of the main initiators of legislation and can amend legislative proposals submitted to them by the executive authority. On average, around 16% of national laws adopted between 2014 and 2016 were initiated by parliaments in all EU countries. Partly due to differences in political systems, the share of laws initiated by parliament varies considerably across countries. While almost 60% of laws are initiated by parliament in **Bulgaria** and around 40% in the **Czech Republic** and **Poland,** among the laws adopted between 2014 and 2016 in **Greece** and **Sweden** there are none initiated by their parliaments.

Contrary to their prominent place in the legislative process, parliaments are not very involved in regulatory oversight across the EU. Very few EU countries have a parliamentary body to monitor the quality of individual IA. These parliamentary committees usually check the existence of IAs accompanying legislative proposals and use the information contained in the IA in their deliberations. Six EU countries have a parliamentary body responsible for reviewing the overall framework of the IA. For example, the Regulatory Scrutiny Board[17] in **France** publishes periodic reports examining the various tools used by the French government to evaluate public policies, including the state of play of the implementation of the IA. Parliaments in a number of EU countries

[16] Regulatory Scrutiny Board.

[17] Fench:. Comité d'évaluation et de contrôle des politiques publiques.



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are also involved in ex-post impact assessment initiatives and efforts to ensure that national legislation remains fit for purpose.

The European Parliament scrutinises the quality of the European Commission's impact assessments and ex post evaluation of existing legislation. The Directorate for Impact Assessment and European Added Value under the European Parliamentary Research Service[18] gives a preliminary opinion on all impact assessments prepared by the European Commission and submitted to parliamentary committees. It also carries out other activities, such as preparing supplementary impact assessments or impact assessments on parliamentary proposals to amend legislation. The Directorate also prepares ex-post evaluations of the implementation of existing EU legislation for all proposals that update the existing legal framework. In addition, Parliamentary Committees may request more detailed assessments of the implementation of specific existing EU laws or policies or other analyses of implementation issues.

### 1.2. Stakeholder engagement practices

Engaging with those affected and interested in regulation is key to improving the quality of legislation, strengthening public trust in government and the state as a whole, and increasing the effectiveness of law enforcement. The main objective of regulatory policy is to ensure that regulation delivers net benefits to society. A critical aspect of this objective is communication with those who are interested in and affected by regulatory measures. These are the 'stakeholders'. The modes of communication, consultation and engagement that allow for public stakeholder participation in the regulatory decision-making process as well as in the review of legislation help governments understand the needs of citizens and businesses and increase public confidence in public governance as a whole.

By engaging stakeholders who can contribute their own experience, expertise, views and ideas to the consideration of existing legislation, governments gain valuable information on which to base their public policy decisions. Stakeholder input can help prevent unintended effects and practical problems associated with the implementation of regulatory measures. The use of stakeholder knowledge is also useful in relation to regulatory impact assessments to collect and verify empirical information for analytical purposes, to identify alternative policy options, including those alternative to traditional (legal) regulation, and to measure stakeholder expectations.

Today, there are significant differences in the requirements of EU and OECD Member States on stakeholder engagement in the development of public policies and regulatory measures. They have all adopted a set of formal rules governing stakeholder engagement in the standard-setting process. In general, however, each Member State applies these requirements in different policy areas. The general trend observed is that the current rules governing stakeholder involvement in individual Member States contain more comprehensive and detailed requirements for the later stages of the development of policies and regulatory measures than the earlier. This is the case for 17 of the 28 EU Member States, including **Croatia, Ireland, Latvia, Luxembourg** and **Sweden**.

[18] European Parliamentary Research Service (EPRS) - Directorate for Impact Assessment and European Added Value.



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Countries generally apply more robust consultation methodologies concerning the stage after the decision on public intervention has been formulated, even taken outright, compared to earlier stages of its development. Only **Croatia, Finland, Italy** and **the Slovak Republic** systematically inform the public in advance that a public consultation is planned, e.g. by publishing notices through websites, roadmaps or annual legislative plans and programmes.

Next, when stakeholder consultations are organised, around 60% of EU Member States formally require policy makers to take their comments into account when developing final draft proposals. EU Member States use different approaches, with the majority publishing individual comments received or a summary of contributions on a dedicated consultation website. Oversight and quality control of consultations is weak in the Union countries. In less than half of them public evaluations of stakeholder engagement mechanisms in the regulatory process have been carried out.

As regards regulations, EU Member States' consultation systems are generally less developed than for laws. Only **France, Malta, Portugal** and **Spain** have stricter consultation requirements for regulations than for laws. Countries such as **Bulgaria, the Czech Republic** and **Hungary** have consultation requirements and practices for both laws and regulations. It is important for stakeholders to be informed about draft proposals in addition to laws and regulations, especially given that they often impose new regulatory requirements on business. One possible approach to ensure that stakeholders are sufficiently informed about them is the extensive use of electronic means of communication.

EU Member States tend to engage stakeholders at a later stage in the development of the regulatory measure, i.e. when the preferred option has already been identified. Following this trend, they have generally developed more comprehensive consultation methodologies relating to the later stages of the policy development cycle. These include setting minimum timeframes for consultation, as well as facilitating feedback from the general public. Relatively stronger requirements for stakeholder involvement at an early stage of policy and law development, combined with public consultation at a later stage, are observed in **Bulgaria, Croatia, Lithuania, Malta, Romania** and **the Slovak Republic**.

To ensure that stakeholders are effectively involved, policymakers need to engage them early in the decision-making process. Clear timelines for engagement activities help to ensure that stakeholders have sufficient opportunity and time to present their views on regulatory proposals. EU Member States usually have provisions to set a minimum period for stakeholder consultation. However, most of them do not publish annual legislative programmes (regulatory plans), do not maintain a running list of possible future opportunities for providing information and do not publish other early warning documents that could systematically inform the public in advance of planned consultation activities.

Once consultation on proposed regulatory measures has begun, governments should ensure that those who are usually least represented in the decision-making process are able to express their views. For example, where the views of affected entities are not adequately represented through other means, such as various representative organizations, industry associations, etc., alternative approaches may be necessary. Simply publishing information on the internet without reaching stakeholders is not always sufficient to ensure equal access to public consultation for affected parties. It is therefore recommended that **stand-alone stakeholder engagement programmes (strategies)** are developed. These should be flexible enough to apply in different circumstances and to meet different information needs. Next, having



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an appropriate framework of minimum standards and rules for consultation ensures consistency of stakeholder activities in managing the process and ensures that there is a continuous opportunity for each stakeholder to express their views and provide input. For example, NGOs, business associations or trade unions may need to coordinate a common position with their members or collect different types of information before engaging in consultation, which takes more time and other resources.

Most EU Member States have provisions to ensure a minimum period for consultation. These range from 7 working days in Lithuania, 10 days in **Hungary** and **Romania** and 30 days in **Bulgaria** to 12 weeks for certain procedures in **Sweden**. Some EU countries have set flexible minimum deadlines depending on the stage of policy development, the type of regulatory proposals or the stakeholders consulted. In **Lithuania**, for example, the minimum deadline can be extended to 12 days for complex draft legislative proposals of more than 10 pages. **Poland** distinguishes between laws and regulations. In addition, the minimum period for draft legislative proposals can be extended to 30 days for consultations with trade unions. In the **Slovak Republic**, the minimum period of 4 weeks applies for early consultations with business and can be shortened in case of agreement between decision-makers and consulted parties. Most EU countries publish the opinions they receive during the consultation in a publicly accessible place on the internet. 23 Member States do this for proposals for legislative changes and 20 for proposals for changes to regulations. They take different approaches to this, with the majority publishing individual comments received or a summary of contributions on a dedicated consultation website. However, not many countries commit to clearly demonstrating how comments from the consultation have improved the regulatory proposals. Countries that currently do not disclose respondents' views on either legislation or regulations are the **Czech Republic, Hungary, Portugal, Romania** and **Spain**.

Already in its 2012 Recommendation on Regulatory Policy and Governance. The OECD emphasised the importance of using a wide range of consultation tools to engage a wide variety of stakeholders. Consultation arrangements should reflect the fact that different legitimate interests do not have equal access to the resources and opportunities to express their views to the government, and that a variety of channels for receiving and communicating these views should be established and maintained[19]. EU Member States currently use a wide range of stakeholder engagement modalities, but this generally occurs once the preferred authorisation has been identified and the regulatory measure has been drafted. Both public consultation and non-public forms of stakeholder engagement, including formal and informal consultation, are widely used in EU Member States, although in only a minority of these cases does this happen on a systematic basis.

To maximize the quality of stakeholder input, governments need to choose appropriate consultation tools tailored to the types of stakeholders and the phase of the policy-making process, based on a solid framework of minimum standards and rules. OECD countries have demonstrated a strong affinity for traditional offline communication tools such as official government publications or "newspapers", press releases and conventional media channels such as newspapers, radio or television, only recently investing in online tools as well. Providing access to information electronically has now established itself as an effective way of actively engaging all stakeholders during the decision-making process, and as the

[19] OECD (2012), Recommendation of the Council on Regulatory Policy and Governance.



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"digital gap"[20] continues to decline over time, online communication tools will continue to establish themselves as the primary portal for stakeholder engagement.

EU Member States demonstrate a strong commitment to stakeholder engagement through electronic means. More important to note are the **dedicated online portals** that provide stakeholders with the opportunity to comment on draft regulatory proposals. The results of the 2019 OECD survey show that the most common means of publication are central government portals or ministerial websites. The majority of Union countries publish ongoing consultations either on a central consultation website or on the websites of individual government departments or agencies. Almost 80% of all of them have a central web portal. Levels of transparency are significantly lower for regulations.

EU Member States are taking different approaches to integrating online consultation portals into their institutional framework and regulatory processes. Most of them have websites for ongoing consultation on both laws and regulations. **Austria and Portugal** only publish ongoing consultations for statutory instruments. Currently, **Cyprus and Luxembourg** are the only EU countries without a central consultation portal or separate ministerial websites for ongoing consultations on laws or regulations. The publication of consultations on a central portal does not mean that individual ministries and agencies cannot maintain their own dedicated portals for communication with the relevant stakeholder community. However, central consultation portals are an effective way to provide access to all ongoing consultation processes and to easily access draft proposals and all accompanying documents in one place.

**Practices 4. The Government Consultation Portal of the Slovak Republic**

Public consultations are required for every legislative proposal submitted to the Slovak government. All draft laws and accompanying impact assessments are automatically published on the government portal (www.slov-lex.sk) at the same time as they enter the inter-ministerial consultation procedure. The portal provides a single access point for commenting on draft proposals for regulatory and non-regulatory acts (e.g. Concepts, Green or White Books, etc.). It aims to provide easier orientation and search of legislation to facilitate the inter-ministerial consultation process and to support compliance with existing legal requirements and deadlines.

Both public authorities and the general public can provide comments on the draft proposals and accompanying material. All submitted comments are visible on the website. The deadline for comments is normally 15 working days from publication. The general public can also access all final legislation through the government portal. Written comments can be submitted by members of the general public either as individual comments or as "collective comments" to which individuals or organisations can respond by supporting or rejecting them. Whenever a comment receives support from 500 individuals or organisations, ministries are required to provide written feedback taking the

[20] The term „Digital gap“ refers to the effect of separation between people of different ages, educational and social status, ethnicity and others, which is achieved thanks to new forms of social inequality resulting from unequal access to modern information and communication technologies.



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comment into account and reflecting it in the consulted proposal or explaining why it was not accepted. The feedback provided then forms part of the dossier that is sent to government for consideration.

In practice, all legislative proposals are adjusted after the consultation process. The number of comments received varies considerably from one legislative proposal to another. Impact assessments accompanying legislative proposals are also updated on the basis of the comments received. Following the consultation process, a summary of the comments received is published on the portal for all consultations, together with the reasons for considering or not considering them.

The 2015 OECD Public Governance Review of the Slovak Republic found that the number of comments received through the portal varies and that the portal is not used to the optimum extent by external stakeholders due to the difficulty of use and lack of awareness of the possibility to comment through it. The latest version of the portal, from 2016, includes a range of new features to enhance user-friendliness, including the ability to access and search through the portal all existing legislation that forms part of the Official Journal[21].

Practice has shown that, when used well, **interactive websites** can enable a deeper level of engagement as they facilitate the 'conversation' between policymakers and affected and interested stakeholders. At the same time, they also allow for multi-stakeholder dialogue, which in practice takes place in public for the whole of society to see. Interactive websites enable stakeholders to refer to each other's comments, test the credibility of new ideas, allow for impact analysis and evaluation of alternative solutions. From a policy maker's point of view, this helps to better group stakeholders' views on particular aspects of regulatory proposals.

From a stakeholder perspective, interactive websites allow different experiences to be shared in one central place. For example, many firms may have struggled to comply with a particular regulatory measure, and when one stakeholder presents the difficulties, they have experienced, others can indicate whether they have encountered similar ones or present their enforcement approaches if their experiences differ. This saves time and resources for policymakers and stakeholders. For example, regulatory proposals can be easily grouped through online threads that make it easier for stakeholders to find proposals that may affect them while providing valuable information to policymakers. As a result of using interactive websites, policymakers are better able to target their further consultations with affected parties, with more detailed questions if further information is sought or to provide more detailed explanations where stakeholders have raised particular issues or concerns about specific aspects of a proposed regulatory intervention.

Both OECD countries and EU Member States use mostly interactive websites to consult on the finalised first drafts of regulatory proposals, rather than engaging in discussion with stakeholders at the early proposal development stage. Most of them do not simply publish draft regulations or regulatory measures for online consultation but allow the public to discuss draft proposals on an interactive website. However, EU countries are less likely to use interactive websites to discuss ideas, complaints or impact

[21] Source: OECD pilot database on stakeholder engagement practices in regulatory policy.



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analyses before the decision to regulate is taken. Of all 28 Member States, 13 use interactive online tools to discuss plans to change existing regulations, while 11 consult on plans to regulate. Most of those using interactive websites have developed their own tools, managed by their governments. Use of existing social media tools such as Facebook, LinkedIn or Twitter for stakeholder consultation is relatively scarce. However, many Member States use social media to inform the public about ongoing consultation activities or as a way to link to dedicated consultation websites.

**Practices 5. The Finnish online stakeholder engagement platform "Have Your Say"**

Finland launches **e-participation platform** [22], enabling better interaction with the general public during the early phase of policy development. It aims to encourage and improve dialogue between citizens and public administrations to ensure the quality of the legislation being drafted, to gather information on the different views, impacts and options relating to the practical implementation of the issues under consideration and to increase confidence in regulation and democratic decision-making.

The website allows both administration officials and the general public to initiate discussions on various topics, including the drafting of new laws to reflect the needs and ideas for new policies. Stakeholder engagement is possible through two different tools: discussion forums and web surveys. Projects and initiatives are categorized on the platform by region of the country and by keywords that can be selected by project initiators. Government entities moderate the discussions, for example by providing guiding questions or support materials. More than 90% of the consulted projects are initiated by the government (at national or local level) and only 10% by civil society and individuals. Business organisations or consultancies can initiate discussions by approaching government structures to organise them.

