# 3 The use of regulatory impact assessment across the European Union

Regulatory impact assessment (RIA) provides crucial information to policy makers on whether and how to regulate to achieve public policy goals. RIA examines the impacts and consequences of a range of alternative options and assists policy makers in identifying the most efficient and effective policy before making a decision. This chapter analyses the European Union and the Member States' requirements and use of RIA for both domestic regulations and proposed EU laws. It provides analysis of the application of the proportionality principle of EU Member States' RIA practices in relation to expected impacts, including detailed information collected during a series of interviews with four EU Member States – namely Denmark, Estonia, Germany, and Cyprus.

## Key messages

- While all EU Member States have an obligation to conduct impact assessment to inform the development of legislative proposals a gap between requirements and practices remains, particularly for subordinate regulations. The majority of EU Member States apply the principle of proportionate assessment and recognise that the level and depth of analysis should be aligned with proposals' expected impacts.
- About half of the EU Member States have exceptions to conducting impact assessment, particularly where a regulation is introduced in response to an emergency. The consequences of using such mechanisms are however opaque as the exception decisions are most often not scrutinised or published. Exceptions should be used sparingly and, when used, the decision should be transparent.
- Few EU Member States report using threshold tests to determine whether a regulatory proposal warrants more in-depth analysis. EU Member States using threshold tests often use a variety of criteria to guide their decision and impacts on businesses is a factor considered in most of their thresholds. Threshold tests should be inclusive and based on the size of impacts across society rather than focusing on any specific sector or stakeholder group.
- Policy makers in a number of EU Member States can flexibly apply the proportionality principle to determine the depth of the analysis. This is a factor contributing to the significant variation in the format and depth of final RIA across EU Member States. There is however little scrutiny of the correct application of the proportionality principle and the role of regulatory oversight bodies in ensuring that the depth of the analysis is sufficient and proportionate to the significance of the regulation is unclear.
- Identifying and assessing the impacts of the preferred regulatory option is well established in a majority of EU Member States, although assessing alternative policy options, both regulatory and non-regulatory ones, on average seems to be less systematically assessed in EU Member States than in OECD countries. All plausible alternatives, including non-regulatory solutions, should be taken into account by EU Member States.
- It is essential to always identify all relevant direct and important indirect costs as well as benefits that would emerge if the available regulatory options are implemented. EU Member States focus more strongly on identifying and on quantifying the costs of new regulations rather than their benefits. Less than half of EU Member States quantify the costs and benefits of more than one policy option, suggesting that detailed analysis tends to be limited to the option that policy makers prefer to take forward. EU Member States could do more to comprehensively assess the negative and positive impacts resulting from the range of identified policy options.
- EU Member States should collect information about the impacts of EU legislative proposals on the domestic economy and society and should use this information during the negotiation phase at the European Parliament and/or at the Council of the European Union. This is not a systematic requirement in a majority of EU Member States, although some countries report doing so in practice. The short timing between the publication of the European Commission's impact assessment and the beginning of the negotiation can be a barrier to EU Member States undertaking suitable analysis to inform the domestic negotiation position.
- Regulatory impact assessment is more systematically required to be undertaken during the transposition of EU directives into Member States' national law than during the negotiation stage. Almost all EU Member States are required to assess the impacts of EU directives when transposing them.

- Only six Member States report systematically assessing the impacts resulting from additional provisions added to EU directives, suggesting that decision-makers do not always understand the impacts that these impose on their citizens and businesses in most Member States. EU Member States ought to systematically identify and assess the specific impacts resulting from any national provisions added.
- EU Member States appear to use the European Commission's impact assessment to inform the negotiation of EU legislative acts rather than to inform transposition. EU Member States may benefit from using the European Commission's impact assessment more regularly during the transposition stage as it still contains some information and evidence on the types of impacts that countries can collectively expect to encounter when implementing the directive.

## Introduction

Regulatory impact assessment (RIA) provides crucial information to decision makers on whether and how to regulate in order to achieve public policy goals. RIA assists in developing efficient and effective policy responses that also maximise societal well-being. It does so by critically examining the impacts and consequences of a range of alternative options and by showing the expected impacts and distributional outcomes of proposals, thereby illustrating the inherent trade-offs. Improving the evidence base for regulation through *ex ante* impact assessment is one of the most important regulatory tools available to governments (OECD, 2012[1]).

RIAs should be integrated into the early stages of policy development to aid the formulation of new regulatory and non-regulatory proposals. They should be used to clearly identify policy goals and to evaluate if regulation is necessary and whether it is the most effective and efficient means in achieving these goals (OECD, 2012[1]). One method of doing so is by analysing the expected costs and benefits of regulation and of alternative means of achieving policy goals and to identify the approach that is likely to deliver the greatest net benefit to society. Policy makers should also examine all feasible policy alternatives as part of RIA, to ensure that a variety of solutions are considered and that the most efficient and effective one is used to attain policy goals. Building on the *OECD 2012 Recommendation of Regulatory Policy and Governance* (OECD, 2012[1]), the *OECD Best Practice Principles on Regulatory Impact Assessment* (OECD, 2020[2]) provide more detailed information and guidance for member and non-member countries on the critical elements required to develop and sustain a well-functioning RIA system (see Box 3.1).

The European Commission has recognised RIA as a centrally important regulatory management tool and it has been at the core of their better regulation practices for 20 years. The current European Commission's *Better Regulation Toolbox* (2021[3]) provides policy makers with an extensive amount of information and guidance on how to carry out an impact assessment. The European Commission has adopted RIA as a key component of its regulatory decision-making process and *ex ante* impact assessments continue to be carried out for major primary laws and subordinate regulation.

This chapter analyses EU Member States' RIA requirements and practices as reported in the indicators of Regulatory Policy and Governance (iREG) survey and its extension to all EU Member States. The section below provides an overview of recent reforms based on results from the iREG survey. The second section discusses the requirements and use of RIA in the domestic legislative process. It focuses on the application of the proportionality principle by EU Member States and is complemented by information collected during a series of interviews with four EU Member States, namely Cyprus, Denmark, Estonia, and Germany, carried out by the OECD as part of this project. In addition, this section reviews the requirements and implementation regarding both the use of alternative options in RIA as well as the assessment of costs and benefits in RIA. The final section of the chapter reviews the RIA requirements and processes as they relate to EU-made laws, including during the negotiation and transposition of EU directives and regulations.

### Box 3.1. Summary of the OECD best practice principles for regulatory impact assessment

A well-functioning RIA system can help policy makers identify the potential outcomes of proposed regulations and determine whether regulations will achieve their intended objectives.

RIA should reflect the following critical elements:

- Regulatory impact assessment should be part of the policy implementation process/cycle
- It should start at the beginning of the regulation-making process
- It should clearly and systematically identify the problem and the related regulatory objectives
- Alternative solutions, their costs and benefits are identified and assessed
- It is developed transparently in co-operation with relevant stakeholders
- Its results are clearly and objectively communicated.

The best practice principles relate to the following aspects:

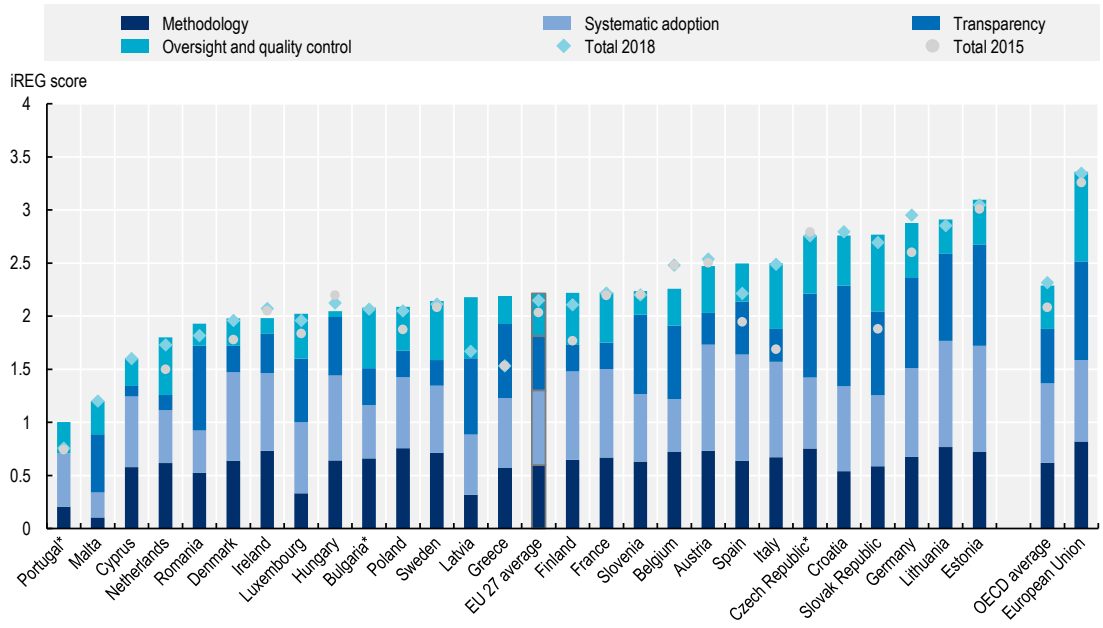
- The role of governments to ensure quality, transparency and stakeholder involvement in the process
- Full integration of RIA in the regulatory governance cycle respecting administrative and cultural specifics of the country
- Strengthened accountability and capacity over RIA implementation
- Using appropriate and well targeted methodology
- Appropriate communication and availability of RIA results to the public
- Continuous monitoring, evaluation and improvement of RIA.

Source: (OECD, 2020[2]), OECD Best Practice Principles for Regulatory Policy: Regulatory Impact Assessment, OECD Publishing, Paris, http://dx.doi.org/10.1787/7a9638cb-en.