Input received from stakeholder respondents varies between lengthy and detailed comments with their own ideas or evidence, and brief comments or positions signaling agreement or disagreement. The data collected can be used by government officials to inform further policy development, for example in drafting regulations, developing action plans or setting reform requirements. Typically, the initiator provides a summary of the discussions or survey results as a follow-up to the consultation process, which is appended to other materials used in government decision-making.

In 2015, a **research project to evaluate consultation practices in the regulatory process**, including the e-participation platform, was launched in Finland by a research group from the University of Helsinki. According to its findings, the focus should be on the scope, transparency and time over which consultation lasts. The results also show that online consultation has not yet achieved

[22] otakantaa.fi.



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a significant breakthrough in Finland, although it has been used successfully in several major case studies related to the drafting of legislation[23].

A number of EU Member States have requirements to systematically inform stakeholders about EU-level regulatory proposals made by the European Commission. In principle, stakeholders can be notified of EC consultations in the same way as for national proposals. A minority of Member States require consultation of local stakeholders during the negotiation phase of draft EU legislation. In contrast, the majority of EU countries have requirements to consult stakeholders when transposing Union directives into national law, usually as part of a routine internal stakeholder engagement process.

Informing stakeholders about consultations with the European Commission is important for at least two reasons. Firstly, it allows the EC itself to engage with the actors concerned, thereby having the opportunity to consider more alternative courses of action and other issues such as initial compliance, administration, enforcement and review of regulatory measures. Secondly, from the perspective of Member States, it helps to identify specific problems existing at national or local level that may not have been identified or addressed at EU level.

**Practices 6. Stakeholder engagement in the development and transposition of EU legislation**

***Malta and Romania*** have dedicated agencies to inform local stakeholders about the European Commission's consultation processes. **Malta-EU Action Steering Committee** [24] provides information on Malta's positions during EU decision-making and a structured consultation process. It brings together representatives of the government, the national parliament, three representatives of civil society and EU-related entities and others.

Through the Ministry of Labour and Social Justice in ***Romania*** **the EU Consultation Platform** aims to provide regular information on the European Commission's ongoing public consultations in order to facilitate the active involvement of civil society in the EU lawmaking process, especially in its drafting and transposition[25].

In ***Italy***, the European Policy Department of the Council of Ministers has a dedicated website to inform the general public about the European Commission's online consultations. The website provides a general link to the Commission's online consultation portal, as well as more specific information selected in line with the government's policy priorities[26].

[23] Source: OECD pilot database on stakeholder engagement practices in regulatory policy.

[24] Malta-EU Steering Action Committee (MEUSAC) (n.d.), , Consultation, https://meusac.gov.mt/consultation/.

[25] Ministry of Labor and Social Justice (Romania) (n.d.), EU-Consultare, http://dialogsocial.gov.ro/eu-consultare/.

[26] Department for European Policies of the Presidency of the Council of Ministers (Italy), Consultazioni, http://www.politicheeuropee.gov.it/it/comunicazione/consultazioni/.



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**Practices 7. Engaging stakeholders throughout the European Commission's policy cycle**

Following the adoption of the 2015 Better Regulation Guidelines, updated in 2017, the **European Commission** is expanding its list of consultation methods to give stakeholders a voice throughout the life cycle of public policies. It uses a series of tools to engage with stakeholders at different points in the regulatory process. Feedback from the consultation is taken into account by the Commission when further developing regulatory proposals. At the initial stage of policy development, the public has the opportunity to provide feedback on the Commission's policy plans through **roadmaps and initial impact assessments**, including data and information they may have on all aspects of the planned initiative and impact assessment. The feedback is taken into account by the Commission services when further developing the policy proposal. The feedback period for roadmaps and the initial IA is 4 weeks.

As a second step, a **consultation strategy** is prepared, setting out the consultation objectives, target stakeholders and consultation activities for each initiative. For most major initiatives, a 12-week public consultation is carried out through the **multilingual "Have your say" portal**.[27], which can be accompanied by other methods of counselling. Consultation activities allow stakeholders to express their views on key aspects of the proposal and the main elements of the impact assessment in the process of their preparation.

Stakeholders can provide feedback to the Commission on its proposals and the accompanying final impact assessments once they have been adopted by the Collegium of the Commission. Stakeholders' feedback is presented to the European Parliament and the Council and is intended to feed into the further legislative process. The consultation period for adopted proposals is 8 weeks. Draft delegated acts and important implementing acts are also published for stakeholder feedback on the European Commission website for a period of 4 weeks. At the end of the consultation process, a **summary report** is produced which presents all the results of the various consultation activities carried out.

The Commission is also consulting stakeholders as part of the **ex-post evaluation of existing EU legislation**. This is done by obtaining feedback on the roadmaps for the revision of existing legislation, in the ex-post evaluations of regulatory measures introduced and in the "fitness checks" themselves. In addition, stakeholders can provide their views on existing EU legislation at any time on the "Have your say: Help simplify!" website.[28], which makes a direct link to the “Fit For Future” Platform (F4F).

Conducting stakeholder engagement early in the policy development process is necessary to identify specific internal issues and sensitivities to EU regulatory initiatives. This, in turn, helps to take

[27] https://ec.europa.eu/info/law/better-regulation/have-your-say.

[28] https://ec.europa.eu/info/law/better-regulation/have-your-say-simplify_bg



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these issues more appropriately into account during the development of the proposals themselves at EU level and thus reduce or avoid potential delays in transposing EU directives later in the regulatory process.

It is now generally accepted that decision-making without stakeholder involvement can lead to confrontation, disputes, disruption, boycotts, mistrust and public discontent. The majority of individual Member States do not inform local stakeholders about the EC's regulatory proposals to help them form a negotiating position. Currently, the 11 EU Member States that require stakeholder engagement to take place at the negotiation stage are ***Cyprus, Denmark, Estonia, Finland, France, Hungary, Italy, Latvia, Poland, the Slovak Republic and Slovenia.***

**Practices 8. The Polish experience of consultation within government at the negotiation stage for European Union legislation**

The mechanism for consultation on draft legislation in Poland has been established at the Ministry of Economy and is being piloted under the Better Regulation 2015 programme. Explicit guidelines detailing the involvement of national stakeholders in the development of the Polish negotiating position have been adopted. Following the formal presentation of a draft EU legislative act by the European Commission, a specially appointed lead expert forwards the text to internal and external stakeholders for comments to discuss the basis of Poland's negotiating position. An impact assessment of the draft EU legislation on Polish legislation is also prepared.

Throughout the further legislative stages, the lead expert forwards any relevant documents to stakeholders. Contact between the lead expert and the stakeholders is maintained through regular exchanges of information to update the Polish position and inform them of the next steps in the EU legislative process. The lead expert should consider changes to Poland's position in the event of amendments to the draft EU law, for example, due to adjustments made by the Council or the European Parliament[29].

Reporting on the effectiveness of stakeholder engagement in decision-making helps governments to better structure their policies, address identified problems and better prioritise reforms to focus on areas where regulation is needed or where regulation already in place is unnecessarily burdensome. Last but not least, it allows capturing public perceptions on regulation. Among OECD countries, evaluations of stakeholder engagement practices are much less frequent than those on IA outcomes. Although the number of these assessments has increased since 2014, less than a third of OECD countries currently assess and report on their stakeholder engagement practices[30]. Results from the 2019 OECD survey show that EU Member States rarely review the effectiveness of their consultation systems. However, when such evaluations have been undertaken, they have proven to be a powerful tool for improving the effectiveness of stakeholder consultation.

[29] Source: OECD, Regulatory Policy and Governance Survey Indicators 2017. Government Law Centre of Poland.

[30] OECD Regulatory Policy Outlook 2018.



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**Practices 9. Assessing the effectiveness of stakeholder engagement in the Netherlands**

In 2017, the Netherlands is reviewing how its online consultation system is perceived by citizens, companies and public administration officials, and whether the objectives it pursues in the legislative process have been achieved. The results show that internet consultation is used systematically by public officials while pointing out a number of weaknesses. For example, the review report concludes that more methodological guidance for civil servants is needed and that there is a lack of sufficient visibility for citizens and businesses on how consultation comments are taken into account[31].

### 1.3. Practices of ex-ante regulatory impact assessment

Regulatory impact assessment is both a tool and a process designed to help inform policy makers about whether and how to regulate to achieve public policy objectives. Improving the evidence base for policy and regulation development through ex-ante impact assessment is one of the most important mechanisms available to governments. The aim is to improve the design of regulatory measures by helping policymakers to identify and consider the most effective and efficient options, including non-regulatory ones, before making a decision. One method of doing this is by analysing the expected costs and benefits of regulation and alternative ways of achieving policy objectives and identifying the approach that is likely to deliver the greatest net benefit to society.

Considering a range of alternative approaches to traditional "command and control" regulation[32], including those such as co-regulation, helps to ensure that the most effective and efficient interventions are used to achieve policy objectives. Experience shows that governments need to take a firm course towards overcoming the inertia of risk aversion associated with introducing more flexible measures and moving away from a culture of "regulate first, ask questions later"[33]. At the same time, it must be taken into account that when it is decided to use less intrusive approaches such as self-regulation, there are sufficient safeguards to ensure that public policy objectives are achieved.

Already in 2012, in its Recommendation on Regulatory Policy and Governance, the OECD instructed member states to integrate regulatory impact assessment into the early stages of the process of formulating policies and creating new regulatory proposals, calling on them to clearly identify policy objectives and to consider whether the regulatory measure is necessary and how it can be most effective and efficient in achieving those objectives. For nearly 20 years, the European Union has focused on improving regulatory outcomes through its Better Regulation initiatives. The ex-ante IA has been recognised as the central tool for managing regulation by the European Commission.

Currently, there are quite different impact assessment systems in EU Member States, which is reflected in the differences in the criteria used by the IA for regulatory measures. The general observation is that countries have strict requirements for ex-ante IA. ***Italy and Lithuania*** have **official threshold**

[31] Source: https://zoek.officielebekendmakingen.nl/blg-777197.

[32] Eng. “Command and control”.

[33] Eng. “regulate first, ask questions later”.



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**tests** to determine whether an IA should be prepared at all. ***Austria, Denmark, Estonia, Lithuania and Spain*** have formal threshold tests to determine whether a simplified or full IA should be undertaken. ***Croatia, Hungary, Ireland, Italy and Slovenia*** provide for formal (procedural) inadmissibility consequences in cases where regulatory proposals bypass the IA system.

**The transparency of impact assessment** is relatively low in EU Member States and is slightly below the OECD average. IA is not publicly disclosed for consultation at an early stage of policy development and even after a regulatory decision has been taken. Only half of EU Member States systematically publish IA for consultation.

**The supervision and quality control of IA** are the weakest of all surveyed districts and lower than the OECD average. Common quality control mechanisms, such as assessing their own IA systems and parliamentary oversight, are practices generally observed in only a few EU Member States. General oversight is relatively strong in the IA systems of ***Estonia, Germany and Lithuania***.

In terms of **impact assessment methodology**, EU Member States tend to analyse a narrower set of economic, social and environmental impacts of proposals for regulations than of proposals for bills. This may be partly explained by the fact that the regulatory requirements for IA are less comprehensive in the case of subordinate legislation than for draft laws. Nevertheless, it is not at all clear why the IA requirements, simply because of the legal force of the enactment and its place in their hierarchy, should be less stringent for subordinate legislation than for statutory legislation. In fact, this may create bad incentives for policy makers to draft their proposals as subordinate legislation, which would normally be more appropriate in the form of draft laws, to avoid the higher IA requirements as well as possible parliamentary scrutiny.

The majority of EU Member States have a **universal requirement to carry out impact assessments** for the purpose of informing the process of developing proposals for legislative change. The application of IA to subordinate legislation is of concern according to the OECD because only half of the countries have a universal requirement to conduct assessments on them. However, 6 Member States have a requirement to carry out IA in relation to key regulations. It is important to recall that regulations are generally not subject to, or are subject to, significantly less parliamentary scrutiny than laws. However, they can have a significant impact on the well-being of society. Moreover, they often 'give life' to the underlying laws and are therefore often responsible for a significant part of the regulatory and administrative burden imposed on citizens and businesses. It is therefore important to ensure that they are developed on the basis of an appropriate and robust evidence base of facts, data and evidence, including scientific evidence.

Although there are generally extensive requirements to conduct an IA, EU Member States currently provide for a number of **exemptions** from these. Around 40% of EU countries provide for an exemption from the conduct of an IA when the regulatory measure is introduced in response to an emergency situation. Exemptions are also currently in place for the European Commission for IA relating to emergency measures and for proposals that have a minor impact. Several Member States exclude the application of IA requirements where the measure is related to the application of international law and the like.



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For example, in ***Belgium***, laws relating to the organisation (structure and administration) of the State itself, to the implementation of cooperation agreements between the federal State and regional authorities, or those relating to national security and public order are excluded from the IA. In ***Ireland***, laws which are proposed as a result of a consolidation of existing legislation where no changes to regulation are introduced are excluded from the IA. The same applies to laws which are the direct consequence of a judicial decision and leave no discretion to consider alternative options or to allow substantive consultation. The IA is also excluded in cases where its publication might be inappropriate, for example when imposing new tax obligations or charges due to their sensitivity and the need to prevent their possible avoidance or evasion.

**The proportionality principle of impact assessment** is embedded in its essence. It defines the depth and scope of the analysis to be carried out as part of the assessment process, the coverage of stakeholders to be consulted, etc. Proportionality requirements exist in about 60% of EU Member States. The OECD has been promoting the application of the proportionality principle to IA since 1995. Formal proportionality requirements are part of IA systems in almost 70% of OECD member countries.

**Practices 10. Threshold tests for determining the need for an impact assessment**

**Impact assessment threshold tests** are important for several reasons. Firstly, they help to ensure that regulatory measures with a significant impact on society are adequately assessed before they are introduced. Secondly, they ensure that public resources are not spent on evaluating proposals with minor impacts where the costs of the evaluations themselves would outweigh the benefits of these proposals. Thirdly, they also help to avoid consultation fatigue, with consultations only taking place where the impacts of regulation are expected to be significant. Fourthly, where criteria are clear and simple to apply in practice, they help to improve the transparency of the IA system as a whole. This also helps to build public confidence that proposals have been appropriately subjected to an IA, or have accordingly been excluded from the scope of the assessment as provided for in the legislation.

It is important that the threshold tests for IA are based on the expected significance of impacts. Impacts can be both positive and negative and in any area of public life and as such should be broader than assessing impacts in relation to business, for example. However, despite their importance, data from the 2019 OECD survey shows that only two Member States, **Italy and Lithuania**, have a threshold test for determining whether an IA should be prepared at all. However, neither of these countries' tests is explicitly based on the expected significance of the economic, social and environmental impacts of the proposal. Nevertheless, Italy's threshold test takes into account whether compliance costs are expected to be low, that there are a small number of affected entities, that the proposal requires few public resources and that there is a limited expected impact on the competitive structure of the affected market.

A larger number of states in the Union have a threshold for determining whether to do a full IA (or a simplified one), but they are still the vast minority. The lack of a threshold at this stage in the development of national regulatory policies more reflects the deficiency of two-tier IA processes (pre-simplified/simplified and full) in EU Member States. Overall, the general observation is that countries



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have requirements to adhere to the proportionality principle of IA, but often lack a formal threshold test with transparent criteria for when and to what extent IA should take place.

Similar to stakeholder engagement, individual EU Member States have procedures in place that require IA to take place at the transposition stage for EU legislation, but much less so at the negotiation stage. Practice has shown that IA provides the greatest net benefit to policy makers when initiated early in the decision-making process. The same is true for EU-generated laws. Once the European Commission has taken a decision to regulate, individual Member States can begin to consider the individual impacts of regulation. Currently, 13 EU Member States have requirements to conduct an IA when determining a negotiating position on European Commission proposals and these are: ***Austria, Bulgaria, Estonia, Finland, Germany, Hungary, Ireland, Italy, Lithuania, Malta, Poland, the Slovak Republic and Slovenia.***

### 1.4. Practices of ex-post regulatory impact assessment

In recent years, there has been a steady trend for the volume of laws and regulations to increase rapidly in most OECD countries as well as in those of the EU. However, not all regulations are rigorously evaluated and even where they are, not all effects can be identified. Moreover, many of the characteristics of an economy or society relevant to particular regulatory measures change over time. In some circumstances, formal ex-post impact analysis processes can be more effective than ex-post analysis in informing ongoing policy debate.

Ex-post evaluations of the effectiveness of regulation should be symmetrical with ex-ante evaluations: by checking whether the stated objectives have actually been met, determining whether there have been unintended or unforeseen consequences, and considering whether alternative approaches could have done better. The reviews, which additionally include proposals for change and a review of the original purpose of the intervention and its ongoing appropriateness or legitimacy, are particularly useful for improving policies and regulatory measures[34].

The overall trends identified by the OECD towards the end of 2020 show that, despite the high potential benefits of the improvements made to existing instruments for managing national regulatory policies, ex-post evaluation is still an underdeveloped practice within the OECD. However, EU Member States show an even weaker level of integration of ex-post evaluation into their legislative governance systems. Countries like ***Croatia, Cyprus, Greece, Latvia and Romania*** have not yet developed systematic approaches for ex-post evaluation. On the other hand, there are also a few countries that systematically carry out ex-post evaluations, such as ***Germany*** for example. Relatively recently, ***Italy*** has strengthened its ex-post evaluation system by introducing a new set of ex-post evaluation procedures and reforming the responsible institutions.

The majority of EU Member States have integrated different aspects of ex-post evaluation into their regulatory governance system. However, there is no systematic implementation or a solid

[34] OECD Best Practice Principles for Regulatory Policy: Reviewing the Stock of Regulation, OECD Publishing, Paris, 2020.



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methodological framework for conducting an ex-post evaluation. Evaluations often focus only on administrative burdens and not on whether laws and regulations have achieved their objectives. Ex-post evaluation requirements and practices relating to regulations are less common than those relating to proposed legislative changes. In general, ex-post evaluation systems are less pronounced in the 'newer' EU Member States. Of the 13 Member States that joined the EU after enlargement in 2004, only ***Estonia, Poland*** (for laws) and ***Lithuania*** have ex-post evaluation systems in place at a level higher than the EU average.

In general, good practice involves the application of a broad 'portfolio' of approaches to subsequent regulatory review. In the most general sense, these are ex-post impact assessments, planned reviews, reviews initiated ad hoc or those conducted as part of ongoing regulatory governance processes. Reviews as a concept are broader in scope than ex-post impact assessments, as they usually include proposals for future change and may often require a reconsideration of the original purpose of the regulation and its ongoing appropriateness and legitimacy.

**Practices 11. Methods for ex-post evaluation and regulatory review**

The approaches used to review regulatory measures, as well as the measures themselves, must be fit for purpose. Broad review approaches are usually classified according to different points in the policy and regulatory measure life cycle at which they are applied. Although they are different tools and methodologies, they have some common features among themselves.

**Scheduled revisions** generally focus on the implementation of regulatory measures at a specific point in time or when a clearly defined situation arises. For regulatory measures with a potentially significant impact on society or the economy, especially those that contain innovative features or where their effectiveness is uncertain, it is desirable to include review requirements in the regulatory framework itself. Planned revisions include so-called **sunset clauses**, which provide a useful "fail-safe" mechanism to ensure that the entire body of laws and regulations remains fit for purpose over time. **Post-implementation reviews**, which are carried out over a shorter time frame (e.g. 1-2 years), belong to the same group. They are relevant for situations where the ex-ante impact assessment is considered inadequate (e.g. by a supervisor) or a regulatory measure is introduced despite known shortcomings or anticipated risks.

**Ad Hoc Revisions** are usually conducted as the need arises. **Public inventory control** provides a periodic opportunity to identify current problem areas in specific sectors or the economy as a whole. **Principle-based reviews** use criteria or a screening principle to allow a specific focus on particular performance issues or impacts of the measures introduced. **In-depth public reviews** are appropriate for major regulatory regimes that involve significant complexity or interactions, or that are highly controversial, or both. **Inter-jurisdictional reviews** are a useful mechanism for identifying opportunities for improvement based on comparisons between different national jurisdictions that have similar policy frameworks and goals.



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**Ongoing management of the current legislation** is not done at a specific point in time and is part of actions concerning the overall regulatory environment. Mechanisms need to be in place to enable enforcement authorities to understand what the performance is 'on the ground' of a regulatory measure. **Compensatory approaches to regulation** (such as the 'one in, one out' rule) and burden reduction targets should include requirements that measures intended to be repealed, if still in force, first undergo some form of assessment of their suitability. The review methods themselves should be periodically reviewed to ensure that they remain fit for the purpose they pursue[35].

Today, of the 28 EU Member States, only 14 have provisions for mandatory periodic evaluation of existing laws, while 11 countries do so for subordinate legislation. This is broadly in line with the overall picture of OECD members, according to which only 26% of countries systematically require periodic ex-post evaluation of existing laws and 21% for regulations[36]. In most of the above 14 EU countries, the requirements only apply to laws in specific policy areas. Only ***Austria, Denmark, Germany, Hungary, Italy and the Netherlands*** have a requirement to systematically conduct periodic ex-post impact assessments of regulation in all policy areas.

**Practices 12. Subsequent evaluation and regulatory review**

The ***French*** Court of Auditors is carrying out an in-depth review of policies and regulations on access to social housing for disadvantaged people. Studying six different local areas, it concluded in 2017 that current policy is too focused on new build. As a result, the government launched a housing plan that focuses on mobility and transparency of choice for disadvantaged people, alongside building new social housing.

In 2016, the ***Danish*** Ministry of Energy, Utilities and Climate compared the transposition of the Energy Efficiency Directive in Denmark with its implementation in Sweden, Finland, Germany and the United Kingdom. The report identifies inconsistencies in the definition of large enterprises subject to mandatory energy audits, which have subsequently been clarified by the European Commission.

In 2013, the ***Netherlands*** conducted a study comparing the regulatory burden on SMEs in the bakery sector in selected EU Member States. The evaluation compares the impact of the regulations in place in the Netherlands, Lithuania, Spain and Ireland. The evaluation includes the effects of EU Directives, EU Regulations and national laws and regulations. The aim of the study is to assess whether there are significant differences in the implementation of EU legislation at national level leading to regulatory burdens and to make recommendations on how to achieve significant sector-specific relief. The review identifies opportunities for improvement in national legislation as well as in EU legislation. For example, the report concludes that the use of exemptions and lighter regimes for SME bakeries in

[35] Source: OECD Best Practice Principles for Regulatory Policy: Reviewing the Stock of Regulation, OECD Publishing, Paris, 2020.
[36] OECD Regulatory Policy Outlook 2018, OECD Publishing, Paris, 2018.



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EU legislation could reduce the regulatory burden and improve the economic viability of these businesses.

In 2016, ***Italy*** compared its notification requirements for food business operators with those in France, Spain and the United Kingdom. The review reveals cases of gold-plating of EU law[37]. In particular, some of the information required to be provided to the public administration in notification forms for registration of food businesses has been identified as redundant or not required by Union law. As a result of the review, Italy is reviewing and standardising notification requirements in line with practices in other European countries.

***The European Commission*** has adopted the concept of "fitness checks" to assess specific areas of regulation in greater depth. Fitness checks have increased since the launch of the REFIT programme in 2012, which aims to assess administrative burdens in the EU. In recent years, the Commission has carried out a series of fitness checks, assessing the regulatory framework covering specific sectors or policy areas, such as consumer law. This practice of cumulative reviews based on comparisons between countries or regions is particularly useful given that all EU Member States respect the same Union law, resulting in a significant amount of identical legislation and policy objectives set out in the EU Treaties.

Governments are now increasingly seeking to limit the flow of costs arising from new regulatory measures and to reduce the existing volume of legislation. One approach that has been gaining momentum over the last five years is **regulatory offsetting approaches.** Here, the introduction of new regulatory measures is necessarily accompanied by the repeal of existing ones. While not in the strict sense forms of evaluation per se, these approaches of linking new legislation to requirements to repeal old legislation or setting targets related to achieving a net reduction in regulatory burden provide a source of strong motivation for those in power to evaluate the suitability of existing legislation.

The application of rules to streamline existing regulations when introducing new ones (such as the "one in, one out" approach) is not yet widespread among EU Member States. Currently, only 10 Member States have formalised rules to link new legislation to obligations requiring the removal of existing legislation or the reduction of regulatory (and therefore administrative) burdens to a certain percentage or amount on an annual basis. Of the countries that have implemented regulatory offsetting approaches, only ***France, Germany and the UK*** have carried out independent evaluations of the effectiveness and efficiency of their programmes, indicating that there is still a lack of knowledge on how such approaches affect the standard-setting process and regulatory outcomes.

**Practices 13. Implementing compensatory regulatory measures**

[37] From Eng. "Gold-plating". A term used to describe the practice of national authorities to adopt provisions that go beyond, exceed requirements, set higher objectives and standards, or go beyond the prescriptions of EU law when transposing or implementing it at Member State level.



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Although the basic idea of the regulatory policy promoted by the OECD is always based on a comparison of the costs and benefits arising from regulation in order to conclude on the necessity of public intervention in the market and public relations itself, many OECD countries have adopted other tools and techniques for managing regulation focused on measuring and reducing individual regulatory costs.

The offsetting approach is rooted in the setting of net quantitative targets to reduce administrative costs and later compliance and regulatory costs, pioneered by ***the Netherlands.*** In the 1990s, it introduced a method of quantifying the administrative burden in monetary terms, known as the Standard Cost Model, which was accompanied by a government commitment to reduce the administrative burden by 25% over the next 5 years.

***The UK*** was the first OECD and EU country (pre-Brexit) to introduce the 'One In, One Out' approach as official government policy in 2011. The programme was deemed so successful that the government decided to go further and double compensation by introducing a 'One In - Two Out' approach. In 2015, the approach was strengthened even further so that every pound of newly created regulatory costs had to be offset by a reduction of £3, i.e. it became 'one in - three out'.

***France*** adopts regulatory compensation policy in 2013. "Regulatory freeze"[38] requires ministries both to compensate for increases in costs to business and to remove or, if not possible, simplify existing legislation when introducing new. Costs to local authorities and citizens are also being considered. This approach was replaced by the two-for-one policy in 2017. This doubles the offsetting obligation with the intention of imposing greater controls on the flow of new legislation being proposed and reducing the volume of existing legislation.

In ***Germany***, the "one in, one out" rule was introduced by the government in 2015 as part of its "Red Tape Reduction and Better Regulation" programme. With the launch of the programme in 2006, the German government set itself the goal of reducing the costs of bureaucracy and avoiding new information obligations.

Just recently, ***Spain*** is presenting its version of compensatory regulation and ***Finland*** is completing a pilot project testing a "one in - one out" policy.

Evaluations of laws and regulations, as well as the regulations themselves, should be based on a sound methodological framework. Setting quality standards for ex-post evaluations and providing guidance to the competent authorities ensures both the development and maintenance of sufficient expertise in the public administration and quality control of ex-post evaluations carried out through outsourcing. Around half of all EU Member States have methodological guidance documents for bodies carrying out ex-post evaluations. This includes those countries that systematically require a periodic review of existing legislation. Countries such as ***Belgium, France, Poland, Sweden and Bulgaria*** have

[38] French: „Gel de la réglementation“.



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also published guidelines, although they do not have a formal requirement to conduct systematic ex-post evaluations. A third of the Union countries have invested in the development of standardised ex-post evaluation techniques such as scientific and statistical methods to be used when evaluating existing legislation.

In order to effectively review and make recommendations to improve the current legislation, it is important to determine whether the regulatory framework has achieved the desired objectives, whether the legislation is being implemented effectively and efficiently, and the extent to which any, including unexpected, impacts of regulatory intervention have been properly addressed. Today, only 4 EU Member States and the European Commission require a systematic ex-post evaluation of the main objectives of existing legislation. These are ***Austria, Denmark*** (for laws), ***Germany and Italy***.

In most EU countries, **evaluations are carried out by the administration responsible** for drafting the legislation. However, depending on the complexity and sensitivity of the area under consideration, there are different arguments for providing internal or external resources to carry out follow-up evaluations. For a significant number of regulations, ex-post evaluations are best carried out within the administration or ministry responsible for the policy, given their familiarity with developments that have taken place during the life cycle of the measure, and the ability to use existing internal capacity, thus carrying out reviews at relatively low cost. The use of external consultants is useful to complement the skills and experience of the administration, especially where specialist skills are required. The rationale for using a "hands-on" body or an organisation providing an independent review process is more solid the more sensitive a regulatory measure is and the more significant its economic or social impacts.[39].

In most EU countries, ex-post evaluations of laws are carried out by the officials or departments responsible for drafting them. Approximately one-third of Member States delegate the ex-post evaluation to external consultants from the private sector or academia. Given that almost three-quarters of Member States evaluations are carried out by the policy-making units of the public administration, the provision and development of more and better methodological guidance for them becomes even more important. A surprising finding from the 2019 OECD survey data is that in only a few EU Member States are ex-post evaluations carried out by bodies outside the executive. In only about a quarter of them are evaluations carried out by a permanent body, a unit in parliament or the legislature, or a group or committee outside government.