## General trends in RIA across the EU

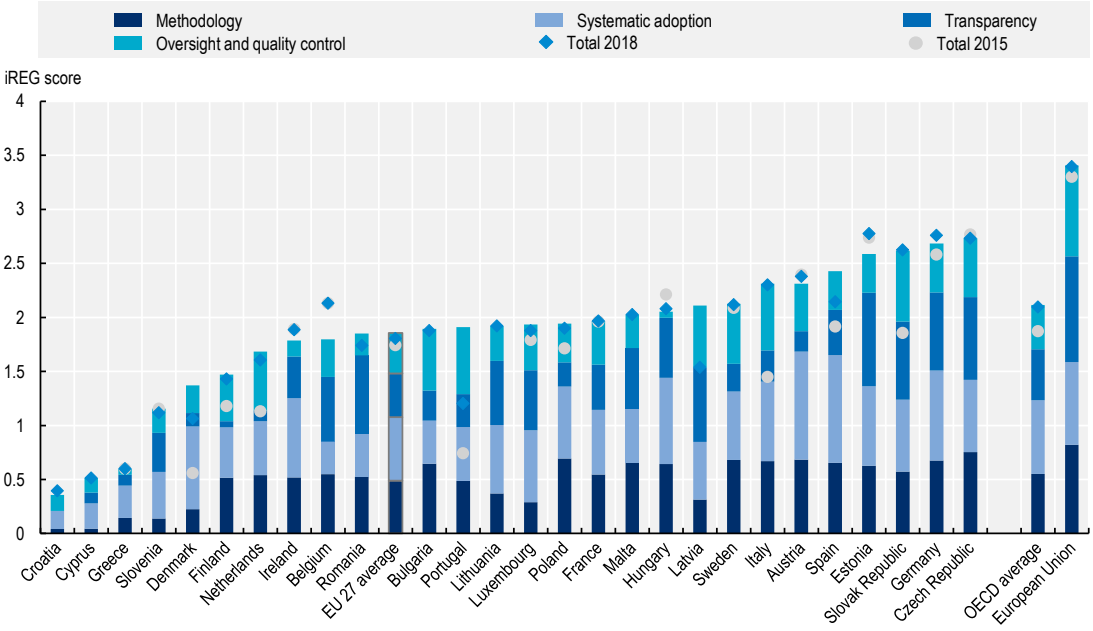
On average, EU Member States' RIA practices have improved little in relation to primary laws and subordinate regulations, with marginally more improvements in the former. The largest improvement has been on the oversight and quality control of regulatory impact assessments. There has also been improvement in the systematic adoption of RIA, but to a lesser degree.

## Figure 3.1. Composite indicators: regulatory impact assessment for developing primary laws, 2021




Note: Data for 2015 is based on the 34 countries that were OECD members in 2014 and the European Union, which included 20 of the current 27 EU Member States. The OECD average is based on the 38 member countries at the time of the survey. Data for 2018 and 2021 includes the remaining EU Member States of Latvia, Lithuania, Bulgaria, Croatia, Cyprus, Malta and Romania. The more regulatory practices as advocated in the *2012 Recommendation* a country has implemented, the higher its iREG score. * In the majority of EU Member States, most primary laws are initiated by the executive, except for Bulgaria, the Czech Republic and Portugal, where a higher share of primary laws are initiated by the legislature.
Source: Indicators of Regulatory Policy and Governance Surveys 2014, 2017 and 2021.

## Figure 3.2. Composite indicators: regulatory impact assessment for developing subordinate regulations, 2021




Note: Data for 2015 is based on the 34 countries that were OECD members in 2014 and the European Union, which included 20 of the current 27 EU Member States. The OECD average is based on the 38 member countries at the time of the survey. Data for 2018 and 2021 includes the remaining EU Member States of Latvia, Lithuania, Bulgaria, Croatia, Cyprus, Malta and Romania. The more regulatory practices as advocated in the *2012 Recommendation* a country has implemented, the higher its iREG score.
Source: Indicators of Regulatory Policy and Governance Surveys 2014, 2017 and 2021.

Some EU Member States have nevertheless undertaken recent reforms to their RIA system, including **Greece**, **Latvia**, **Portugal**, and **Spain**.

- Regulators in **Greece** are now required to assess and quantify the impacts of regulations on a large range of factors, including gender equality and social goals.
- **Latvia**'s recent substantive reforms include a requirement to assess a wider range of costs in RIAs, such as financial, budgetary, and administrative costs, as well as an expectation to prepare RIAs early in the policy-making process to later undergo public consultation with the draft law.
- **Portugal** formally established the use of RIA and has since expanded it, particularly for subordinate laws. Portugal has also reinforced the scrutiny of quality of RIA for subordinate regulations.
- **Spain** too has introduced bodies whose functions include watching over the legal quality of regulations initiated by the executive and providing feedback and recommendations on Impact Assessments to regulators.

RIA has the potential to improve resulting policies and this is demonstrated by recent experiences of both OECD members and EU Member States (see Box 3.2). However, nearly a decade of OECD research illustrates that RIA systems across OECD member states continue to experience the same range of fragilities – see OECD (2021[4]; 2019[5]; 2018[6]; 2015[7]). Policy makers appear to focus more systematically on the preferred policy option and generally do not dedicate the same efforts to analyse alternatives, particularly non-regulatory ones. RIAs thus tend to be conducted late in the policy process, when the policy option has been chosen and when the regulatory proposal is already drafted. In such cases, RIA can become akin to a "box-ticking" exercise where the impacts, costs, and benefits of a regulation are calculated *ex post* in order to justify a policy decision that has already been made. These issues are core to the success of RIA within OECD countries as a whole but are also relevant to EU Member States. This chapter attempts to examine some of these topics in more detail, by reviewing the extent to which EU Member States are required to identify alternative policy options, the types of impacts analysed in their RIA, the extent to which regulatory costs and benefits are assessed, and the transparency of their RIA systems.

### Box 3.2. Examples of EU Member States and OECD members where RIAs improved the resulting policy

The Ministry of Labour and Pension System, Family and Social Policy in **Croatia** used evidence from the RIA and from relevant policy papers to inform the legislative proposal regarding the introduction of a minimum pension wage. Analysis of the previous pension system and evidence collected as part of the analytical process were key in determining the policy taken forward.

**France** introduced a new "*Loi relative à la protection des enfants*" (Child Protection Act) in 2022. The accompanying RIA examined a number of policy options and helped policy makers choose the most efficient alternatives. For example, one option considered a referral process to a panel composed solely of juvenile judges. Analysis however highlighted that a large number of judicial courts in France have fewer juvenile judges than would have been necessary under this proposal and the policy option was subsequently discarded for a less stringent alternative.

In **Germany**, the use of RIA when reorganising the national sub-statutory regulations for biocidal products resulted in savings of approximately EUR 50 million. These savings emanated from the decision to follow performance-based regulation, whereby the adopted act prescribed a specific regulatory goal but businesses were free to decide how to implement it to meet the set objectives.

An impact assessment on the opening of the national road maintenance market was carried out in **Latvia**. Two possible models were analysed: one where the market stayed closed and one in which the market was open to competitors and service providers were chosen via public tendering. Each model included financial data, an outline of possible risks and benefits, as well as information about the model in other countries. Based on the analytical results, the government decided that the open market model would result in higher benefits and would be more efficient. The impact assessment allowed the policy makers to make an informed decision and advised stakeholders about its expected benefits.

The Department for Digital, Culture, Media and Sport (DCMS) in the **United Kingdom** sought to establish a policy on the security of consumer connectable products. Due to lack of evidence and data of the cyber security risk that 'internet of things' (IoT) posed, DCMS conducted a series of research projects whose findings informed policy options that fed into the impact assessment on regulating consumer connectable products to ensure they meet basic cyber security standards. Through the research, it became clear that the labelling scheme was not a good option. Research found that consumers already assumed that a device would be secure and thus DCMS instead explored options that removed the burden from the consumer.

Source: Supplementary material to the Indicators of Regulatory Policy and Governance (iREG) Survey 2021.

## The use of regulatory impact assessments in domestic legislation

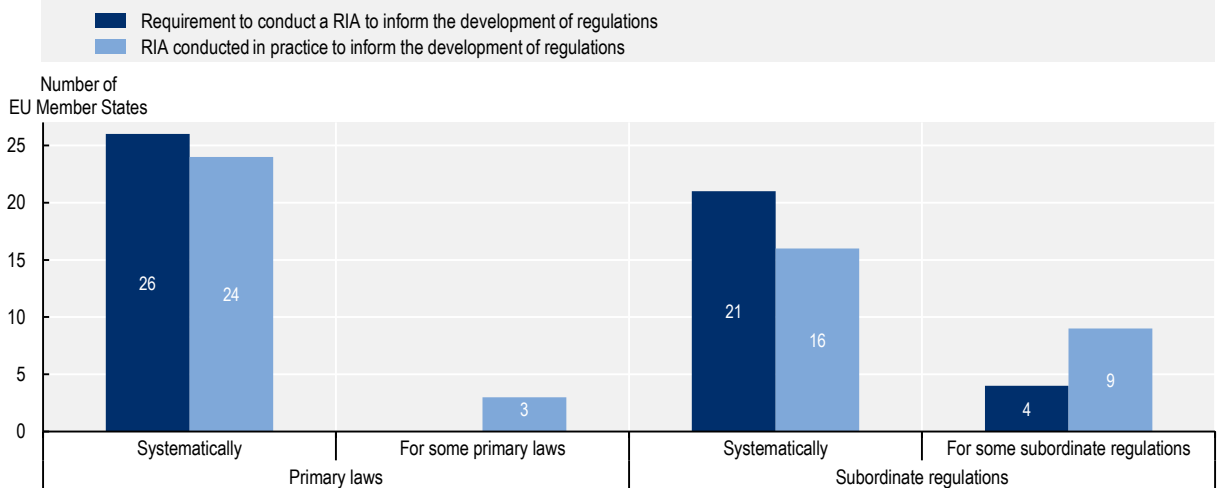
EU Member States have adopted the requirement to conduct impact assessments to inform the development of policy proposals and, in the majority of countries, the depth of the analysis must be aligned with the proposals' expected impacts. Approximately half of the EU Member States have exceptions to conducting impact assessment, particularly where a regulation is introduced in response to an emergency, however their consequences are blurred as the exception decisions are most often not scrutinised or published. Whilst few EU Member States report using threshold test as a filter to decide which regulatory proposal warrant in-depth analysis, there is strong heterogeneity in the way EU Member States apply the proportionality principle. A number of national policy makers throughout the European Union can flexibly choose the level of analysis with little scrutiny. The format and the depth of the final RIA product can thus vary significantly and it is unclear what role regulatory oversight bodies have in ensuring the appropriate application of the proportionality principle. EU Member States have established requirements to identify and assess the impacts of the preferred regulatory option, although such impacts appear to be less systematically required to assess alternative policies, particularly non-regulatory ones. Finally, EU Member States appear to focus their analytical efforts towards assessing the costs of new regulations, rather than their benefits.