When the legislator is involved in conducting ex-post evaluations, it can play a crucial role in institutionalising ex-post evaluation in the standard-setting process. In ***Belgium***, the Parliamentary Committee for the Monitoring of Legislation is in charge of evaluating laws that were adopted at least 3 years ago. It has to identify possible implementation difficulties due to complexity, gaps, inconsistencies, ambiguities, contradictions, etc. and assess how the law has achieved its original purpose. A large number of interested parties can submit comments: any administration responsible for implementing the law, any body responsible for enforcing the law, any natural or legal person, deputies and senators. The Commission's work is supported by reports from the courts and by decisions of the Constitutional Court.

[39] OECD Best Practice Principles for Regulatory Policy: Reviewing the Stock of Regulation, OECD Publishing, Paris, 2020.



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EU Member States apply different **stakeholder involvement mechanisms when revising existing legislation** in order to increase the transparency of the process. Stakeholder involvement is particularly useful in ex-post impact assessment because it provides information on how legislation is working 'on the ground' and serves as a port for decision-makers to obtain feedback from them. Stakeholders can be involved both in the process of identifying areas in need of reform and during the review itself.

The majority of EU Member States involve stakeholders in subsequent impact assessments. Similar to OECD practices, this is mostly done ad hoc for individual policies rather than consistently across all areas of regulation. Stakeholder involvement in ex-post IA is less frequent than in the preparation of new legislation. The EU Member States that have committed to more systematic stakeholder involvement in ex- post impact assessments are ***Estonia, Italy, Luxembourg and Sweden***. In addition to direct stakeholder involvement in the revision of existing legislation, the majority of EU countries have various ongoing mechanisms through which the public can provide feedback and recommendations for changes to existing legislation. These range from electronic mailboxes, which are the most commonly used mechanism for providing feedback, to proposals for change submitted through an ombudsman or review petitions.

**Practices 14. Stakeholder involvement in identifying the regulatory burden of current legislation**

**The Danish Business Forum** for Better Regulation was established at the initiative of the Danish Minister for Business and Growth in 2012. It aims to ensure that improvements in business regulation take place in close dialogue with the business community, identifying those areas that business perceives as most burdensome and proposing simplification measures. These may include changing rules, introducing new processes or reducing processing times. In addition to administrative burdens, the Forum's definition of burdens includes compliance costs more broadly, as well as adjustment costs, including "one-off" costs associated with adapting addressees to new and changed regulations. Members of the Business Forum include representatives of employers' and trade unions' organisations, businesses, and experts with experience in simplification. They are invited by the Department for Business and Growth in their personal capacity or as representatives of relevant organisations. The Business Forum meets three times a year to decide which proposals to send to Government for simplification. In addition, stakeholders themselves can submit suggestions for potential simplifications via the Business Forum website. Information about the meetings and the resulting initiatives is published online.

The proposals from the Business Forum follow the **principle "comply or explain"**[40]. This means that the government is committed to either introducing the new (simplifying the current) legal proposals or justifying why it will not. The cumulative annual reduction in the burden of some initiatives due to the Forum's activities is estimated at DKK 790 million. Information on the progress of implementation of all proposals is available via a dedicated website. The results are updated three

[40] Eng. “Comply or explain”.



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times a year (at www.enklereregler.dk). The Business Forum publishes annual reports on its activities. The Danish Minister for Business and Growth also sends annual reports on the activities of the Business Forum to the Danish Parliament[41].

Information on how the ex-post evaluation system works in practice is crucial for assessing whether it is being properly implemented and whether it is achieving its objective of establishing whether the regulations remain appropriate. Given that most EU Member States have not yet developed effective systems for reviewing existing legislation, ex-post evaluations are particularly valuable for identifying areas for improvement and reform. This information provides useful data for improving decision-makers' compliance with the requirements to conduct ex-post evaluations. However, reports on the functioning of ex-post evaluation systems are in practice much rarer than reports on the effectiveness of the ex-ante IA system. This is not surprising given that few countries systematically carry out ex-post evaluation.

Only 5 out of 28 EU Member States evaluate the effectiveness of their ex-post evaluation system, of which 3 do so regularly. ***Austria***, for example, publishes annual reports on its ex-post evaluation system, which contain the results of an annual review of the ministries' ex-post evaluation activities, as well as giving an insight into the effectiveness of the ex-post evaluation system as a whole.

In ***France***, assessments of the ex-post evaluation system are published ad hoc. In 2017, the General Secretariat for State Modernisation commissioned an external evaluation of the public policy evaluation system introduced in 2013. Reporting entities note that stakeholders should be more actively engaged when evaluations are conducted.

Information on the effectiveness of the **European Commission**'s ex-post evaluation system is published in the Regulatory Scrutiny Committee's annual report. It reviews ex-post evaluations and fitness checks of key legislation and may issue a negative opinion if evaluations are not up to standard.

**2. Approaches**

Quality regulation is about continuously improving the effectiveness, efficiency and content of regulations and administrative rules. First and foremost, the concept of regulatory quality encompasses the processes of lawmaking and enforcement, i.e. the ways in which regulations are developed and implemented. These processes must be consistent with the well-established principles of openness, transparency, accountability, evidence-based and other principles. Second, the concept of regulatory quality also covers outcomes, i.e. whether regulations have been effective, efficient, consistent and clear. In practice, this means that regulatory measures should:

1. serve clearly defined policy objectives and be fit for purpose;
2. be clear, simple and easily enforceable by their users;
3. have a sound legal and empirical basis,
4. be consistent with other regulations and policies;

[41] Source: OECD, Pilot database on stakeholder engagement practices in regulatory policy: first set of practice examples. OECD Publishing, Paris, 2016.



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5. produce benefits that justify the costs, taking into account the distribution of effects in society and taking into account economic, environmental, social and all other impacts;

6. are applied in a fair, transparent and proportionate manner;

7. impose minimal costs and avoid market distortions;

8. promote innovation through market-based incentives and approaches based on objectives and

9. be compatible, as far as possible, with the principles of competition, trade and investment facilitation at domestic and international level[42].

Regulatory policy and governance of regulation are not only critical to improving the quality of different interventions. Researchers working in this field agree that they are also essential for building trust in their value and for the everyday lives of businesses and citizens. According to Lind and Arndt, good design of procedures for the development and administration of regulatory measures undoubtedly leads to an increase in the justice consciousness of their addressees because of an increased sense of fairness[43]. *Van den Bos, Van der Walden and Lind* consider that attitudes towards laws and regulations and compliance with them (understood as the alignment of human behaviour with regulatory decisions) are often so strongly influenced by addressees' experiences and perceptions of the process of their creation that they are equal in importance to the outcomes achieved by their implementation[44]. The links between outcomes, perceived fairness of processes and the adoption of rules and decisions are all the more important at a time of deepening distrust in institutions[45].

### 2.1. Quality regulation and the burden on business

There are a variety of cases where individual countries have achieved significant reductions in burdens on business and citizens through regulatory policy instruments. If businesses and citizens see tangible results, investing in better regulation is a worthwhile investment. That regulatory policy is critical to creating a favourable environment for investment and thus for economic growth and innovation is confirmed by the methodologies used by global rating agencies such as Moody's. These include the quality of the regulatory frameworks in place as one of the key variables in conducting assessments, building country credit profiles and others. In some countries, regulatory quality and stability reach up to one third as a weight in the rating methodology, as a good and stable framework directly translates into higher creditworthiness, lower funding costs and potentially higher investment[46].

[42] OECD Regulatory Policy Outlook 2015, OECD Publishing, Paris, 2015.

[43] Lind, E. and C. Arndt (2016), "Perceived Fairness and Regulatory Policy: A Behavioural Science Perspective on Government-Citizen Interactions", OECD Regulatory Policy Working Papers, No. 6, OECD Publishing, Paris.

[44] Van den Bos, K., L. Van der Velden and E. Lind (2014), "On the Role of Perceived Procedural Justice in Citizens' Reactions to Government Decisions and the Handling of Conflicts", Utrecht Law Review, Vol. 10/4, p. 1.

[45] OECD Regulatory Policy Outlook 2018, OECD Publishing, Paris, 2018.

[46] Moody's Investors Service (2013).



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**Approaches 1. Reducing the regulatory burden on business**

Between 2012 and 2017, the ***Netherlands*** reported a reduction in the regulatory burden for businesses, citizens and professionals of €2.48 billion. Measures include simplified accounting and reporting rules for small and medium-sized businesses, a new online tool that generates a personalised privacy statement for businesses, and the development of an app that trains employees on how to follow companies' emergency response plans.

In 2014, the company launched a new emergency response plan. The **OECD** is launching a Regulatory Policy Assessment Framework, including specific concepts and indicators for input, intermediate and output outcomes of regulatory policy. Although the demonstrated direct causal link between the management of regulatory instruments and public policy outcomes is not universally accepted, the application of the framework is still seen today as one approach to practically measure the effects of regulatory policy implementation, which ultimately contributes to the achievement of regulatory objectives[47].

In March 2016, ***United States*** federal agencies published their first reports assessing the impact of streamlining, revising, and eliminating a significant number of existing regulations. In total, U.S. agencies estimate savings to businesses and subnational governments of $28 billion over five years.

The **European Commission**'s REFIT programme is leading to a series of cost-saving initiatives, including more ambitious waste prevention and recycling targets, which are delivering savings of €1.3 billion a year. This is the 'one-stop shop' practice that allows a business to declare VAT in the Member State where it is established, reducing compliance costs by €2.3 billion a year. The unified digital portal helps companies save more than €11 billion a year[48].

### 2.2 Qualitative regulation and transformative technologies

Regulatory policy is all the more important given the transformative changes taking place in modern economies and societies. **Transformative technologies** are a type of innovation that rely on rapid advances in computing power, connectivity, mobility and the capacity to store vast amounts of data. These modern phenomena on the one hand offer opportunities for increased economic benefits, productivity growth and improved living standards, often also filling gaps in consumer preferences. On the other hand, however, they hold the potential to fundamentally change and 'disrupt' an established market, which is why they are also referred to as **technological disruption**. On the third hand, they can pose a real risk of significant regulatory challenges, such as the governance of public relations and employment in a digital economy, balancing the progress and impact of artificial intelligence and robotics in a range of sectors, and ethical issues in genetic technologies.

Digital markets and online platforms are an essential part of today's global economy. They are a complex ecosystem populated by several market players spanning all economic and social environments.

[47] OECD (2014), OECD Framework for Regulatory Policy Evaluation, OECD Publishing, Paris.

[48] European Commission (2017), REFIT Scoreboard.



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Digital data is key in this ecosystem and in the platform economy, where interactions, transactions, consumption and production are enabled by or based on digital data and information. The digital data economy currently poses serious challenges for policy makers in terms of data protection and privacy, competition impacts and consumer protection. Furthermore, new sophisticated identifiable owners of big data through certain algorithms can influence the perception of facts and news transmitted by digital intermediaries, having a real impact on freedom of information and media pluralism. Policymakers and regulators are struggling to figure out how to proceed and how to approach existing economic bottlenecks and find the optimal balance between the static and dynamic market value of the information and data economy on the one hand, and respect for individual and collective fundamental rights on the other.

Given the undoubted potential for both significant gains and losses, governments need to choose appropriate approaches where they encourage the adoption of innovative technologies and simultaneously manage or mitigate the risks they pose. On the one hand, they should be vigilant in adopting regulations that mitigate and serve as prevention against any potentially adverse economic and social impacts of such technological transformations. On the other hand, the regulatory environment should not unduly restrict innovation. This trade-off is compounded by the fact that these technologies increasingly blur the boundaries between consumers and producers and between traditional policy areas, thereby making regulatory interventions even more difficult to manage.

**Approaches 2. Quality regulation in the context of transformative technologies**

According to the OECD, governments have taken different approaches to develop tailored regulatory measures that both encourage innovation and reduce the associated risks in an equitable and proportionate way. These range from heavy-handed approaches that explicitly prevent the development or adoption of new technologies, to lighter ones, such as adopting exemptions (waivers) from existing regulatory requirements for a limited period of time for new innovative entrants that pursue general regulatory objectives such as consumer protection. This is the **"regulatory sandbox" approach**[49] . In many sectors and markets, given the pace of technological progress, regulators have opted for a **"wait and see" approach**[50] , to allow time and identify which of the anticipated risks will actually materialise.

This "disruptive" environment is a justification on its own for a more systematic application of the principles and tools for managing national regulatory policy. Indeed, tools such as regulatory impact assessment, stakeholder engagement and ex-post evaluation offer opportunities to reflect and gather different perspectives on the impact of regulation on innovation, while protecting the public interest. The majority of countries assess the impact of new regulatory measures on innovation as part

[49] Eng. „Regulatory sandbox“. The regulatory sandbox means a 'safe space' in which businesses can test innovative products, services, business models and delivery mechanisms without having to immediately suffer all the usual consequences of the legislation regulating the activity in question.
[50] Eng. „wait and see“.



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of the regulatory impact assessment process, a new development since the last OECD regulatory policy review in 2015.

The use of **behavioural insights** [51] throughout the policy cycle also helps to obtain and use evidence in decision-making and ensures that issues related to the implementation and enforcement of policies and legislation are taken into account early in their development. They are seen as tools that contribute to better policies and regulation, tailored regulatory solutions and innovation. By encouraging experimentation and a better understanding of actual human behaviour applied to regulatory policy, these approaches can be successfully used as elements of ex-ante and ex-post impact assessment, as well as to promote informed stakeholder engagement in decision-making. Last but not least, the application of behavioural approaches also leads to behavioural change in institutions, regulators and regulated entities.

**Approaches 3. Innovations and public administration**

One of the great advantages of new digital technologies is that decision-makers and public administrations can take advantage of them to increase their capacity for effective regulation. Innovations, particularly those in information technology, create opportunities to promote the adoption of evidence-based, inclusive and effective public policies and regulatory measures.

**Artificial intelligence, the use of algorithms and the increasing penetration of open data**, as well as **social media**, are just a few examples of how new technologies can help decision-makers and administrations to gather timely information, perform data analysis, engage diverse communities through consultation in decision-making and ensure greater policy coherence. Also, the opportunities offered by **'big data'** will enable the development and implementation of regulations based on risk analysis[52].

**Approaches 4. A new regulatory framework related to market transformation in Australia**

In April 2018, the Australian Competition and Consumer Commission published a market research report on the communications sector that confirmed a significant shift in its development. It cited local developments and changes in global technology and business trends, in the way we communicate and use networks to deliver services as reasons. In the presence of a rapidly changing environment and technological change, it is necessary for regulators to be informed of market developments that can lead to problems arising quickly. In this regard, the Commission is focusing its efforts on further information gathering and monitoring in the sector, particularly on emerging markets

[51] Eng. Behavioural Insights. An inductive approach to policy making that combines insights from psychology, social science and others with empirically tested results to discover how people actually make choices.
[52] OECD Regulatory Policy Outlook 2018, OECD Publishing, Paris, 2018.



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such as those based on the "Internet of Things".[53]. Thus, in relation to the relatively nascent "Internet of Things" sector, it concludes that its initial development should be allowed to take place without the introduction of any specific regulation. Taking into account the rapid development and relative immaturity of the sector, the Commission sees a non-interventionist approach through regulation to promote investment and competition in this market, combined with ongoing monitoring of its evolving processes, as appropriate[54].

**Approaches 5. Lessons from a regulatory modernisation initiative in Canada**

The Canadian Transportation Agency's Regulatory Modernization Initiative seeks to address issues related to the regulation of rapidly evolving standards, practices and technologies. An important aspect of the initiative is the agency's collaboration with other federal departments, organizations and international partners to resolve issues to avoid duplication or contradictions between perceived new regulatory authorizations. In recent decades, technological advances have led to rapid and dynamic changes in business models and operating practices in the transportation sectors. At the opposite pole are the increased expectations of consumers (travelers and shippers) regarding transport services. As an independent regulator, the agency implements regulatory measures that span Canada's national transportation system, covering all modes: air, road interprovincial and international rail, interprovincial and international marine, and oversees economic and accessibility issues for all, including persons with disabilities.

The outdated regulation of some relations is a problem, leading to problems for the economy, passengers and shippers and the efficiency of all economic activity in the sector. This is the reason why a regulatory modernisation project was launched in 2016, which includes reviewing and updating the current regulatory measures. Its main objective is to ensure that regulation is up-to-date and relevant to changes in business models, consumer expectations, technology and best practice in the regulated area. The Regulatory Modernisation Initiative includes four consultation phases - on accessible transport, air transport, air passenger protection and rail transport. In terms of transport accessibility, it consolidates existing regulations and voluntary codes of conduct into one comprehensive and binding set of regulations called the Accessible Transport Rules for People with Disabilities.

The new regulatory measures respond to issues related to the changing technological environment. In particular, the rules set accessibility requirements for technology and equipment commonly used by transport providers and passengers. They benefit all Canadians, with or without

[53] Eng. Internet of things (IoT). The relatively new concept that the creation of ever-smarter physical devices, vehicles, buildings and other features of our surroundings enables them to be connected via the internet into a common network, which in turn allows them to collect and exchange data with each other, work in sync and make people's lives easier.
[54] Source: OECD Shaping the Future of Regulators: the Impact of Emerging Technologies on Economic Regulators, 2020.



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disabilities, who use the national transportation system. Examples would include online check-in, self-service kiosks and others.

Another aspect of the project relates to air passenger protection. In accordance with the Transportation Modernization Act, the agency is adopting new rules establishing minimum airline obligations to passengers in a number of areas, including clear communication, delayed or cancelled flights, denied boarding, landing delay of 3 hours, accommodation of children under 14 years of age, damaged or lost baggage and transportation of musical instruments. It is these new regulations that have facilitated a transparent, clear, fair and consistent regime in the Canadian marketplace, and have aligned national regulations with best practices in other international regulatory regimes.

An essential element in the presence of technological challenges to promote accessibility across jurisdictions is international cooperation. In this regard, the availability of ever larger and more personalised mobility tools leads to complexity and more involvement in different countries to coordinate transport, especially for airlines. The Agency's solution is to establish a **multi-stakeholder Mobility Assistance Forum** to help develop short-term goals and recommendations to promote the safe storage and transportation of mobility aids. The agency and other representatives from participating countries are using new data-sharing technologies to create an easily accessible compendium of regulations and policies to promote a harmonized approach to affordable international travel. The main results achieved are the exchange of information and best practices, the alignment of national legislation with international legislation and with new technologies, and the promotion of the implementation of international transport and mobility standards.[55].

**Approaches 6. New transport regulation in Finland**

In 2019, the Finnish Transport and Communications Agency was established to continue the activities of the Finnish Transport Agency and the Communications Agency. The main objectives envisaged in the reform of transport regulation it has launched are to improve the ability to respond to changes in customer needs and the operating environment. An additional objective is to improve the efficiency and performance of the competent administration through more flexible and efficient use of resources. The reform aims at better use of transport-related data in the private sector and the introduction of new business activities and processes. Next is the establishment of better use of data for the benefit of society, digitisation, better targeting of transport services and the creation of transport markets through the introduction of new regulations in the sector. In this way, better connectivity between the transport and communications sectors is pursued.

In order to achieve greater efficiency and to foster a favourable regulatory environment for business and innovation in the face of market transformation and rapidly evolving technologies, the Agency concludes, on the basis of a sector inquiry, that regulation should be flexible, regularly tested

[55] Source: OECD Shaping the Future of Regulators: the Impact of Emerging Technologies on Economic Regulators, 2020.



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for its suitability to achieve objectives, and that a variety of instruments should be available for action, rather than expecting one accepted model to meet all objectives. The main features in the development of the transport system relate to the Finnish authorities' achievement of stimulating technological development through optimal adequacy of regulation and compliance with best practices in various areas. As an example of this, the **digital driving license** has been developed and the ongoing development of this process, which includes the introduction of **digital licenses for pilots.**

Better and more consistent customer service and ease of operation are supported by rules on the collection and use of data relating to vehicle, ship and aircraft registration, as well as licenses for staff in the different modes of transport. Tracking and promoting developments in the sector is achieved through cooperation with experts in data protection and cyber security. These developments in Finland are helping the agency to develop common approaches in many sub-sectors, such as transport registers, passenger rights, the right and duty of doctors to pass on information to the transport authority, and others. In areas such as digitisation, cyber security, automated vehicles and the environmental impact of transport, the Finnish approach relies on research and the adoption of best practices and experiences at international level[56].

**Approaches 7. New strategies towards big data and misinformation in Italy**

The communications and media sector and the institutions responsible for its regulation are at the frontline of addressing the challenges posed by technology and market dynamics in the digital policy area. They have traditionally regulated communications networks, which are the 'backbone' of the digital ecosystem, and most often the services provided by digital platforms are substitutes for traditional communications, information and audiovisual services.

The main 'disruptive' aspect of the online platform economy relates to the establishment of a business model based on global digital transactions, where data is implicitly exchanged through cheap or free services in a multi-sided market context. The other relevant and potentially 'disruptive' economic characteristic of digital platforms is that they can dramatically reduce consumer transaction and search costs, enabling cost-effective outcomes similar to those that would occur in perfect competition. The larger the digital platforms are, i.e. approaching all possible subscribers and covering more and more traditional markets, the more efficient their algorithms and services are. Reducing transaction and search costs reduces the time consumers spend searching for information. Digital platforms thus enable digital information overload and efficiently select relevant information, thus perfectly exploiting users' preferences and needs for informative content. This inevitably undermines pluralism. This process is perceived as leading to pathological information phenomena, such as the polarisation of citizens and society, i.e., the tendency to receive information mainly in line with their ideological preferences, misinformation such as fake news, for example, and other.

[56] Source: OECD Shaping the Future of Regulators: the Impact of Emerging Technologies on Economic Regulators, 2020.



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The Italian Communications and Media Regulatory Authority[57] operates in precisely this context. Its main objective is to undertake new regulatory measures and actions linked to the adoption of new public policies, united in a new common paradigm towards big data, aimed at understanding and tackling the phenomena of digital transformation, focused on both big data and disinformation strategies, which are strictly interconnected. Based on its extensive 2018 data market study, AGCOM concludes that due to the structural and enduring failures and complexity of the digital ecosystem, a **holistic regulatory approach** to its networks and services is needed. It should address and respond to the interdependencies of the system in a way that neither risks negatively impacting innovation nor provides incomplete or merely formal protection of consumer and citizen rights. In other words, a **horizontal regulatory framework** for the digital economy is needed to protect and empower consumers and citizens in all markets and segments of the digital ecosystem where consumer information and data are critical.

As a first step of the new regulatory paradigm, opening the "black box" and addressing complex and combined digital data transactions. Consequently, regulators must be granted appropriate inspection powers to identify and assess, among other things, the timing and methods of data collection and storage, the functioning and accountability of the algorithms applied, the methods of data analysis and the extraction and use of information.

The second important point is that the dynamics of big data, together with the Internet of Things, artificial intelligence and 5G, make it necessary to overcome the traditional distinction between different types of data - personal, non-personal, sensitive, etc. - so that the new approach must simply refer to data as it is (data 'per se'). Third, regulators must be given the mandate, competence and authority to address or minimise the risk of new market failures, such as hidden transactions, incomplete markets, information asymmetries, etc.

In order to understand phenomena such as online information distortions, fake news and misinformation, AGCOM conducts market research on "News Consumption" and "Online Misinformation Strategies and Supply Chain of Fake Content". Through these, it has found that digital platforms are now playing an increasingly important role in an information system that has been structurally changed by big data. This is mainly due to the ability of digital platforms to collect personal information and extract value from data through accurate profiling, making their participants 'world leaders' in the online advertising sector. Big data is also crucial in terms of online pluralism, as it underpins the platforms' algorithms and allows for the personalisation of information generation and dissemination, and thus misinformation, polarisation and other pathological information phenomena.

Against all this variety of problems, AGCOM decided to adopt measures of **self-regulation and co-regulation.** In this regard, a technical committee on pluralism and trustworthy information on digital platforms has been established, including AGCOM and representatives of most of the market stakeholders, e.g. social networks-Facebook, Google search engines, press editors and audio-visual service providers, etc. It aims to create consensus, identify and promote solutions for self-regulation

[57] Authorità per le Garanzie nelle Comunicazioni )AGCOM).



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and co-regulation of online misinformation problems. The Committee comprises five working groups responsible for adopting methodologies to classify and detect online misinformation, monitoring economic advertising flows aimed at financing false content, fact-checking, media and digital literacy, and conducting awareness campaigns against misinformation targeting consumers.

The main outcome of AGCOM's actions on big data and disinformation strategies has been a partial opening of the 'black box' and a partial filling of the information gap, achieved by carrying out market research, often in cooperation with other public authorities, e.g. competition, privacy, cyber security and digitalisation agencies and specific studies commissioned to universities and research centres. On this basis, cooperation has been achieved with all major market players and stakeholders, with whom data-driven approaches to self-regulation and co-regulation have been adopted to tackle phenomena such as misinformation, 'hate speech', fake news, etc.

As a side positive effect of the new approaches, increased public awareness of the impact of the digital and data economy has been achieved. In addition, national policy makers in the sector have realised the critical importance of assessing the impact of digitalisation and disruptive technologies on the regulatory capacity of national public authorities, in order to understand whether and how the competences, powers of regulators and cooperation mechanisms need to be rethought and redefined both to facilitate the development and exploitation of the potential benefits of the digital and data economy and to address its challenges.[58].

**3. Recommendations**

The OECD has long identified the potential that so-called transformative technologies have to fundamentally change the way we live and work together. To help policymakers and unlock the potential of technology and innovation, while ensuring the protection of society in a context of high uncertainty, the OECD Regulatory Policy Committee[59] and the OECD Network of Economic Regulators [60] have developed a joint work programme structured around the following main pillars:

1. Creating good practices to address regulatory challenges posed by emerging technologies and support socially beneficial innovation;

2. proposing data-driven approaches for more effective and efficient standard-setting and regulatory solutions.

As part of this agenda, the organisation is launching a public online consultation in mid-2021 on a draft OECD Recommendation on Flexible Regulatory Governance to Benefit from Innovation[61].

The main objectives of the Recommendation are:

[58] Source: OECD Shaping the Future of Regulators: the Impact of Emerging Technologies on Economic Regulators, 2020.

[59] OECD Regulatory Policy Committee.

[60] Network of Economic Regulators.

[61] Public consultation on the draft OECD Recommendation on Agile Regulatory Governance to Harness Innovation (Forthcoming): https://www.oecd.org/fr/gov/politique-reglementaire/regulation-and-emerging-technologies.htm.



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✔ Improving knowledge and understanding of regulatory quality in light of the deficits in existing approaches, and the high levels of uncertainty associated with rapid innovation and technological change;

✔ reaching agreement on the basic elements of modern regulatory frameworks to ensure that innovation serves key objectives and improves the prosperity of societies. This includes addressing how stakeholder engagement, impact assessment, risk assessment, institutional cooperation (including international regulatory cooperation, which is crucial) are to be carried out in a context of rapid innovation and technological change;

✔ promoting effective cross-border regulatory action to ensure coherence and interoperability of innovation-related regulatory frameworks;

✔ promoting the key role of regulatory policy in governments' broader innovation strategies.

In this regard, the paper makes several sets of key recommendations.

**Recommendation 1. Adjust regulatory policy management tools to achieve regulation fit for the future**

Countries should ensure that the new regulatory measures they adopt are fit for the future. In this regard, they are recommended to develop **more adaptive, iterative and flexible regulatory assessment cycles**, while taking advantage of new technological solutions to improve the quality of evidence by:

1. using regulatory management tools in a flexible and integrated way to inform a continuous learning and adaptation process throughout the policy cycle;
2. introducing monitoring mechanisms as well as approaches for ex-post regulatory reviews that contribute to meeting the needs arising from rapid and dynamic innovation;
3. introducing regulatory governance tools that allow the impact of regulation on innovation to be assessed as far as possible, including within administrations and across borders;
4. using new data sources and continuous monitoring to better understand the effects of regulation and thus produce broader, more reliable and timely impact assessments; and
5. providing competent authorities for regulatory oversight with the mandate and resources necessary to enable comprehensive quality control, including the operation of new and modified regulatory governance tools.

Countries are called upon to put in place **mechanisms to engage stakeholders and the general public** in the regulatory process, including citizens and innovative small and medium-sized enterprises early in the policymaking cycle to increase transparency, build trust and benefit from more and different sources of expertise.

Countries are advised to take into account the existence of an **international innovation ecosystem** from which to benefit by adopting the most appropriate evidence and regulatory approaches to innovation. They are therefore encouraged to enhance coordination and cooperation between the different national institutions and units responsible for policy and regulatory action, and to strengthen, at the next level, bilateral, regional and international regulatory cooperation to address the cross-border implications of innovation policies.



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**Recommendation 2. Adapt institutional governance frameworks for flexible and future-proof regulation**

The OECD recommends the introduction or adaptation of institutional governance frameworks and regulatory approaches that are **forward-looking**, rely on the development of organisational capacity and accordingly mandate clear mandates, conduct systematic updating and scenario analysis, anticipating and monitoring the regulatory implications of innovations with significant impact.

Countries are advised to develop more outcome-focused approaches to regulation to enable accelerated innovation, leveraging the opportunities offered by digital technologies and (big) data by:

1. limiting the use of strict rules to cases where they are necessary, in particular to ensure adequate protection for citizens and the environment;
2. providing clear guidelines for implementation and encouraging the complementary use of 'soft law' instruments[62], such as voluntary standards where appropriate and
3. exploiting the opportunities provided by digital technologies and the emergence of new data sources to support the development, monitoring and implementation of outcome-focused regulatory measures.