### *The principle and use of proportionate impact assessment across the European Union*

EU Member States have recognised the importance of developing RIA requirements and practices that improve the evidence-base underpinning their domestic policy decisions. Almost all EU Member States have requirements – mostly expressed in law, statutory requirements, or in mandatory guidelines – to conduct RIA to inform the development of primary laws, but in practice, some EU Member States do not systematically do so (Figure 3.3). Formal impact assessment requirements can help governments establish foundations for a good and sound RIA. Furthermore, they help to ensure that established regulatory management processes and rules are aligned and followed so that unnecessary duplication is avoided, consistent and good quality RIAs are carried out in practice and their use is maximised. These requirements must however be appropriately applied and enforced, to improve the quality of decision making.

RIAs for subordinate regulations can also significantly impact citizens and businesses but are less systematically required (and conducted in practice) than for primary laws. Fewer EU Member States have a requirement to conduct RIA for subordinate regulations and the gap between requirements and practice is wider than for primary laws (Figure 3.3). Although subordinate regulations are not subject to parliamentary oversight, they represent a substantive part of the regulatory burden faced by citizens and businesses. The impacts of subordinate regulations therefore ought to be systematically assessed to promote policy effectiveness, efficiency, and coherence.

### Figure 3.3. Almost all EU Member States require RIAs to be carried out systematically but a gap between requirements and practice remains



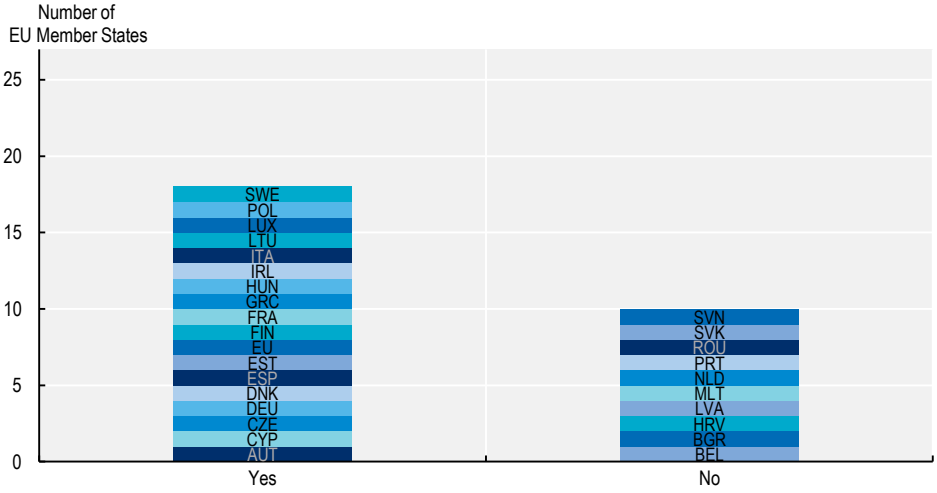

Note: Data is based on 27 EU Member States.
Source: Indicators of Regulatory Policy and Governance (iREG) Survey 2021.

Governments have limited resources and must use them appropriately and judiciously when developing policies as not all proposals have the same anticipated impacts. The OECD recognises that every regulatory proposal is different and does not need the same level of consideration or scrutiny (OECD, 2020[2]). Some proposals are procedural and will result in minor changes, so their development does not warrant as much time and effort as those of proposals that are likely to have major impacts on citizens and businesses. It does take time and resources to conduct *ex ante* analysis, therefore RIA should be undertaken where the costs of doing so are outweighed by the benefits of improving the policy (OECD, 2020[8]).

The *2012 Recommendation* emphasises that RIA should be proportionate to the significance of the anticipated impacts of the policy proposal (OECD, 2012[1]). OECD members' analytical efforts should be targeted towards proposals that are expected to have the largest impacts on society, to ensure that all such proposals are appropriately examined. Sufficient evidence and analysis should also be provided to stakeholders during consultation on such proposals, so they may be informed – and help to estimate – the scope of the potential impacts. The European Commission recognises the significance of the proportionate use of better regulation instruments, acknowledging that "the scope and depth of the analysis should always be proportionate and consistent with the importance and type of initiative and the nature and magnitude of the expected impacts" (European Commission, 2021, p. 81[3]). The principle of proportionality in the context of the European Commission's regulatory practices are covered in more detail in Box 3.3.

The majority of EU Member States recognise that the level and depth of analysis should be aligned with the proposals' expected impacts. Seventeen EU Member States require that impact assessment practices be proportionate to the expected significance of proposals for primary laws (Figure 3.4). Proportionality requirements for primary laws now exist in approximately two-thirds of EU Member States, compared to approximately three-quarters of OECD member countries. The number of countries with such requirements has increased since the previous edition of *Better Regulation Practices across the European Union* (2019[5]) as **Greece** has introduced the requirement that RIAs for primary laws be proportionate to the significance of the proposal in 2019. In contrast, 15 EU Member States require that RIA practices be proportionate to the expected impacts of subordinate regulations, a figure that has not changed since 2017 and that remains below the proportion of OECD members with the same requirements.

## Figure 3.4. Most EU Member States have requirements that impact assessment is proportionate to the significance of the regulation




Note: Data is based on 27 EU Member States and the European Union. This figure combines data for both primary and subordinate regulations as all EU Member States, except Cyprus and Greece, have the same requirements for both types of regulations. Cyprus and Greece both require RIAs to be proportionate to the significance of the regulation for primary laws but not for subordinate regulations.
Source: Indicators of Regulatory Policy and Governance (iREG) Survey 2021.

EU Member States' definition of what proportionality is and what the objectives of proportionate RIA are is consistent with the OECD's and the European Commission's definition. Information provided by EU Member States suggest they generally consider that resources and efforts dedicated to a specific regulatory proposal should be proportionate to the type of intervention and the scope of the expected impacts. For example, according to the Government of **Cyprus**, the analytical efforts should be proportionate to the issues addressed by the relevant proposal as well as the intensity of effort required for the carrying out of an impact assessment (collection and analysis of the relevant data and information) (Government of Cyprus, 2016[9]).

### Box 3.3. Proportionate RIAs in the European Commission

The impact assessment prepared by the European Commission, in accordance with their guidelines (2021[10]), must be proportionate and consistent with the significance and the type of initiative as well as the nature and magnitude of expected impacts. All expected economic, social and environmental impacts should be considered proportionally to their significance. The proportionality principle not only relates to the impact assessment report but also to all stages of the assessment process.

In order to determine the appropriate depth of the analysis, the following need to be decided:

- The resources and time allocated to the overall assessment process, including data collection, stakeholder consultation and conducting external studies;
- Resources required to answer each of the impact assessment key questions;
- The specific focus of the each step of the analysis – i.e., whether the comparison of policy options should focus on broad options or alternative measures within a given policy option; the level of aggregation at which the assessment should take place; which aspects should be analysed more in depth.

The lead Directorate-General with the interservice group are responsible for determining the depth and level of impact assessment, while taking into account all relevant factors as well as time, resource and data constraints. The depth of the analysis should be determined as early in the planning process as possible and the indication of the level of the analysis should be included in the call for evidence.

The proportionality of the impact assessment report with regard to the measures considered and their impacts is an element in the scrutiny carried out by the Regulatory Scrutiny Board.

Source: European Commission (2021[3]), *Better regulation Toolbox*, https://ec.europa.eu/info/sites/default/files/br_toolbox-nov_2021_en_0.pdf.

Using preliminary threshold tests to decide whether undertaking a RIA at all is necessary for a given regulatory proposal is not a common method to ensure proportionality across EU Member States, as only **Italy** and **Lithuania** do so (Box 3.4). This preliminary reflection takes the form of a threshold test, whereby some assessment is used to determine if the impacts of the regulatory proposal are significant enough to warrant investing resources in conducting a RIA. Using some preliminary assessment to identify whether a RIA is necessary is a less common practice in EU Member States compared to OECD member countries, with approximately one-fifth having such a threshold test in place.

### Box 3.4. Threshold tests to determine whether RIA is undertaken in Italy and Lithuania

The new Decree+ Handbook in **Italy** does not fix a single monetary threshold. The proportionality of analysis is met by four conditions, which constitute the set of criteria to be used for determining the "significance" of the expected impacts. This significance may vary. In fact, for each individual regulation/legislation under preparation, a proposal of RIA exemption shall be presented to DAGL by the individual ministry, and DAGL verifies if the decision (of not carrying out RIA) is grounded or not. In other words, on each proposed exemption from RIA, DAGL scrutinises the evidence that demonstrates the low expected impacts of the new legislation/regulation.

In **Lithuania**, the threshold used to determine whether a RIA ought to be undertaken is based on legal factors rather than analytical ones. Regulatory impact assessments must be conducted when a legislative proposal concerns a policy area that has not been regulated before or when it amends an existing regulation.