The OECD invites countries to start allowing greater experimentation, testing and trialing of innovations to stimulate them by:

1. facilitating the use of regulatory exemptions to allow controlled testing of innovations and to encourage regulatory learning;
2. encouraging cross-sector and cross-jurisdictional experimentation to provide firms with an environment in which to test cross-sector innovations and improve regulatory cooperation by promoting interoperability of regulatory frameworks and
3. proactively engaging stakeholders on key aspects of the development, implementation (including monitoring and reporting mechanisms) and evaluation of testing initiatives.

**Recommendation 3. Adapt enforcement activities to the "new normal"**

The OECD recommends that countries adapt their regulatory strategies and enforcement activities to promote enforcement, help innovators navigate the regulatory environment, and at the same time continue to protect the public interest, including across jurisdictions, by:

1. adopting data-driven, appropriate approaches to identify, assess, and manage risks, revising existing risk management frameworks as appropriate;
2. systematically incorporating law enforcement issues and considerations into legislative proposals and related assessments;
3. expanding collaboration among institutions and organizations conducting research and responsible for enforcement of innovation-related regulatory measures, both within the individual state and, where feasible, across jurisdictions; and

[62] Eng. „Soft law“. Here, regulation is done through non-legally binding acts such as policies, guidelines, standards, voluntary codes, concepts, white papers, green papers, etc.



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4. adapting regulatory powers to focus on risk management and outcomes rather than being primarily oriented towards the enforcement of specific rules and procedures.

In its updated 2017 Better Regulation Guidelines, the European Commission introduces a completely new and improved tool for **assessing the impact on research and innovation**[63]. compared to the previous one It outlines the main considerations related to approaches to developing modern and innovation-oriented legislative proposals. The tool is not limited to examining impacts on technological innovation alone, but can also be used to explore other forms of innovation, such as social innovation, innovative business models or public sector innovation.

The assessment of the potential impacts of legislation on research and innovation depends on the type of regulatory measure and its overall objectives. It is based on the extent to which the initiative could have positive or negative impacts on research and innovation capacity at firm, sectoral or EU level, such as whether it would create or reduce barriers to innovation or weaken or strengthen incentives to invest in innovation, etc.

The tool includes the following main steps, presented below.

***Step 1. Broaden the consultation*** to cover innovators' perspectives. The aim is to establish whether addressing the identified problem is likely to have significant impacts on innovation and research and this is an issue that should be central to the consultation strategy. The generally accessible online stakeholder consultation should include questions on potential impacts on research and innovation, on emerging technologies and on impacts on growing companies. It should reach out to all relevant stakeholders and in particular to start-ups.

***Step 2. Assess potential impacts on research and innovation***. This step is carried out by completing a specially prepared checklist containing an indicative set of questions that should identify whether the regulatory measure being assessed would affect:

1. the research, testing or demonstration phase;
2. the application of innovative authorisations or their market uptake;
3. incentives for investment, growth, jobs or expansion of companies in the EU.

***Step 3: Consideration of the design of the regulatory measure***. Underlying this is the understanding that the overall impact on research and innovation depends on a number of factors, including the content of the regulatory measure itself, its administration and its implementation by the addressees. This is why it seeks to establish:

1. the potential impact of the proposals on the very ways in which research and innovation are carried out and their outcomes;
2. the potential for reducing negative impacts on research and innovation and
3. how innovation can be used to better achieve the objectives of the specific policy.

***Step 4. Implement tools to harness the potential for innovation and reduce negative impacts.*** It contains a non-exhaustive list of tools and approaches that can be used to improve the design of legislation so that it is more open to innovation and uses innovation to better achieve policy objectives.

[63] Tool #21. Research & Innovation, Better Regulation Toolbox SWD (2017) 350.



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**Recommendation 4. Application of experimental clauses**

Experimental clauses allow authorities charged with administering and enforcing legislation to have some flexibility with respect to innovative technologies, products or approaches, even if they do not meet all existing legal requirements. They may be appropriate where legislation requires the characteristics of a product to be defined in detail and this objective can be achieved in the future through different innovative solutions. They can also be proposed with the explicit intention of encouraging innovation and experimentation. Complex experimentation clauses are sometimes referred to as a 'regulatory sandbox', a framework that allows innovation to be tested in a real-world environment, subject to regulatory exemptions, safeguards and support.

**Recommendation 5: Adopt results-based legislation**

Results-based legislation sets a measurable target without prescribing the precise mechanisms for achieving it. It gives stakeholders the flexibility to decide how to achieve the objective. Results-based legislation should, in principle, always be the preferred option unless there is a clear need to define the precise mechanisms by which an objective is to be achieved. It prevents 'lock-in' to a particular technology or approach and creates a more level playing field for innovative technologies and approaches to compete with existing ones.

**Recommendation 6. Application of sunset clauses**

Sunset clauses terminate or repeal some or all of the provisions of a piece of legislation after a specified date, unless further action is taken by the competent institutions to continue them. They can be used to ensure that legislation does not become a barrier to innovation in a rapidly changing market and technological environment. They can also be a tool for legislative experimentation as they allow the legislator to test a new approach or framework of regulation against new technologies in a clearly defined way. However, the decision to use them should take into account the risk of regulatory uncertainty.

**Recommendation 7. Test of alternatives**

The test of alternatives requires those proposing regulatory measures to consider potential alternatives and to justify why their chosen solution is the optimal option for achieving the policy objectives. Strictly applied, the alternatives testing requirement has the potential to encourage innovation and the search for new approaches to existing objectives.



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The test of alternatives may also be applicable where particular projects, products or technologies would have a negative impact on a major regulatory objective, such as consumer or environmental protection, or where they cannot meet certain standards but the regulatory decision-maker has reason to approve them because of their wider benefits. In these cases, the test of alternatives can help ensure that the desired wider benefits are achieved by using the best available technology.

**Recommendation 8: Apply the "Top runner approach"[64]**

The 'Top runner approach' refers to legislative provisions that provide for the updating of certain standards or legal requirements to reflect higher levels of performance made possible by scientific or technical (technological) progress. If an innovation achieves a higher level of performance, this new level becomes the new level to which the producers concerned should aspire. "The 'Top runner approach' encourages innovation by rewarding pioneers, as other market players are obliged to adopt this innovation or to seek their own innovation that yields at least as good or better results.

## 4. Achievements

In its 2019 study, the OECD has carved out a separate chapter presenting the profiles of individual Member States, viewed through the lens of their regulatory policies and the achievements in the governance and use of regulatory policy instruments. They provide an overview of regulatory practices, including key achievements and areas for improvement. The aggregated results of the EU Member States presented illustrate the current situation in each of them in terms of the application and effectiveness of ex-ante impact assessment, stakeholder engagement and ex-post evaluation in national regulatory processes. The profiles also provide information on the use of regulatory governance tools for national and EU legislation, and describe the institutional structure for regulatory oversight in each country.

**Achievements 1. Czech Republic**

According to the OECD, the Czech Republic has a well-developed process for assessing the impact of legislation, including quality control mechanisms through the **Impact Assessment Board**, which is "at arm's length" from the government. All draft laws and regulations prepared by the executive must be accompanied by a basic impact assessment. A full IA is carried out for the same types of draft proposals, but which are expected to have new and significant impacts. There is room for improvement in the quality of the IA, especially in terms of quantitative representations of impacts. The IA is not mandatory for legislative initiatives by Members of Parliament. They represent about 40% of all draft laws submitted.

All bills proposed by the government are published on a government portal accessible to the general public. Consultation is mandatory as part of the IA process and the results are summarised in the assessment reports. However, there are no binding rules setting out the duration or format of these

[64] Eng. Top-runner approach.



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consultations. It is recommended that the Czech Republic standardises the public consultation process and encourages stakeholders, including the general public, to contribute to the consultations.

The Czech Republic is one of the first EU Member States to launch a **programme to reduce administrative burdens**. Cutting red tape is still a priority for the government, but unlike many other countries, the focus has not yet been extended to other regulatory costs. Evaluation of the implementation of existing legislation is usually done ad hoc and is used quite rarely. The Czech Republic plans to introduce more systematic ex-post reviews of existing regulations.

**The Government Legislative Council** is an advisory body to the central executive that monitors the quality of bills before they are presented to the government. One of its working committees, **the Impact Assessment Board,** assesses the quality of assessments and compliance with the procedures set out in the statutory IA guidelines. It assists the drafting bodies on request and provides advice on whether or not draft legislation should be subject to a full IA, provides methodological assistance and issues further guidance on the IA process.

The Cabinet Office's **Government Legislation Unit** is responsible for monitoring the quality of bills in terms of legal technique. Its functions are part of the inter-ministerial coordination procedure when draft legislation is presented to the Government Legislative Council and its working committees.

**Achievement 2. Poland**

The OECD found that Poland has made a number of changes to its regulatory governance practices in 2015, based on the new rules of procedure of the Council of Ministers under its **Better Regulation Programme.** The rules applicable to the Polish Council of Ministers, which have been in force since the same year, introduce public consultation as a general principle of the decision-making process and require a report on the results of completed consultations. In the event that consultations were not carried out, ministries are required to provide detailed justifications for this in the IA. There has also been a significant improvement in stakeholder and public engagement through the introduction of a **central government website**. It also maintains an active list of stakeholders who have indicated that they wish to be informed of new draft proposals for regulation.

IA are required for all legislative and regulatory proposals. Changes made in Poland include the development of **new impact assessment guidelines** and the distribution of **standardised impact assessment forms**. Subsequent impact assessments are also prepared at the request of the Council of Ministers or individual ministries and departments. The tendency is to extend these assessments over time and to focus on the overall social, economic and environmental impact of regulation alongside the administrative burden.

The Prime Minister's Office is responsible for the central oversight of the instruments governing regulation in Poland. The Ministry of Economic Development is responsible for the systematic improvement of regulation and the Better Regulation agenda in Poland. The IA Coordinator and the Government Programme Board are jointly responsible for ensuring quality control of stakeholder



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engagement and IA, and the Board is also responsible for checking the quality of subsequent impact assessments. Another body, the Legislative Council, is responsible for ensuring quality control of regulatory proposals. Parliamentary scrutiny in Poland is limited to checking the legal content of acts and is carried out both for laws initiated by the executive authority as well as for those initiated by parliament.

**Achievement 3. Belgium**

In Belgium, the IA is mandatory for all laws and regulations submitted to the Council of Ministers at federal level and is usually shared with the social partners as a basis for consultation. Periodic ex-post review of legislation is mandatory for certain legislative proposals. Sometimes sunset clauses are also used. As part of the Executive authority, **the Prime Minister's Office's Administrative Simplification Agency**, which is focused on assessing administrative burdens post-2013, is responsible for the overall policy of 'better regulation'. It supports the work of the **Impact Assessment Board**, which is an advisory body on impact assessments. It also produces annual reports on the quality of all IA and the evaluation process as a whole. The members of the IA Committee are appointed by the relevant administration and its composition may change without a formal procedure.

However, consultations with the general public are not systematic in Belgium. There is also currently no single central government webpage on which to publish all ongoing consultations. Thus, although the social partners are consulted on the IA, the general public cannot participate in the consultation process.

**Achievement 4. Denmark**

In Denmark, regulatory reform has been an important item on the government's agenda since the 1980s. Its initial focus on competitiveness has subsequently been extended to reducing the burden of regulation, and more recently to **promoting innovation-friendly regulation** in the economic sphere. In 2015, an **EU Enforcement Committee** was set up to monitor the operation and effects of the implementation of EU economic legislation. From 2018, all Danish legislation must comply with the newly introduced principles of flexibility and proven digital readiness.

The Government periodically reviews existing legislation with significant impact. In 2015, the business regulation IA methodology was updated, as was the target for a net reduction in regulatory burden. They include additional assumptions that IAs should be carried out for both draft laws and regulations above certain thresholds. Denmark systematically engages stakeholders and uses interactive websites for consultation later in the policy formulation and drafting processes.

**The Danish Business Authority's Effective Regulation Team** is responsible for quality control of IA regulations imposing significant burdens on business. It also provides guidance and training on the use of appropriate regulatory management tools, including IA. The Effective Regulation Team, as



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well as the EU Law Enforcement Committee of the Danish Ministry of Employment, check the quality of the implementation of EU business legislation. These are the two national bodies that systematically promote improvements in regulatory governance and identify areas where it can be made more effective.

**The Danish Ministry of Finance** is responsible for quality control of compliance with the principle of **proven digital readiness** and measures the effect of regulation on GDP**. The Department of Justice** oversees and implements overall **judicial oversight of regulatory quality**.

**Achievement 5. Netherlands**

The Netherlands has a long tradition of regulatory reform with a strong focus on reducing burdens for businesses and citizens. While the main focus of ex-ante impact assessment remains on measuring the costs of regulation, in 2015 this framework was updated, **introducing impact assessments on innovation**, SMEs, gender equality and developing countries. Periodic ex-post evaluation of the effectiveness and efficiency of regulation is mandatory for all draft laws adopted since 2001. Today it also includes an assessment of regulatory burden and is complemented by reviews of administrative burden and initial compliance costs in specific sectors.

In recent years, the Netherlands has placed a strong emphasis on the accessibility and transparency of the regulatory process. To this end, it has launched a **digital calendar** that allows the public to follow the legislative process. Public consultations are further promoted through a central interactive website. This has led to its increased use for consultation on draft proposals as well as on policy documents that inform the public about the nature of the problem and possible solutions. SMEs can make suggestions in the early stages of the development of regulatory measures as part of the SME test introduced.

Within the executive authority, **the Judicial Affairs and Better Regulation Policy Unit in the Dutch Ministry of Justice and Security** is responsible for verifying overall compliance with the IA framework. **The Regulatory Reform and ICT Policy Unit in the Ministry of Economic Affairs** coordinates the regulatory burden reduction programme and provides oversight of the quality of regulatory burden assessments.

**The Regulatory Burden Assessment Advisory Board,** which is an 'arms-length' body from the government, advises departments on the quality of individual burden assessments early in the development of proposals and can recommend improvements to assessments if it considers them inadequate.

According to the OECD study, ***Bulgaria*** has significantly reformed its regulatory governance system as a direct result of the entry into force of the amendments to the Regulatory Acts Act on 4 November 2016. It has also led to the creation of a central portal for consultations that are better



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integrated into the national mechanism for ex-ante and ex-post impact assessment of regulations. The central public consultation portal also provides an opportunity for direct feedback to stakeholders. It provides stakeholders with an account of how their views and opinions have contributed to shaping the final draft legislative proposals.

The OECD notes that the RA has also introduced a new system of impact assessment requirements whereby proposals for legislation are now subject to a partial or full prior assessment. At the end of 2016, a department was established within the administration of the Council of Ministers in Bulgaria to act as a supervisor of the quality control of IAs within the executive branch and to assist in their implementation. Following the enactment of the RA, all new laws, codes and regulations of the Council of Ministers are subject to ex-post evaluation within five years of their introduction.

The Council of Ministers is responsible for promoting the overall regulatory policy in Bulgaria, including stakeholder engagement and the preparation of ex-ante and ex-post impact assessments. The Supervisory Authority in the Modernisation of Administration Directorate of the Bulgarian Council of Ministers is responsible for the quality control of the regulatory management tools. The Administrative Reform Council, established in 2009, acts as an advisory body to the Council of Ministers to coordinate activities to reduce the regulatory burden for both businesses and citizens.