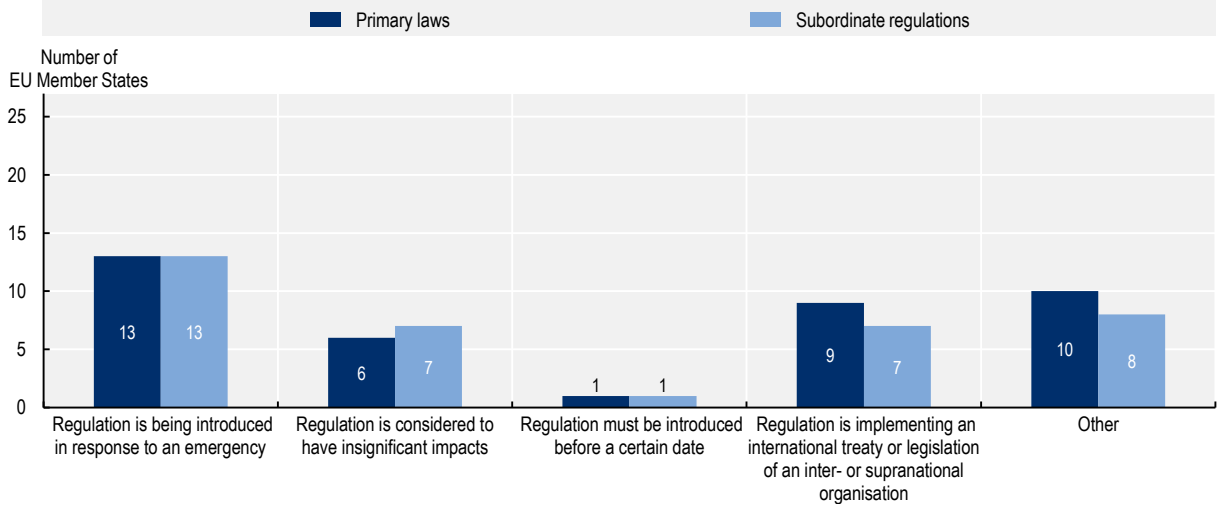
Source: Indicators of Regulatory Policy and Governance (iREG) Survey 2021 and OECD (2020[8]), A closer look at the proportionality and threshold tests for RIA. Annex to the OECD Best Practice Principles on Regulatory Impact Assessment, http://www.oecd.org/regreform/Proportionality-and-threshhold-tests-RIA.pdf.

### *Exceptions to the use of RIA*

There are cases, for example in genuinely unforeseen emergencies or when a policy has truly negligible impacts, where not carrying out RIAs can be a proportionate and appropriate way forward. During the COVID-19 pandemic it was sometimes necessary to regulate before undertaking a full RIA. However, policy makers should still attempt to use any information that can be reasonably collected *ex ante* to help inform decision making, and to use it as a basis for later reviews of the policy. There may still be opportunities to undertake *some* impact assessment, for example a focus (perhaps even only qualitatively) on the immediate anticipated effects of the policy. For instance **Canada** adjusted its RIA requirements for COVID-related proposals. Proposals could be developed using adjusted analytical requirements, including cost-benefit analysis and the small business lens analysis. These could be based on qualitative and quantitative data, but the requirement to monetise impacts was relaxed. In addition, proposals could be recommended for exclusion from the one-for-one rule (OECD, 2021[4]). In **Denmark**, COVID-related regulatory proposals were reviewed to assess whether the resulting administrative costs were above the threshold that would have triggered an in-depth RIA under normal circumstances. No COVID-related regulatory measures to date were identified as resulting in impacts above the threshold.

EU Member States have generally adopted exception mechanisms to RIA requirements where it is warranted, and particularly where a regulation is introduced in response to an emergency. In around half of EU Member States such regulations are except from RIA requirements (Figure 3.5). This is in line with the *2021 Regulatory Policy Outlook* that found that nearly half of OECD members have exceptions to conducting RIAs where regulations are introduced in response to an emergency and that several members used this mechanism to bypass their RIA requirements for some of the regulations introduced in response to the COVID-19 pandemic (OECD, 2021[4]).

## Figure 3.5. In some instances, regulations are excepted from RIA requirements




Note: Data is based on 27 EU Member States.
Source: Indicators of Regulatory Policy and Governance (iREG) Survey 2021.

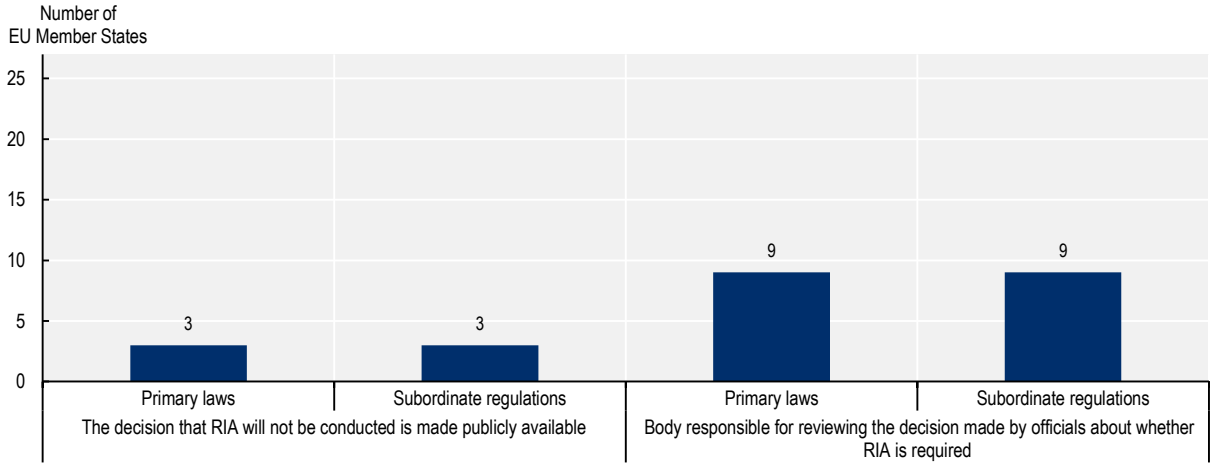
In addition to emergency responses, some EU Member States except regulations from RIA requirements under other circumstances. One-quarter of EU Member States do not require RIAs to be carried out for regulations that are considered to have insignificant impacts whilst one-third report to have exceptions to RIA requirements when a primary law at hand is implementing an international treaty or a legislation of an inter- or supranational organisation (Figure 3.5). These exceptions have not changed since 2017. In **Belgium** the exceptions to RIA apply to legislation concerning co-operation agreements between the federal state and the regional entities and the national security or the public order. In addition, RIA is excepted for autoregulations (i.e. regulations that concern the organisation of the State itself). In the **Czech Republic**, amendments to the Constitution, Acts on State budget, State Final Account, legislation introducing only parametric changes, government resolutions, and legislation that is granted exception by the chairperson of the Government Legislative Council are all excepted from RIA requirements. In **Ireland**, if a legislation is consolidating existing legislation and there are no regulatory changes being introduced, it is excepted from the requirement to undergo a RIA. In addition, legislation drafted as a direct consequence of a Court decision that leaves no discretion to consider alternative options or allow for meaningful consultation are excepted to RIA requirements.

Exceptions to RIA requirements also exist in the EU institutions, as EU policy makers can be excepted from carrying out RIAs when a regulation is being introduced in response to an emergency or is considered to have insignificant impacts. The European Commission recognises that better regulation practices should be applied flexibly and in a proportionate manner that reflect the circumstances of each individual initiative and there can be occasions where the better regulation procedures have to be shortened or simplified (European Commission, 2021[3]). Prior approval is however necessary for such exceptions and must be approved by the European Commission's Secretariat General or by the Vice-President for Better Regulation in more important cases. In addition, all such exceptions should be published in the call for evidence as well as in the explanatory memorandum accompanying the European Commission's regulatory proposal.

Whilst exception mechanisms for RIA are valid and relevant to ensuring that proportionate resources are allocated to the relevant policy proposals, policy makers should be accountable for using them. The events that trigger the exception, such as an unforeseen emergency or the significance of the impacts, must be real and genuine. Transparency of the decision to bypass RIA is an effective way to hold policy makers to account for utilising exception mechanisms and to ensure these are not abused. For example, the *OECD Best Practice Principles on Regulatory Impact Assessment* (2020[2]) calls for the application of thresholds – which includes exceptions to RIAs – to be publicly shared and call for the involvement of regulatory oversight. As such, involving regulatory oversight in reviewing the decision to except a regulation from RIA requirements and publishing said decision not only improves transparency and trust in policy making, it also ensures exceptions and scarce RIA resources are correctly and appropriately utilised.

EU Member States could benefit from providing more transparency around decisions to bypass RIA as scrutiny remains limited. Similarly to the findings from the *OECD Regulatory Policy Outlook* (2021[4]), the transparency surrounding the decisions to except proposals from conducting RIA in EU Member States remains blurred. Only three EU Member States – the **Czech Republic**, **Italy**, and the **Slovak Republic** – currently publish the decision that RIA for a primary law will not be conducted where it ought to have been (Figure 3.6). In addition, only nine EU Member States have a body responsible for reviewing the decision made by officials about whether a RIA for a primary law is required (Figure 3.6). A majority of EU Member States can use the exception mechanisms to bypass RIA with little scrutiny on whether this decision is appropriate or proportionate to the regulatory proposal at hand.

## Figure 3.6. EU Member States could benefit from more transparency and oversight in the decision to bypass RIA in case of exceptions




Note: Data is based on 27 EU Member States.
Source: Indicators of Regulatory Policy and Governance (iREG) Survey 2021.

### *Threshold tests as a method to implement the proportionality principle in EU Member States*

Countries can use different practices and methodologies to implement proportionality in their RIA processes. Whilst EU Member States generally recognise that the resources and depth of analysis should be targeted to the proposals with the largest expected impacts, proportionate RIA practices can take various forms. Some of the methodologies used by EU Member States and OECD member countries to establish whether legislative proposals require a certain level of analysis include (OECD, 2020[2]; OECD, 2020[8]):

1. **Setting quantitative threshold tests:** The level or depth of analysis is dependent on the total impacts to society. The policy maker needs to estimate the total impacts quantitatively, usually as part of a preliminary step in the development of a new regulation;
2. **Multi-criteria analysis:** The depth of RIA is based on a mix of quantitative and qualitative criteria in a number of key areas. The criteria may include, for example, the number of affected businesses, a certain level of $CO_2$ emissions or a subjective assessment of the significance of impacts on key sectors. These impacts are sometimes quantified but usually not monetised;
3. **Single-issue test**: The analytical depth of RIA is based on impacts to one sector or stakeholder group. For example, a full RIA is only required when costs to businesses exceed a certain amount; or
4. **A general principle of proportionate analysis, applied at policy makers' discretion:** The choice of RIA depth is left to the administration itself based on the principle of proportionality. An oversight body could potentially intervene and suggest a deeper analysis where the proportionality principle is deemed to have not been appropriately applied.

A categorisation of the methods used to ensure proportionality in a sample of EU Member States is provided in Table 3.1.

### Table 3.1. EU Member States use various methods to apply proportionality in the analysis of the expected impacts of the regulation

A selection of EU Member States where impact assessments are required to be proportionate to the significance of the anticipated/expected impacts.

| | Threshold tests | | | General principle of proportionate analysis, applied at policy makers' discretion |
|---|---|---|---|---|
| | Quantitative threshold test | Multi-criteria analysis | Single-issue test | |
| Austria | | ✓ | | |
| Croatia | | ✓ | | |
| Cyprus | | | | ✓ |
| Czech Republic | | | | ✓ |
| Denmark | | | ✓ | |
| Estonia | | ✓ | | |
| Finland | | | | ✓ |
| France | | | | ✓ |
| Germany | | | (informally) | ✓ |
| Ireland | | | | ✓ |
| Italy | | ✓ | | |
| Latvia | | | ✓ | |
| Lithuania | | ✓ | | |
| Luxembourg | | | | ✓ |
| Poland | | | | ✓ |
| Spain | | ✓ | | |
| Sweden | | | | ✓ |
| European Union | | | | ✓ |

Source: Indicators of Regulatory Policy and Governance (iREG) Survey 2021, OECD (2020), OECD Best Practice Principles for Regulatory Policy: Regulatory Impact Assessment, OECD Publishing, http://dx.doi.org/10.1787/7a9638cb-en, and OECD (2020[8]), A closer look at the proportionality and threshold tests for RIA. Annex to the OECD Best Practice Principles on Regulatory Impact Assessment, http://www.oecd.org/regreform/Proportionality-and-threshhold-tests-RIA.pdf.

In effect, quantitative tests, single-issue test, and multi-criteria analysis can all be considered as part of a two-tiered approach to RIA where a shorter and less rigorous assessment process is used as a filter to identify proposals that should be subject to additional analysis (OECD, 2020[8]). Threshold tests usually take the form of preliminary analysis, either through the use of a "simplified" RIA or through preliminary calculations and measurements. The shorter and less rigorous RIA process might be sufficient in cases of low expected regulatory impacts and may be used to identify proposals where more in-depth analysis is necessary. In other words, if the anticipated impacts of a proposal are above a certain threshold, it must undergo a more thorough and detailed impact assessment process (OECD, 2020[8]). The *Annex to the OECD Best Practice Principles on RIA* (2020[8]) identify elements that policy makers should consider when developing threshold tests and proportionality rules in general (see Box 3.5).

### Box 3.5. Annex to the OECD Best Practice Principles on Regulatory Impact Assessment: A closer look at proportionality and threshold tests for RIA

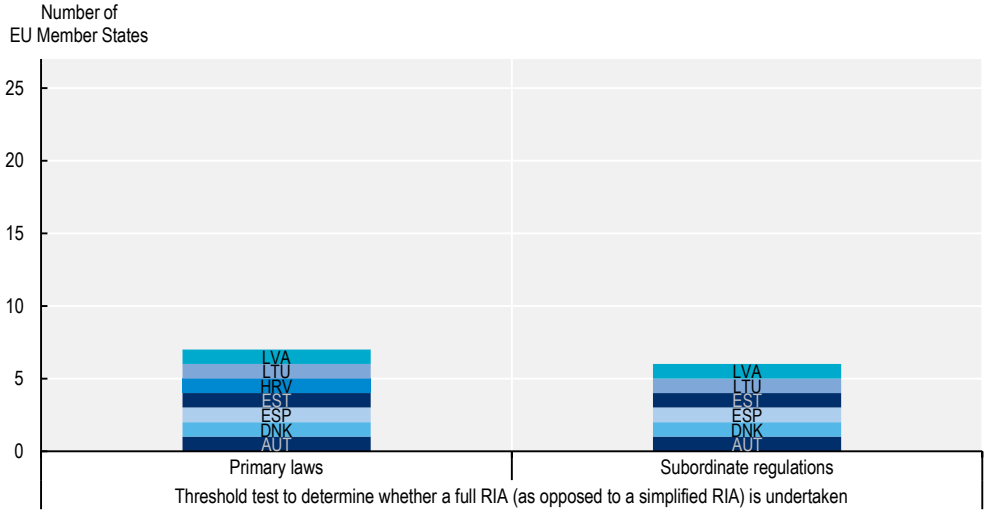
OECD countries should consider the following, when developing proportionality rules or threshold tests:

1. Determining the scope of RIA should start at an early stage when policy makers are evaluating the problem – potentially even before considering the need for intervention – and identifying regulatory and non-regulatory alternatives. Preferably, this process should start already in the phase of legislative planning.
2. An oversight body should assess whether the policy maker has characterised the problem correctly, including its magnitude, when it still has the flexibility in formulating a regulation or policy. The earlier policy makers understand the magnitude of the problem, the better the government may target resources to developing solutions.
3. During the early stage of RIA, policy makers should begin to introduce an economic rationale and data to determine the scope of the issue. This does not mean an in-depth analysis at an early stage (e.g. a well-developed cost-benefit analysis). Policy makers should be broadly scanning an issue, before undertaking an in-depth analysis.
4. The time and resources devoted to the development of regulation and its analysis should relate to the size of the impacts, the size and structure of the economy, the impacts per capita, the flexibility of the policy, and the relative resources of the government.
5. If a country chooses to use quantified thresholds for RIA, they should be inclusive and base the thresholds on the size of impacts across society, rather than focusing on any specific sector or stakeholder group. There may also be a risk in using one single value threshold that captures impacts across society. One stakeholder group may be disproportionately affected but the total impacts are below the threshold, so countries may wish to consider a threshold that also incorporates a per capita or stakeholder threshold.
6. Regulations should only be exempt from completing the RIA process in genuinely unforeseen emergencies, when a significant delay could objectively put the wellbeing of citizens at risk. Oversight bodies should be very critical of ministries that overuse such exemptions. Ministries should also be required to conduct an *ex post* evaluation to establish whether the regulation was effective after a defined period of time.
7. Regulations with limited policy options or flexibility (e.g. transposition of EU directives or supranational laws) might have a less rigorous process. When fewer policy options or instruments are available, even if the impacts may be quite significant, policy makers have less flexibility to improve a policy at this stage. Despite this, governments should be mindful that EU directives or other supranational instruments might still have a degree of flexibility in their implementation.
8. The time and resources for regulation development and analysis should also scale with the capacities of the government. It is important that governments continuously build the expertise of policy makers in RIA and stakeholder engagement to make analysis more effective. Governments must build capacities in ministries before they can require significant levels of analysis.

Source: OECD (2020[8]), A closer look at the proportionality and threshold tests for RIA. Annex to the OECD Best Practice Principles on Regulatory Impact Assessment, http://www.oecd.org/regreform/Proportionality-and-threshhold-tests-RIA.pdf.

Threshold tests are not as common in EU Member States as they are amongst OECD member countries. One-quarter of EU Member States use thresholds to determine the scope and depth of analysis and decide whether more in-depth RIA should be undertaken (Figure 3.7), compared to approximatively half of OECD members. The EU Member States using a two-tiered approach are **Austria**, **Croatia**, **Denmark**, **Estonia**, **Latvia**, **Lithuania**, and **Spain** (Figure 3.7). It is worth noting that **Latvia** and **Croatia** have threshold tests in place even though there are no formal requirements for RIAs to be proportionate to the expected impacts.

## Figure 3.7. Two-tiered approaches and threshold tests are not common amongst EU Member States




Note: Data is based on 27 EU Member States and the European Union.
Source: Indicators of Regulatory Policy and Governance (iREG) Survey 2021.

There is strong heterogeneity in the methods used to identify regulatory proposals that necessitate more in-depth analysis. As explored in Table 3.1, EU Member States appear to use multi-criteria analysis (as defined above) as a common method to ensure proportionality in RIA practices. By definition, a wide range of factors can be included as part of multi-criteria analysis and this is the case amongst EU Member States, where heterogeneity is so strong that it is difficult to identify a common pattern and to classify countries within specific categories. It is worth noting that the impacts on businesses is a factor considered in the threshold of most of the EU Member States with a two-tiered approach to proportionality. Some countries, such as **Croatia** and **Denmark** use regulatory impacts on particular groups as a guide to define how proportionality should be applied. For example in **Denmark**, in-depth RIAs are triggered when regulatory proposals result in a certain level of costs on businesses. In **Croatia**, it is the impact on citizens and on the population that defines the depth of the analysis. In contrast, other EU Member States such as **Austria**, **Lithuania**, and **Spain** consider a wider range of factors that are more representative of the economy and society as a whole to determine the scope of analysis. In addition, threshold tests can be adapted as RIA practices in countries evolve. This is for example the case in **Estonia** where formal threshold tests and in-depth RIAs have been replaced by more comprehensive analysis that includes core regulatory elements. Further examples of multi-criteria analytical practices across EU Member States are explored in Box 3.6.

Two-tiered approaches are sound methods to implement the proportionality principle, but some important points must be considered when developing and utilising threshold tests:

- First, as noted in the *Annex to the OECD Best Practice Principles on RIA* (2020[8]), thresholds for RIA should be inclusive and based on the size of impacts across society rather than focusing on specific sector or stakeholder group. Policy makers should also consider what happens when regulatory proposals have a large impact on factors that are not considered in the definition of a threshold test. This is particularly relevant for those EU Member States and OECD member countries where the proportionality principle is applied on the basis of a narrow set of criteria. For example, in countries where the threshold test is driven by the impacts on businesses, policy makers must ensure that legislative proposals that have a minor impact on businesses but a major impact on other factors, say the environment, are also appropriately and proportionately assessed. Applying the proportionality principle means that the depth of analysis should be proportionate and appropriate to the significance of *all* impacts, not only those reviewed in the threshold test. Policy makers in countries with narrower proportionality methodologies and with a focus on the impacts on businesses must ensure that they do not neglect proposals that have a major impact on factors that are excluded from the threshold test.
- Second, threshold tests should not be viewed as an opportunity to bypass RIA requirements. They should guide policy makers to apply the most appropriate level of resources given a proposal's significance, but should not motivate shaping the regulation in such a way that avoids stricter RIA requirements. There is a potential role for regulatory oversight bodies to ensure that threshold tests, and the proportionality principle in general, are appropriately and correctly applied, as will be explored at the end of this section.