The description of the profiles of the individual EU Member States in terms of the tools for managing regulation concludes with a dedicated annex, presented for the first time in this form, providing information on the shares of draft national laws submitted to national legislations for consideration by parliamentary representatives. In Poland's profile, the OECD explicitly highlights that the requirements of regulatory policy vis-à-vis the executive authority do not apply to laws proposed within parliament.

In the section of the report dedicated to Bulgaria, it is pointed out that the indicators presented in the country profile for stakeholder engagement and IA for draft laws only cover the procedures carried out by the executive, which at that time proposed approximately 42% of the laws in Bulgaria. There are requirements to conduct IAs to inform the development of draft laws proposed by MPs, although these are relatively less stringent than those for the executive. Thus, Bulgaria is the absolute EU-wide leader in the negative ranking, which indicates the objective picture of compliance, respectively non-compliance, with the requirements for better regulation with the extremely high score of 58% (today 61.1%[65]) of bills submitted by Members of the National Assembly. And it is precisely in this part of the national law-making process that none of the instruments of "better regulation" are qualitatively applied. Far behind us in the same ranking is the Czech Republic, where the percentage is 41%, and Poland with 40%.

In terms of innovation, Bulgaria has been named an emerging innovator in the European Innovation Index 2021.[66], and its performance has slowly improved over time compared to overall EU levels. This group of emerging innovators also includes Croatia, Hungary, Latvia, Poland, Romania and Slovakia. Half of business sector R&D spending in the country is related to large multinationals. Bulgaria is

[65] Based on data from the National Center for Parliamentary Research's Study of Legislative Activity in the 44th National Assembly:
https://parliament.bg/pub/ncpi/20210329041138Изследване%20на%20законодателната%20дейност.pdf.

[66] European innovation scoreboard 2021: https://ec.europa.eu/growth/industry/policy/innovation/scoreboards_en.



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specific for having the largest share of funding coming from abroad among all other EU countries. The low level of public resources hinders the development of cooperation with the private sector and is an obstacle to attracting researchers. In addition to the lack of resources, there is a poor distribution of public R&D funding among universities and research institutes. A serious problem is also the weak link between these units and the activities of enterprises.

The trend in OECD countries is the opposite. An increasing share of public funding is directed towards collaborative innovation efforts between research institutions and industry. Directing additional funds to such activities is also important for Bulgaria due to the lack of interconnection between research and enterprise activity. Links with multinational companies that are major innovators are important for national firms and researchers[67] to exploit.

In Bulgaria, a relatively new methodological framework is in place for the key regulatory management tools applied within the executive, such as stakeholder engagement in decision-making and ex-ante and ex-post impact assessment of legislation. In these, the dimension of 'innovation' is explicitly recognised in the 2019 Guidance on ex-ante impact assessment.[68] It points out that, given the approach currently adopted in the country, when assessing the need for a comprehensive ex-ante impact assessment, the question of the possible negative effects of the regulatory measure under assessment on competitiveness, market relations, competition, innovation or consumers should be examined, among others.

In the key analytical step of the IA process of determining the economic impacts of the options being assessed, the Guidance indicates that, in terms of innovation and research, it should be established whether each individual option:

1. stimulates or hinders R&D;
2. facilitates the introduction and diffusion of new production methods, technologies and products;
3. affects intellectual property rights (patents, trademarks, copyright, know-how rights); and
4. encourages or restricts academic or industrial research.

**5. Selection**

This interim research report contains the findings, findings and conclusions of the benchmarking study conducted to select the best solutions in the field of quality regulation and innovation with the potential for successful implementation in Bulgaria (Activity 2). The results are presented as a "Long list" of best practices, approaches and achievements from the EU and Member States and key recommendations and conclusions from OECD analyses, guidelines and developments in the field of better regulation with a particular focus on R&D and innovation.

Once this list has been reviewed, discussed and approved by the Contracting Authority, the final selection of best practices, approaches, conclusions and recommendations will be presented in a "Shortlist" with the most relevant ones suitable for follow-up, replication and implementation in Bulgaria when the final report of the study (Activity 3) is prepared and based on expert adaptive analysis.

[67] OECD Regulatory Policy Outlook 2015.

[68] Adopted by Decision No 728 of the Council of Ministers of 05 December 2019.



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## III. ANALYSIS OF COLLECTED DATA AND FINDINGS

### 1. Key findings on regulatory policy

Both the European Union and its Member States show a strong common political commitment to regulatory reform. Starting their Better Regulation initiatives at the turn of the millennium, further reinforced by the 2015 Better Regulation Package, updated in 2017, and the 2016 Interinstitutional Agreement, the European Commission, the European Parliament and the Council recognise stakeholder engagement, ex-ante IA and ex-post evaluation in the Union level standard-setting process as essential tools to improve the quality of regulation.

Despite the significant overlap between Member States, the EU invests less on average in the areas of stakeholder engagement, ex-ante IA and ex-post evaluation compared to the OECD average. The difference is particularly striking in the area of ex-post evaluation, where EU Member States have not yet developed effective systems for reviewing existing legislation.

Over the last 20 years, there has been a trend of increasing regulatory oversight bodies across Europe. Their institutionalisation provides safeguards against government interference in their supervisory activities. However, they often remain linked to and accountable to governments, for example by sharing a common administration with them and, most importantly, by spending budgets set by them. As the supreme law-making body, national parliaments should also play a crucial role in regulatory policy and oversight of regulatory quality.

### 2. Key findings on stakeholder engagement

Although all EU Member States have invested in stakeholder consultation on regulatory proposals, there are significant differences between countries both in their requirements and in the practices applied. All countries have consultation requirements in place and these typically provide ample opportunities for input not only from stakeholders but from society as a whole. Consultation requirements are less stringent for regulations than for laws. In recent years, the European Commission has also invested significantly in improving its dialogue with stakeholders. In particular, it has a structured approach to informing the public about upcoming consultation activities and to engaging affected members of the public throughout the policy development process.

In order to maximise the value of stakeholder engagement, it is important that decision-makers are consulted both early and late in the policy development process. The requirements for consultation early in the same process where a regulatory problem has been identified and options are being considered are far less developed than where the decision to regulate has been made and a preferred regulatory option has been identified. This prevents stakeholders from contributing to the regulatory process at a stage where they can suggest other options for consideration by the decision-makers. This, in turn, can leave stakeholders with the perception that their input is not valued, negatively affect the credibility of decisions made, and potentially cause additional costs to the government later on due to insufficient compliance and enforcement.

For any regulatory measure developed, whether or not there have been any other forms of stakeholder engagement beforehand, good practice requires that a structured consultation process is conducted. Stakeholders need to be aware that there are certain procedures that any regulatory proposal



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must go through in which all stakeholders have the opportunity to engage. EU Member States have made significant investments in seeking input on their draft laws from affected parties, particularly through electronic communication means. The general trend is that they have fuller consultation requirements later in the policy development process.

Member States generally do not use annual plans, roadmaps or other similar tools to inform stakeholders in advance of possible future requests for their input into upcoming consultations on regulatory proposals. This deprives stakeholders of the opportunity to provide better considered feedback in upcoming consultations, and also prevents decision-makers from receiving more meaningful input at a time when the development of the policy or regulatory measure is in its infancy.

EU Member States have invested in a wide range of methods, as well as in seriously improving their online communication tools, to ensure that all affected parties are notified of consultations. Most now have central online consultation portals in addition to individual ministry websites. In some countries, these websites are quite advanced, allowing stakeholders to comment 'live' on draft laws and also to enter into discussion with a range of other stakeholders. While these investments should be recognised as successful, it is still often unclear how and whether the input and comments received are taken into account by policymakers. Like OECD countries, EU Member States are reluctant to assess whether their stakeholder engagement practices are actually delivering the expected results. Consequently, it is not known whether and to what extent stakeholders have improved the design of regulatory proposals and how this in turn has helped to improve the overall well-being of society.

**3. Key findings on the ex-ante regulatory impact assessment**

Regulatory impact assessment is a key tool for policymakers when deciding whether and how to regulate to achieve public policy objectives. The use of IAs has expanded over the last 30 years in EU countries. Almost all EU Member States have implemented the IA mechanism as a core part of their regulatory governance tools and generally enjoy explicit high-level political support for IA. There is a significant difference between the application of IA in practice towards laws and regulations. This is a particularly acute problem given the lack of regulatory oversight for most of the regulations. Only half of the EU Member States systematically publish the IA for the purpose of consultation on regulatory proposals.

A basic principle of the IA is that it should be proportionate to the level of expected impacts of the policy or measure being assessed. Part of the proportionality principle relates to the need to filter proposals to ensure that impact assessment resources are appropriately targeted. Despite their importance, EU Member States do not use threshold tests for this purpose, even though the majority have a requirement that the level of impact assessment undertaken is proportionate to the expected impact of the regulatory proposal.

Only around half of EU Member States have a requirement to consider the baseline option or else the 'do nothing' option. Perhaps more worryingly, in relation to regulations, less than half of the countries make it mandatory to identify and assess alternative options. However, an integral part of a well-functioning IA system ensures that all possible options - including non-regulatory options - are systematically considered and evaluated. Exploring different options helps to inform decision-makers about the expected impact of proposals and thus helps to reduce the risk of regulatory failure.



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The European Commission requires an IA to be carried out for proposals with significant economic, environmental or social impacts. The Commission publishes introductory impact assessments that outline issues in specific public policies and pre-assess expected impacts. Following a public consultation on the inception IA, the Commission undertakes a full IA, including data and evidence gathering and stakeholder consultation. The IA is subject to scrutiny by the Regulatory Scrutiny Committee, following whose decision the regulatory proposals themselves may need to be revised in addition to the assessments.

In relation to EU laws, IA is much more often required for the transposition of EU directives than for forming the basis of the negotiating position of individual EU Member States. Where they do not have formal requirements to conduct an IA at the negotiation stage, reliance is placed solely on the European Commission's impact assessments. In general, when an IA is conducted to transpose EU directives, the same procedures apply as in the case of national laws. About half of the EU Member States systematically require an assessment of "gold plating", i.e., whether provisions have been added at a national level that go beyond the requirements set out in the EU Directives as part of the national IA, when transposing EU Directives.

Evaluations of the effectiveness of IA systems have been carried out in a number of EU Member States, and these have included suggestions for improving current regulatory practices. However, these evaluations would be more useful if their focus were even more on how systems can be improved over time.

**4. Key findings on ex-post regulatory impact assessment**

Only once laws are in place can governments assess their full impact on society. Many of the characteristics of an economy or society that are relevant to particular legislative decisions change over time, so that even regulatory measures that were perfectly appropriate to achieve a given objective when they were adopted may become outdated over time. In order to ensure that regulatory measures remain fit for purpose, countries should regularly review their existing legislation. However, ex-post impact assessment remains relatively undeveloped among OECD members and many EU countries.

Most EU Member States lack a systematic approach to ex-post evaluation of individual pieces of legislation. Less than one-fifth of them systematically assess whether laws and other regulatory measures are achieving their objectives as expected. When policymakers are required to identify the actual costs and benefits of measures introduced, this is usually only for selected areas of regulation.

In recent decades, efforts to revise existing regulations have been driven largely by the motivation to reduce regulatory burdens. This objective has largely remained central to approaches to the subsequent revision of legislation. While almost all EU Member States have carried out reviews focusing on administrative burdens, only a quarter have carried out in-depth reviews to assess the wider impacts and cumulative effects of regulation introduced in a particular area in order to inform forthcoming reforms.

The European Commission uses a range of review approaches, combining systematic evaluations of individual regulatory measures with in-depth reviews of specific policy sectors. Through the "evaluate



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first" principle[69], also referred to as the "principle of first ex-post evaluation"[70], The Commission is committed to carrying out ex-post evaluation of all measures put in place before making a new proposal in a given area of regulation. According to the 2015 Better Regulation Package, updated in 2017, major ex-post evaluations and revisions are subject to quality control by the Regulatory Scrutiny Committee, which contributes to enhanced oversight of ex-post evaluations.

While almost all EU Member States have guidelines for ex-ante evaluations, only half have guidelines for ex-post evaluations as well. A robust methodological framework is integral to a well-functioning ex-post evaluation system, ensuring that ex-post evaluations are fit for purpose and of sufficient quality to inform future changes or reforms. In most EU Member States, ex-post evaluations are carried out by the departments responsible for developing the regulatory proposal. Only a minority have bodies and committees outside government responsible for carrying out ex-post evaluations. The more sensitive a regulatory measure is and the more significant its economic or social impacts, the more useful external and independent review is.

The EU Member States generally value stakeholder input in the ex-post evaluation of the impacts of existing legislation. Three-quarters of them have mechanisms in place through which the public can provide recommendations for changing legislation and for engaging stakeholders in ex-post evaluation. However, in most countries, this is only possible for selected policy areas. In addition, the OECD believes that EU countries should publish ex-post evaluation reports online more frequently to ensure transparency of the results of evaluation activities. This is currently done by less than half of all Member States.

Only 5 EU Member States have evaluated the effectiveness of ex-post evaluation systems. Where these have been carried out, they have provided valuable information on how they could be improved.

## IV. CONCLUSIONS FROM THE RESEARCH AND ANALYSIS

Public policies and regulatory measures are the main tools in the hands of governments to determine the behaviour of citizens and their communities and to promote the well-being of societies and the economic growth of countries. Regulation affects all areas of business and indeed our lives in general. It regulates the requirements that determine the quality of the products we eat, the ways in which we move from one place to another, whether walking, using public transport or driving our own cars, the rules that determine our health and safety, and so on. Although they are vitally important to us, today we usually take regulations for granted.

Regulation is a central part of government activity that affects all areas of public life. Regulatory measures are adopted by states to protect citizens, consumers, workers, businesses, the environment, etc. When they are good, they improve people's lives. When they are too restrictive, ill-conceived, unnecessary or inadequate, the rules they impose can make it difficult to start a new business, trade abroad or go through basic administrative procedures such as renewing identity documents, obtaining

[69] Eng. “Evaluate first”.

[70] Allio, Lorenzo. “Ex post evaluation of regulation: An overview of the notion and of international practices”, in Regulatory Policy in Perspective: A Reader’s Companion to the OECD Regulatory Policy Outlook. Paris, OECD Publishing, 2015.



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permits to carry out an activity or registering a new company, for example. Overly complex regulatory frameworks, a lack of transparency in rule-making and ineffective or incorrect enforcement can be harmful rather than helpful. Unbalanced or disproportionate regulations can lead to losses for the administration or society, to over-empowerment of decision-making and even to corruption. Worse, inadequate rules may fail to achieve their objectives and thus fail to protect us, leading to a loss of citizens' trust in institutions and in the state as a whole.

Good regulatory policy provides the necessary preconditions for the creation of norms and rules that improve citizens' well-being. Over the last 30 years, countries have made efforts to improve the practices and approaches of their regulatory policies to ensure their continued high quality. However, as societies continually raise their standards and demands for regulatory quality, regulation itself has become increasingly complex. The increasing pace of technological change and deepening globalisation separately pose significant challenges for national regulators.

Almost a decade after reviewing better regulation practices in the EU (out of 15 countries) in 2019, the OECD is for the first time systematically assessing stakeholder engagement in regulatory processes, ex-ante impact assessment and ex-post regulatory impact assessment across all EU and EU countries, comparing them to its own regulatory policy and governance standards, as well as those adopted in its member countries.

In terms of national regulatory policies, the findings are that all EU Member States have now adopted policies promoting regulatory reform covering different areas of regulatory governance. While policies relying on ex-ante IA, stakeholder consultation, administrative simplification and burden reduction (regulatory and administrative) are prevalent in almost all Member States, ex-post evaluation is less common.

Despite its leading role, regulatory oversight is still one of the least developed areas of regulatory policy in the EU. Although all EU countries have established bodies responsible for promoting regulatory policy, and for monitoring and evaluating regulatory reform in general, oversight is still uneven and focuses mainly on monitoring the impact assessment of regulation, neglecting other elements of regulatory policy. The majority of regulatory oversight bodies in EU countries are located in the executive branch. It is less common for bodies outside the executive authority to carry out regulatory oversight activities. Contrary to their prominent place in the legislative process, national parliaments are not seriously involved in regulatory oversight across the EU.

Regarding *stakeholder involvement in the national standard-setting process*, the main findings are that EU Member States often do this too late in the policy-making process, which means that it does not always have real impact and value. Even more striking is the finding that in some Member States stakeholder engagement is still not broad enough. The majority of EU countries have invested heavily in setting up online government portals to better communicate with stakeholders when developing laws. While commendable, these investments are not delivering their full benefits. For example, stakeholders are generally not informed by policymakers about how they have helped shape and ultimately improve regulatory proposals. This often leads to frustration among stakeholders, to rejection of imposed regulation, and to reduced voluntary compliance and engagement in future stakeholder consultations.



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Greater accountability for consultation outcomes is needed not only in EU countries but also in OECD countries more broadly. This is a finding made by the OECD based on data analysis already in 2018.[71]

EU countries generally do not facilitate the early involvement of their citizens in the European Commission's regulatory proposals. The Commission uses a range of different tools to engage stakeholders at different points in the policy-making cycle. In this way, EU countries and their citizens have the opportunity to participate, provide evidence and improve EU laws, including at the early stages of their development. However, many Member States do not sufficiently inform their stakeholders about these opportunities to provide input. Instead, most stakeholder engagement in the EU legislative process occurs after the Commission has decided to regulate through the individual transposition procedures. At this stage, the focus of consultation is usually on the implementation of EU directives at national level, rather than on their expected impact on society. To ensure that EU laws benefit fully from stakeholder consultation, Member States should provide better information and evidence during the actual design of draft regulatory measures.

Many EU countries still do not take full advantage of the beneficial effects of *ex-ante regulatory impact assessment* when developing national legislation. They do not systematically evaluate alternatives to the proposed lead option, which most often provides the most intensive regulatory intervention, and tend to focus on the benefits and costs to business only in determining the potential impacts of that option. The IA process still begins only after regulatory proposals have been developed, i.e., decisions are almost made by governments.

EU Member States typically assess impacts on government, business (including SMEs), competition, society and the environment. It should be noted that although ex-ante IA is carried out on the different regulatory options, most often a quantification of costs and benefits is made only for the preferred option, which may distort the final assessment results. Benefit quantification is less common in EU Member States than cost quantification, which often makes it difficult to make a final judgement on whether the measures being evaluated justify their costs.

In relation to the *ex-post impact assessment of regulation*, the conclusion is that all EU countries and the European Union itself remain more adept at making laws than ensuring that they continue to bring benefits to societies. Laws are not systematically subject to ex-post evaluations in almost all EU countries, which creates the risk that outdated norms and rules remain in place. This represents a significant waste of resources for:

1. governments associated with increased costs of administration, compliance checks and enforcement;

2. businesses, due to unnecessary regulatory (and administrative) burdens and

3. citizens, because of the restriction of their freedom and right to choose their behaviour and the increased costs of regulation when it is not well thought through, and the exposure to potential risks when regulations do not keep pace with societal changes.

When ex-post evaluations are carried out, they are often poorly structured and do not allow for systematic public consultation on them. Worse, ex-post evaluations do not systematically assess whether

[71] OECD Regulatory Policy Outlook 2018, OECD Publishing, Paris, 2018.



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the objectives of the regulation have been achieved - something that is vital to establish whether policies and regulatory measures remain fit for purpose.

## V. PROPOSALS FOR INTRODUCING BEST PRACTICES AND APPROACHES IN BULGARIA

In Bulgaria, the main instruments for the management of regulation are defined in the national statute law, also referred to as the "law on laws", such as the Regulations Act. By 2015, when the modern era of better regulation began in the EU, a consensus had been reached in the Bulgarian state and society on the need to integrate public consultation in a structured form, ex-ante IA and ex-post evaluation as imperative, comprehensive and binding mechanisms in our law-making. At the end of 2016, the main package of changes came into force. The largest regulatory reform in modern Bulgaria begins.

In terms of *stakeholder engagement*, we have a requirement for early, informal stakeholder consultation as a procedural stage of a full ex-ante impact assessment. It generally applies to proposals for new laws and codes or to proposals to amend and supplement any (statutory or regulatory) regulations that are expected to have significant effects. This consultation of interested parties precedes the public consultation already carried out on the draft legislation, its explanatory memorandum or report and the impact assessment carried out. Even before the start of the regulatory reform, an official public consultation portal of the Council of Ministers has been in place, which acts as a single interactive information point, including through e-mail notifications to registered users of consultations carried out within the Executive authority[72].

In principle, Bulgaria requires equal stakeholder involvement in the development of laws and regulations. They are used as a source to inform decision-makers about the nature of the problem and to enrich the evidence base on which future solutions to identified problems will be based. Identical consultation requirements and standards applicable to both types of legislation are provided for and operate. At the end of 2019, entirely new Standards for public consultation have been introduced[73], applicable within the executive branch. A new Consultation Document template is also in force from the beginning of 2021, which is publicly available and published on the official public consultation portal [74].

In Bulgaria, the old European model of broad public consultation in the norm-setting process is still in place, which has long given way to the approach of targeted stakeholder engagement in individual policies and regulatory measures. This is achieved through proactive outreach by competent administrations and the application of tailor-made sociological consultation tools that ensure targeted receipt of the data and information sought. This may also explain the relatively low level of stakeholder and public participation in the current consultations on draft legislation by the Bulgarian government.

A systemic shortcoming of parliamentary practice since the beginning of the regulatory reform in the country is that, despite the imperative requirement of the Regulations Act, no public consultations are held within the National Assembly either as a stage of the preparation of impact assessments or as a phase preceding the submission of draft laws for consideration. At the same time, the national law is

[72] www.strategy.bg.

[73] Adopted by decision of the Administrative Reform Council of 16.09.2019.

[74] https://www.strategy.bg/FileHandler.ashx?fileId=22516.

clear and undisputedly applicable to all subjects with the right of legislative initiative, stating that public consultations shall be held with citizens and legal entities when drafting legislation.

As far as the *ex-ante impact assessment* is concerned, the Bulgarian legal system has adopted the two-stage assessment process, according to which the ex-ante IA is divided into partial and full. Partial IA is the assessment in principle. As a rule, it applies to all legal acts that do not fall under the explicit hypotheses for which a full IA is required. This is the case when entirely new laws and codes are drafted. A full IA may also be carried out outside the above hypothesis for new laws and codes at the discretion of the draftsman, and where the partial IA has shown that the proposal can be expected to have significant consequences.

The methodological framework for carrying out a preliminary IA has recently been updated. A new guidance document for carrying out ex-ante impact assessment was introduced at the end of 2019 [75]. Starting from the beginning of 2021, the most significant amendments to the Ordinance on the scope and methodology for impact assessment are in force since its adoption in 2016. [76]. From the beginning of 2021, completely new templates for partial and full ex-ante assessment are also in force [77].

In the RA, the threshold that distinguishes what assessment is to be made is regulated by a relatively definite rule that requires the existence of an expectation of significant effects from the proposed policy or regulatory measure. The Partial Ex-ante IA acts as a kind of filter determining the type of IA required. It can thus signal an expectation of significant effects associated with the proposal being assessed, which implies an obligation to prepare a full ex-ante IA.

Five years after the start of the regulatory reform in Bulgaria, the major shortcoming in Bulgarian regulatory policy relates to the lack of a regulated distinction between the ex-ante IAs carried out for draft proposals submitted on the initiative of individual Members of Parliament. This deficiency has the potential to compromise the effectiveness of regulatory reform in general, given that currently about 2/3 of legislation is proposed by those entities with the right of legislative initiative.

Comprehensive ex-ante impact assessments remain a major challenge for the civil service. Too often, evaluation starts so late in the policy formulation cycle that it largely makes it pointless. There is also the practice of proceeding directly to recommending, at the outset of the report, the option of regulatory (legislative) intervention before the expected impacts of all the alternative options considered have even been analysed and compared, making the assessment a foregone conclusion. This is an extremely flawed approach to structuring the impact assessment, which is a direct manifestation of the so-called "regulatory instinct", which in Bulgaria is prevalent in its most negative form of "legislative instinct". In this case, those in power proceed to make legislative changes on intuition, in almost all cases, regardless of the nature of the problems they are pursuing. This is a flawed approach that is fundamentally opposed to the EU's principles of 'legislating as a last resort' and 'first subsequent assessment'.

From the point of view of the subsequent evaluation of the current legislation, Bulgaria is a big positive exception to the common practice in the EU and the OECD. It has a fully completed legal and

[75] Adopted by Council of Ministers Decision No 728 of 05.12.2019.

[76] Adopted by PMS No. 301 of 14.11.2016, amended and supplemented State Gazette No. 84 of 29.09.2020.

[77] https://www.strategy.bg/Publications/View.aspx?lang=bg-BG&categoryId=16&Id=215.



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methodological framework for ex-post impact assessment of legislation. Since the end of 2020, the first adopted in the modern Bulgarian state "Guidance for conducting ex-post impact assessment"[78], which contains a detailed methodological framework for this type of assessment. The first ever model ex-post impact assessment report, approved by the Administrative Reform Council, has also been in force since the beginning of 2021.[79]. These new methodological tools are applicable to subsequent impact assessments prepared within the executive branch.

In Bulgaria, there is no requirement for systematic follow-up evaluations. The law provides that a follow-up IA shall be carried out within 5 years after the entry into force of the new law, code or regulation of the Council of Ministers, referring to the regulations approved after the 2016 amendments. This is generally the body which is responsible for implementing the regulatory act. Within the executive authority, it may also be the body which traditionally proposes changes to it. The practice of ex-post IA in Bulgaria is still scarce. This is mainly due to the fact that the first 5 years have not elapsed since the entry into force of the amendments to the RA, at which point the phased emergence of the obligations of the competent authorities to carry out this type of assessment will also begin.

According to the annual monitoring reports on the implementation of the mandatory impact assessment in Bulgaria, prepared by experts of the Centre for Legislative Impact Assessment[80], who are a direct participant in the whole process of introducing the new instruments for regulatory governance in Bulgaria, the preliminary expectations that existed around and immediately after the start of the reform have been fully justified. The change of mindset and practices of those in power, who are responsible for proposing and adopting legislation, is very difficult, slow and inconsistent. There have been both covert and overt attempts to circumvent, in whole or in part, the compulsory impact assessment introduced by the RA.

The conclusion that is being drawn is that in Bulgaria after five years of regulatory reform there is no change in the view towards standard-setting. It is not perceived as a well-structured unified cycle of policy formulation and legislation that ensures their optimal high quality. There is no conceptual approach to the law-making process. One of the strengths of adopting this approach would be the shift in perceptions towards regulation through the methods of law. Under this approach, regulations come to be seen as one of many possible options for action aimed at achieving the goals and outcomes set out in national strategies and policies adopted by the state or local government on the basis of a consensus reached on them in society. In following the conceptual approach to legal regulation, the adoption of a new law or the amendment of an existing one is not an isolated act or an act of a subjective decision by a particular group of decision-makers. Nor is it an effort to temporarily solve a problem or to momentarily take advantage of a favourable confluence of factors and circumstances, but is part of an overall strategy, a step in the implementation of a particular concept, action plan or roadmap that has been adopted by the state and society[81].

[78] Adopted by Council of Ministers Decision No 885 of 3rd December 2020.

[79] https://www.strategy.bg/FileHandler.ashx?fileId=24111.

[80] www.ria.bg.

[81] Dimov, Tony. Regulatory Impact Assessment. Sofia, Ciela, 2017.



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Since the start of the 2016 reform, no comprehensive effectiveness evaluation of the new regulatory governance tools has been introduced, such as impact assessment and structured public consultation, has been carried out in Bulgaria. The first suggestion that could be made is precisely to prepare a comprehensive evaluation of the achievements and results of the regulatory reform, given the first 5-year period since its launch.

With regard to impact assessment, the way in which it is applied, or rather not applied, within the legislature and the negative effect that this phenomenon has on the whole standard-setting process should be reconsidered.

The main focus in assessing the effectiveness of public consultation should be on its partial application in the national law-making process, given that it is excluded in legislative proposals made within Parliament.

Bulgaria needs a complete rethink and reboot of the 2016 regulatory reform, which can be achieved through the adoption of a new national **Better Regulation Agenda** or an **Agenda for Improvement and Simplification of National Legislation**.

Due to the uneven distribution of the burden of regulatory reform, linked to the almost complete exemption of the legislature from the implementation of the key instruments of regulatory governance, Bulgaria needs an **Inter-institutional Agreement** between the executive authority and the legislature to make a general commitment to better regulation and high quality national legislation.

The institutional framework for national regulatory reform is incomplete. There is a need to build **correspondent bodies within the executive authority and the legislature** that are responsible for overseeing the implementation of regulatory policy instruments and for monitoring the quality of regulation. Our country also needs the creation of a **dedicated national regulatory oversight body** that covers both national entities equally with the right to legislate. One of the possible options is to build it on the principle of **"at arm's length"** from the government and parliament as a joint regulatory oversight body, which would be independent, built on a fully expert basis and include representatives of the government, parliament, civil society, academia, business, etc.

A future National Regulatory Oversight Body could **initiate networking between** existing advisory or expert units within the executive authority and legislature that focus on particular aspects of regulatory policy, such as stakeholder engagement, reducing administrative burdens, assessing specific impacts such as SMEs, R&D and innovation, etc. It would also become the body responsible for engaging Bulgaria in **international regulatory cooperation**, in which it has not participated so far.



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