### Box 3.6. Multi-level criteria approaches to proportionality and differences between "lite RIAs" and "full RIAs" from selected EU Member States

**Austria**

For all new laws and regulations, an impact assessment is mandatory. The regulation underpinning this instrument provides an explicit list of impact dimensions that have to be assessed. Nevertheless, only impacts above a certain threshold have to be assessed in further detail. Thresholds are mostly quantitative and vary depending on:

1. Financial impacts and impacts on access to finance (if financial impact is expected to exceed EUR 2.5 million or affects more than 10 000 enterprises);
2. Impact on the environment (if $CO_2$ emissions exceed 10 000 tons per year);
3. Impacts on the labour market;
4. Impact on the business (if more than 500 enterprises are affected); or
5. Impact on federal annual budget.

The RIA accompanying the regulatory proposal that fall below all the thresholds have much lighter requirements. Policy makers only have to provide a short (1-2 pages) description about the intent of the new or amended regulation, instead of a full-scale assessment. In addition, such RIAs do not include outcome indicators to measure progress and do not require mandatory *ex post* evaluation five years after their implementation.

The threshold test in Austria was reformed in 2015 to reflect the fact that a large number of minor amendments to laws and regulations that have no significant impact are introduced every year, such as for example renaming a regulatory agency. Such legislation have no significant impact that can be assessed *ex ante* or evaluated *ex post*. As a consequence, only approximately 35% of new laws are

accompanied by a full scale RIA and resources can be directed to proposals where in-depth impact assessments are needed.

**Croatia**

In order for an impact assessment in Croatia to progress from a simplified RIA (Preliminary Assessment) to a full RIA (RIA report), the Preliminary Assessment must fall within at least three combinations that determine the combination of likely direct impacts and effects on the population:

1. Large expected direct impacts and large effects on population;
2. Small expected direct impacts and large effects on population; or
3. Large expected direct impacts and small effect on population.

**Denmark**

Denmark uses threshold tests to determine whether a full or simplified RIA should be undertaken. Danish RIAs combine different elements: One part focusing on other compliance costs for businesses and another part focusing on administrative burdens. Each part has individual threshold tests based on the level of both anticipated one-off costs and regulatory costs, which determines whether a more in-depth assessment is required.

1. For administrative burdens, an in-depth measurement (including interviews with affected companies) must be undertaken if a regulatory proposal is expected to have administrative consequences for businesses over DKK 4 million annually.
2. An in-depth assessment of business economic impacts is triggered if the regulatory compliance costs are expected to be above DKK 10 million.

The concept of proportionality in Denmark is explored in more detail below.

**Estonia**

Formally, thresholds to differentiate between “simplified” and in-depth RIAs exist in Estonia and are based on the following criteria:

1. The scale of the impact;
2. The frequency of the occurrence of the impact;
3. The size of the affected target group; and
4. The risk of accompanying undesirable impacts.

In reality, however, “simplified” RIAs have become increasingly exhaustive and include more of the elements that should be assessed in in-depth analysis. As a result, the practices in Estonia have evolved as the simplified RIAs include more evidence than originally required, thereby making in-depth RIAs increasingly irrelevant and rarely done. The concept of proportionality in Estonia is explored in more detail below.

**Latvia**

Latvian policy makers are allowed to bypass a section of the RIA that includes an assessment of the administrative costs in the RIA if the annual costs are expected to be under EUR 200 for citizens and EUR 2,000 for businesses.

**Lithuania**

In 2020, The Office of Government in Lithuania introduced several criteria for the selection of draft legislation of a higher impact. These include:

1. Impact on public finances higher than EUR 1 million per year or a change to the tax system;
2. Impact on innovation;
3. Impact on competition;
4. Impact on business, defined as additional regulatory or administrative burdens above EUR 1 million and/or impacts on SMEs;
5. Impact on regional development;
6. Impact on employment;
7. Impact on the structure of the state institutions or on the number of public sector employees.

**Spain**

Simplified RIAs can be carried out in Spain if the regulatory proposal does not or insignificantly impacts:

1. The economy (including business, competition, competitiveness);
2. Budget;
3. Administrative burdens;
4. Gender;
5. Family and childhood;
6. Environment.

A simplified RIA is also possible for primary laws that are adopted by the executive in case of extraordinary and urgent public need, as allowed by the Spanish Constitution. The minimum content of a simplified RIA should at least include the following sections:

- Policy issues, objective, and alternatives;
- Explanation of content;
- Legal basis;
- Assessment of the regulatory impacts on the budget and on gender;
- Description of the procedure carried out (including consultations, reports, etc.).

Source: Indicators of Regulatory Policy and Governance Survey, 2021 and OECD (2020[8]), A closer look at the proportionality and threshold tests for RIA. Annex to the OECD Best Practice Principles on Regulatory Impact Assessment, http://www.oecd.org/regreform/Proportionality-and-threshhold-tests-RIA.pdf.

### *Proportionality in the depth of the RIA analysis*

A number of EU Member States rely on the principle of proportionality in their analysis, without the use of methods such as threshold tests to apply it, as demonstrated in Table 3.1. In such cases, the scope of the analysis is at the discretion of the policy makers in individual ministries, who have the choice of deciding how much effort and resources should be allocated to analysing the various regulatory impacts. Public officials may, in some cases, be required to assess a specific range of regulatory impacts but the depth and comprehensiveness of this assessment is their choice. This is, for example, the case in **Germany** where RIAs are required for all legislative proposals and there is no formal threshold to determine the depth of RIA. Whilst policy makers are required to assess how the proposal affects a range of factors such as competition, SMEs, and the environment amongst others for all primary and subordinate regulations, ministerial officials can choose the scope and depth of analysis. The example of Germany is explored in the next section, whilst the application of the proportionality principle at policy makers' discretion in the **Czech Republic** is highlighted in Box 3.7.

### Box 3.7. How the general principle of proportionate analysis is applied at policy makers' discretion in the Czech Republic

Regulatory impact assessment in **Czech Republic** is based on the principle of proportional analysis, which is related to the different depth and scope of the impact analysis and the whole assessment process – the scope of data collection needed for impact assessment, the scope of consultation of stakeholders and number of options assessed. The analysis evaluates and quantifies the potential impacts of the proposed regulation/solution. It is in the hands of the ministry proposing the regulations to carry out the proportionality analysis and determine the level/depth of the impact assessment. When determining the level of analysis, it is always necessary to take into account the significance and extent of the problem to be solved and its expected impacts.

Source: Indicators of Regulatory Policy and Governance (iREG) Survey 2021.

The fact that the depth of analysis varies across EU Member States also signifies that the format of final RIAs can vary significantly. RIAs as "final products" can range from a checklist in which policy makers tick whether the regulatory proposal results in certain impacts to more in-depth reports where individual effects are comprehensively identified, reviewed, and quantified. Amongst EU Member States that use threshold tests, informal evidence suggests that in-depth RIAs in some countries will, in fact, be considered as simplified RIA in others. Whilst a majority of EU Member States are systematically required to assess how the regulatory proposal affects a range of impacts, it is unclear how Member States decide on the depth of analysis and how the level of assessment for each type of factor varies with the significance of the regulatory proposal. Evidence from a series of interviews with **Cyprus**, **Denmark**, **Estonia**, and **Germany**, carried out by the OECD as part of this project and summarised in the following sections, suggest that the depth of analysis is at the discretion of policy makers and ministerial officials in charge of RIA, with little involvement from regulatory oversight bodies.

Regulatory oversight bodies (ROBs) could be involved in reviewing whether the proportionality principle has been correctly applied in the RIAs scrutinised and whether the depth of the analysis is proportionate to the anticipated impacts. As the *Annex to the RIA Best Practice Principles* (OECD, 2020[8]) suggests, as part of ensuring an appropriate allocation of resources, proportionality rules are often considered as a way to align with the capacity of the ROB to scrutinise the quality of RIA. ROBs are thus also impacted by the proportionality principle and reviewing its correct application could be added to their mandates. RegWatchEurope, a network of European regulatory oversight bodies, argues that independent scrutiny can help ensure that ministerial officials apply the proportionality principle appropriately (RegWatchEurope, 2020[11]). It is crucial for the success of RIA to ensure that policy makers do not abuse threshold tests or take advantage of the discretion offered by the proportionality principle and that it remains an appropriate and efficient evidence-based process. Similarly to the role of some ROBs in reviewing the correct use of RIA exception mechanisms, this is particularly relevant for those EU Member States that use threshold tests to implement the proportionality principle, as policy makers may be incentivised to underestimate the impacts of a proposed regulation so that they fall below the threshold in order to avoid triggering RIA requirements (OECD, 2021[4]).

There are no comprehensive data on the number EU Member States with ROBs involved in ensuring that the depth of the analysis is sufficient and proportionate to a given proposal's expected impacts (or the exact role of those ROBs). As discussed in Chapter 1, there are 21 and 22 EU Member States with a ROB responsible for reviewing the quality of RIAs for primary laws and for subordinate regulations, respectively. In addition, ROBs in 13 EU Member States are able to return RIAs for a primary law for revision where it is deemed inadequate, versus 10 for subordinate regulation. RIAs can generally be returned on the grounds of lack of effective consultation, incorrect assessment of compliance or administrative costs, or inadequate justification for the regulatory intervention. Anecdotal evidence, including from the survey

questions on regulatory oversight bodies included in the indicators of Regulatory Policy and Governance (iREG) survey 2017, suggests that discussions on proportionate analysis can sometimes occur informally in meetings between ROBs and the policy officials in charge of the regulatory proposals.

### *Proportionality in Germany*

Germany's RIA system scores highly amongst the EU Member States, as seen in Figure 3.1 and Figure 3.2. RIAs in Germany are required and undertaken for all primary laws and subordinate regulations prepared by the Federal Government. There are no exceptions as all legislative initiatives (of Government) include a proportionate impact assessment and analysis of the resulting compliance costs, even in cases of emergency, and the vast majority of adopted laws are initiated by the Federal Government. Proportionality in the legislative process is grounded within the Basic Law for the Federal Republic of Germany,[1] which provides that regulatory instruments are considered lawful only if they pursue a legitimate purpose and if they are necessary, suitable, and appropriate. The principle of proportionality in Germany is understood in both a broader sense – i.e. to ensure that a law or regulation is necessary, suitable and pursues a legitimate purpose – as well as in a narrower sense, to ensure that the measure is appropriate. The principle of proportionality is thus rooted in the Basic Law and applies to all activities of official bodies and particularly to the legislative powers, to the judiciary, as well as to the public administration including policy makers in charge of RIA. The initiatives introduced by the Parliament (*Bundestag*) and by the legislative body representing the Federal States (*Bundesrat*) must also abide to the principle of proportionality.

There are no formal threshold tests in Germany to determine the depth of RIAs, as policy makers have the discretion to choose the scope of the assessment and the depth at which the various regulatory impacts should be analysed. There is however an informal rule whereby regulatory proposals for which annual compliance costs are expected to be below EUR 100 000 are considered as resulting in minor changes. Therefore, these proposals do not require a detailed quantitative assessment of compliance costs and of other regulatory impacts, such as costs and benefits on citizens. The decision to bypass the quantitative assessment must be based on an estimation of the regulatory compliance costs and must be approved by the *Normenkontrollrat* (NKR) (National Regulatory Control Council).

German policy makers tend to focus their analysis on regulatory costs rather than benefits. They are required to include assessments of a wide range of impacts (competition, SME, environmental, poverty, gender equality etc.) for all primary and subordinate regulations. Policy makers in the ministries decide on the depth of the analysis. In addition, regulators in the Federal Government are required to quantify costs (i.e. compliance costs, which includes administrative costs) for all primary and subordinate regulations – including quantifying costs on individuals, citizens, businesses and the government. These requirements were introduced in the 1990s and their implementation has been improved since. Identifying or assessing benefits is not required in Germany. The State Secretary Committee recommended in 2019 to present the benefits of planned regulations, depending on the political significance of the regulatory proposal.

The NKR is an independent arm's length body that has the legal mandate to review the quality of RIA, including the appropriate assessment of impacts. Where the NKR deems a RIA inadequate, it works with the competent ministry to find a solution to improve it. Where no positive outcomes are reached, the NKR expresses its methodological concerns in an official statement that is presented to the Council of Ministers (i.e. *Bundesregierung*) and published with the RIA. The lead ministry must also prepare a responding statement that must be adopted by the Council of Ministers and subsequently published.

Stakeholder engagement in Germany is formally required for all primary laws and subordinate regulations initiated by the Federal Government as, according to the Joint Rules of Procedures of the Federal Ministries (GGO), federal ministries must consult with state governments, associations, and experts in the specific field affected by the regulation at hand. Consultations are however not required to be open to the general public. Stakeholder engagement appears to be more systematically undertaken when the text of the

regulation has been drafted or proposed. Stakeholder engagement is reportedly subject to the principle of proportionality and, like RIA, federal ministries are formally at liberty to decide what entails proportionate consultation for a regulatory proposal. It is also at their discretion to decide whether public consultations will be carried out, in what format, and for how long.

The consultation period during the development of Government initiatives depends on the draft law being consulted. The decision regarding the required consultation period has to be in line with the proportionality principle of the German Basic Law, and as such, ministries are required to give sufficient time for consultation without defining one period of time for all cases and situations. There is however no formal requirement for a minimum period for consultations with the public, including citizens, business and civil society organisations. The GGO and additional decisions of the Federal Government however recommend four weeks as a standard period. The Better Regulation Unit, a regulatory oversight body located in the Federal Chancellery, has the capacity to review whether stakeholder comments have been considered. In addition, if the format or the depth of consultation and stakeholder engagement is found to be inadequate, the regulatory proposal may be rejected by the *Bundestag*.

The principle of proportionality also applies to the *ex post* evaluation requirements in Germany, which are determined in part by threshold tests as all regulations where annual compliance costs are more than EUR 1 million per annum for citizens, businesses or the administration must be evaluated three to five years after their implementation. Compliance costs are not however the only element in determining whether a regulation must be evaluated, as factors such as political relevance and the level of political risk are also deciding factors. Policy makers have the prerogative to decide which initiatives are considered as politically relevant, although this may also be decided by the Federal Chancellery.

All *ex post* evaluations are required to contain an assessment and quantification of costs, but only an assessment of benefits. *Ex post* evaluations regarding major primary and subordinate laws are also required to include a comparison of the actual versus predicted impacts of the regulation being reviewed. In November 2019, the German government introduced additional requirements for independent quality control of *ex post* evaluations which the NKR is performing.

### *Proportionality in Denmark*

Regulatory impact assessment and use of regulatory management tools overall tend to anchor around business impacts in Denmark. RIAs are required and undertaken in practice for all primary laws. Denmark has introduced exceptions to conducting RIAs if a regulation is introduced in response to an emergency and if there is insufficient data to undertake the analysis, but there are otherwise no exceptions to the RIA requirements. In such cases where it is decided that a RIA will not be conducted, this decision is neither reviewed by a regulatory oversight body nor is it made publicly available.

RIAs practices in Denmark are required to be proportionate to the significance of the regulation, (i.e. the expected impact). In line with the findings from the *Annex to the Best Practice Principles on RIA* (OECD, 2020[8]), proportionality, and particularly thresholds, are seen as a way to allocate resources of the oversight body appropriately, to ensure that it scrutinises relevant proposals and to identify which proposals should be subject to a full RIA. It also helps assess whether the implementation and enforcement strategy is proportionate to the perceived risks of regulation.

Threshold tests are used in Denmark to determine whether a full or simplified RIA should be undertaken. The format of RIA and the depth of the analysis is guided by the impacts, and particularly the costs, on businesses. Danish RIAs combine different elements, with one part focusing on other compliance costs for businesses and another part focusing on administrative burdens. Each part has an individual threshold test based on the level of both anticipated one-off costs and recurring costs, which determines whether a more in-depth assessment is required.

- For the administrative burden assessment, an in-depth measurement (including interviews with affected companies) must be undertaken if a regulatory proposal is expected to have administrative consequences for businesses over DKK 4 million annually; and
- An in-depth assessment of business economic impacts is triggered if the regulatory compliance costs are expected to be above DKK 10 million.

The two thresholds are assessed independently. As a result, in-depth assessment on the administrative burdens can be triggered independently of the other compliance costs resulting from the legislative proposal. If a legislative proposal is found to impact only one of the two threshold tests, then this individual section of the RIA will be longer and more in-depth than the other sections. In a full RIA, the consequences for businesses are more thoroughly assessed on the basis of interviews and of cost-benefit analysis, as per the standard cost-model.

Danish policy makers are required to include assessment of a range of impacts (competition, SME, public sector, environmental, poverty, gender equality, regional, UN Sustainable Development Goals, etc.) for all primary laws. In addition, policy makers are required to quantify costs (including administrative burdens and compliance costs) for all regulatory proposals, with particular emphasis on the impacts on businesses. The assessment of regulatory benefits is subject to the same requirements as the assessment of costs and are thus also required to be identified and quantified. The relevant ministry decides on the depth of analysis based on co-operation and dialogue with other relevant ministries and extensive co-operation between the various ministries takes place informally. The depth of analysis of the impacts on businesses is however decided or at least approved by the regulatory oversight body.

Regulatory oversight in Denmark is organised around the impacts on businesses and particularly around regulatory costs. The Danish Business Authority's Better Regulation Unit (BRU) is involved in reviewing the quality of business RIAs for regulations that have an impact on the business community. The Danish Business Regulation Forum (DBRF) is reported to also ensure that regulations are proportionate, in the sense that they do not go beyond what is strictly necessary to resolve the policy issue identified. The business-focus on the DBRF but also of the Better Regulation agenda in Denmark in general is the result of the organisation of membership within the Forum, which does include a majority of business representatives. It is crucial to note that the DBRF however does include members from consumer organisations, from labour organisations, and from non-business groups and that consensus amongst the various members is key to the functioning of the DBRF. The DBRF will not make recommendations on improving the Danish business environment that come at the expense of consumers or workers.

Stakeholder engagement in Denmark is required and must be open to the public for all primary laws. Stakeholder engagement is done systematically when the text of the regulation has been drafted or proposed as part of the public consultation, while formal and informal consultations are held before a preferred policy option has been identified, although there is no requirement to do so. There are no formal requirements for a minimum public consultation period, as the online consultation period must be adapted to the specific circumstances surrounding the legislative proposal. It should however be long enough to enable stakeholders to adequately prepare, so a consultation period of four weeks is recommended under normal circumstances. Other than a requirement for public consultation to be systematically held over the internet, policy makers have discretion to engage with stakeholders how they see fit. There is currently little information on how bilateral engagement with stakeholders, either formally or informally, is undertaken and on what basis policy makers decide to engage and with whom.

*Ex post* evaluation is required for some laws and there are no thresholds or factors used to identify regulations that will be evaluated. It is at the discretion of the party undertaking the evaluation – either the ministry itself or the DBRF – to decide which regulation will be evaluated. Ministerial officials' decision to undertake an *ex post* evaluation is reportedly based on the political importance of the legislation, but they have the liberty to decide what regulation ought to be evaluated as well as the depth of the evaluation analysis. The DBRF is also completely independent to undertake evaluations on any issue they wish to

review, to evaluate regulations as well as their implementation and interpretation. Their decision is reportedly influenced from a bottom-up approach, as the DBRF identifies regulations (or implementation thereof) to evaluate based on feedback from businesses on what they experience as burdensome. In addition, if the Better Regulation Unit, which is responsible for some of the core regulatory oversight functions, considers that an *ex ante* RIA is not adequate, it has the mandate to call for an *ex post* assessment to be undertaken by ministries.

### *Proportionality in Estonia*

RIAs in Estonia are required for all legislative proposals and in practice are carried out for all primary laws but only for some subordinate regulations. RIAs are used early in the policy development process as Estonian policy makers are required to publish documents of legislative intent (i.e. roadmaps) that set out the policy problems, the regulatory objectives, and that highlight a range of suitable policy alternatives. The document of legislative intent is used to guide stakeholder engagement and to gather feedback to guide the development of the legislative proposal. In addition, there are no exceptions to conducting RIA as an impact assessment of the final policy must always be included in the explanatory memorandum that accompanies the legislative text.

RIA practices are required to be proportionate to the significance of the proposed regulation both for primary laws and subordinate regulations and, formally, threshold tests have been in place since 2014 to apply this requirement. The significance of the regulation is officially identified through a qualitative assessment of the impact on target groups using four criteria:

1. The scale of the impact;
2. The frequency of the occurrence of the impact;
3. The size of the affected target group; and
4. The risk of accompanying undesirable impacts.

If the legislative proposal is found to have a significant impact on any of the four criteria, policy makers are required to undertake a more thorough assessment and must collect more information about the expected impacts. In-depth RIAs must also include further information on the regulatory objectives, the assessment methodology, the costs and benefits from a regulatory proposal, how the policy option achieves the regulatory objectives, and set out obligations regarding monitoring and *ex post* evaluation.

In practice, however, simplified RIAs have become increasingly exhaustive and include more of the elements that should be assessed when the threshold test triggers more in-depth analysis. RIA practices in Estonia have evolved since their inception and have adapted to the realities of the legislative system, to such an extent that the procedural norms are no longer aligned with the requirements and that the threshold system has not been as effective and useful as initially expected. Simplified RIAs now include more evidence than originally required and have come to replace in-depth RIAs, which have become largely irrelevant and rarely done. In the past, the decision not to conduct in-depth RIA would always be published and reviewed by the regulatory oversight body, however in practice this is no longer the case as in-depth RIAs have become redundant and since simplified RIAs are conducted without exception. Currently, the four criteria that supposedly trigger in-depth RIAs are instead used as a guide to policy makers' analytical reasoning and are considered as evidence that should be covered in the RIA.

The analysis of regulatory impacts is ensured through a checklist that must be completed and, in practice, a qualitative assessment is included in all RIAs. The depth of the analysis is, however, at the discretion of the ministerial officials in charge of developing the RIA. Estonian policy makers are required to assess regulatory impacts on a wide range of factors such as competition, poverty, environment, etc. for all primary laws and subordinate regulations. Regulatory costs of the preferred policy option, particularly costs for the government, are supposed to be identified and quantified for all legislative proposals. The benefits must be identified for all legislative proposals but only quantified in some cases. The depth of the analysis

depends on each individual ministry and its analytical capacities. Informal evidence suggests that, in the majority of cases, the numbers of parties impacted by the regulation is calculated but the extent of the impacts is less systematically measured as it depends on availability of evidence. For example, ministries in charge of financial, economic, and social affairs are able to analyse regulatory impacts in more depth thanks to the availability of suitable data. Ministries in charge of other policy areas, such as health or environment, reportedly do not have access to as much data and therefore undertake a more qualitative assessment.

Guidance material listing the different regulatory impacts that policy makers should explore is available. The regulatory oversight body in Estonia, the Legislative Quality Division located in the Ministry of Justice, scrutinises the explanatory memorandum accompanying the legislative text to ensure that the relevant regulatory impacts and affected parties have been correctly identified, although it is not able to comment on whether the depth of the analysis is sufficient. If the Legislative Quality Division determines that the RIA inadequately assesses regulatory impacts, it will return the RIA and work with policy makers to improve the analysis.

Stakeholder engagement in Estonia must be undertaken and open to the public for all primary laws and for major subordinate regulations once the legislative text has been drafted. Whilst all legislative proposal must be openly consulted with the public (including citizens, business and civil society organisations) for a minimum of four weeks, there are no rules regarding bilateral discussion between stakeholders and policy makers. Ministerial officials thus have discretion to choose if and whom they engage with and with whom the draft legislation will be shared. Policy makers can be subject to criticism for carrying out inappropriate stakeholder engagement but there are no formal consequences. For example, the Legislative Quality Division can voice its opinion in instances of inappropriate stakeholder engagement, but has no formal power to return the legislative proposal if this is the case.

*Ex post* evaluation of existing regulations in Estonia is mandatory for some primary laws and subordinate regulations. There exists a threshold test to determine whether *ex post* evaluations should be undertaken, but only for primary laws. The requirement for undertaking *ex post* evaluation was originally dependent on the threshold test for in-depth RIA, whereby legislative proposals that triggered an in-depth assessment would also trigger *ex post* evaluation. In practice however, the threshold test has also become redundant for *ex post* evaluation and the four criteria test described above are not used to identify legislation whose efficiency and effectiveness must be evaluated. Estonia is instead currently developing a new *ex post* evaluation strategy whereby legislative proposals introduced in response to an emergency must always be evaluated. Currently, it is at the discretion of the ministerial officials to decide whether an *ex post* evaluation should be carried out, although the Legislative Quality Division plays an important role in ensuring appropriate *ex post* evaluation as they can make suggestions regarding which laws and regulations should be reviewed. If the line ministry is of the view that *ex post* evaluation is unnecessary, then the reasons for it have to be shown in the explanatory letter of the draft law.

### *Proportionality in Cyprus*

A new RIA framework was established in Cyprus in 2015. RIAs are required for all primary laws but only for some subordinate regulations, as impact assessments must accompany all draft bills submitted to the House of Representatives, although there are some exceptions to conducting RIA. Indeed, a draft law can proceed to the House of Representatives without a RIA if, amongst others:

- If it is being introduced in response to an emergency;
- If it is considered to have insignificant impacts, that is, it does not introduce substantial additional or new provisions;
- When the bill is implementing an international treaty or legislation of an inter- or supranational organisation (e.g. EU);

- For legislations related to the budget, to the management of public finance, to procedural content, or to defence policy;
- Other provisions for exceptions as outlined in the *Impact Analysis Guidelines and Questionnaire* (Government of Cyprus, 2016[9]).

The Law Office of the Republic of Cyprus and the House of Representatives are aware which draft legislation may proceed without a RIA. If it is however decided that a RIA will not be conducted, this decision is not made publicly available and this decision is not reviewed.

Impact assessments in Cyprus are required to be proportionate to the significance of the proposed regulation for primary laws. According to the Government of Cyprus, the analytical efforts should be proportionate to the issues addressed by the relevant legislation as well as the efforts required to undertake an impact assessment (i.e. the collection and analysis of the relevant data and information). Some factors that policy makers should consider in determining the scope of analysis include:

- The level of interest and sensitivity surrounding the legislative proposal;
- The policy development stage and whether the policy is innovative, controversial or irreversible
- The scale and duration of the expected impacts;
- The availability of data; and
- Available resources, time and capacity for further analysis.

There are no threshold tests in Cyprus as it is at the discretion of policy makers to decide the depth of the analysis, however they are bound by the framework established in the *Impact Analysis Guidelines and Questionnaire* (Government of Cyprus, 2016[9]). The guidelines establish the following levels of RIA analysis:

- Level 1: Description of the main groups expected to be affected by the proposal (such as businesses, public sector, consumers);
- Level 2: Full qualitative description of the regulatory impacts (e.g. positive or negative), the magnitude of the impacts, and their intensity for each group;
- Level 3: Quantification of regulatory impacts, such as the number of affected parties and estimation of the compliance costs and administrative burdens;
- Level 4: All cost categories and benefits are monetised.

At a minimum, the analytical depth observed in all RIAs should reach level 2, where a qualitative description of all regulatory impacts is provided. Levels 3 and 4 require a quantitative and monetary analysis that might not be feasible for all legislative proposals and policy makers have the discretion to choose whether the regulatory impacts of the legislative proposal warrant such levels of analytical depth. In cases where analysis at levels 3 and 4 does not take place, a more in-depth analysis of levels 1 and 2 should be undertaken.

There is no body outside of the ministry sponsoring the regulation which is responsible for reviewing the quality of the overall RIA and that examines whether the depth of the analysis is proportionate. Whilst the inclusion of an impact assessment as part of the package accompanying legislation for their introduction to the House of Representatives is verified by the Legal Quality Service (Law Office of the Republic of Cyprus), there is no scrutiny on the quality of RIA.

One exception is the involvement of the SME Envoy Cyprus (under the Ministry of Energy, Commerce, and Industry), which is responsible for reviewing the SME Test for regulations that are expected to affect small and medium enterprises. The SME Test and the analytical methodology underpinning it are thoroughly described in the Guidelines (2016[9]), and it details the various analytical stages that policy makers should follow. The SME Envoy reviews whether policy alternatives and mitigation measures have been appropriately identified, whether the analysis of the impacts on SME is adequate, and whether

stakeholders have been appropriately consulted. The SME Envoy is not involved in reviewing any assessment unrelated to SMEs and does not comment on the depth of the analysis of non-SME impacts. In addition, specific environmental impact assessment is carried out for proposals that are likely to significantly affect the environment.

Stakeholder engagement in Cyprus must be undertaken for all primary laws and tends to be more systematically carried out once a legislative draft exists. In addition, stakeholder engagement must be open to the public and a central e-consultation platform is currently being constructed. Stakeholder engagement in Cyprus is sometimes proportionate to the significance of the regulation, as policy makers are reported to undertake additional rounds of consultation for legislative proposals with expected high impacts. Stakeholder engagement is at the discretion of the civil servant in charge of developing the legislative proposal and there is no formal oversight. The House of Representatives does however invite stakeholders to provide their opinion during parliamentary debate, in cases where the House finds that stakeholders were not appropriately consulted in the initial stages of the legislative process.

*Ex post* evaluation of existing regulations is not required in Cyprus and is not undertaken in practice. There is therefore no established framework for *ex post* evaluation in Cyprus.

### *The policy options considered in EU Member States' analysis*

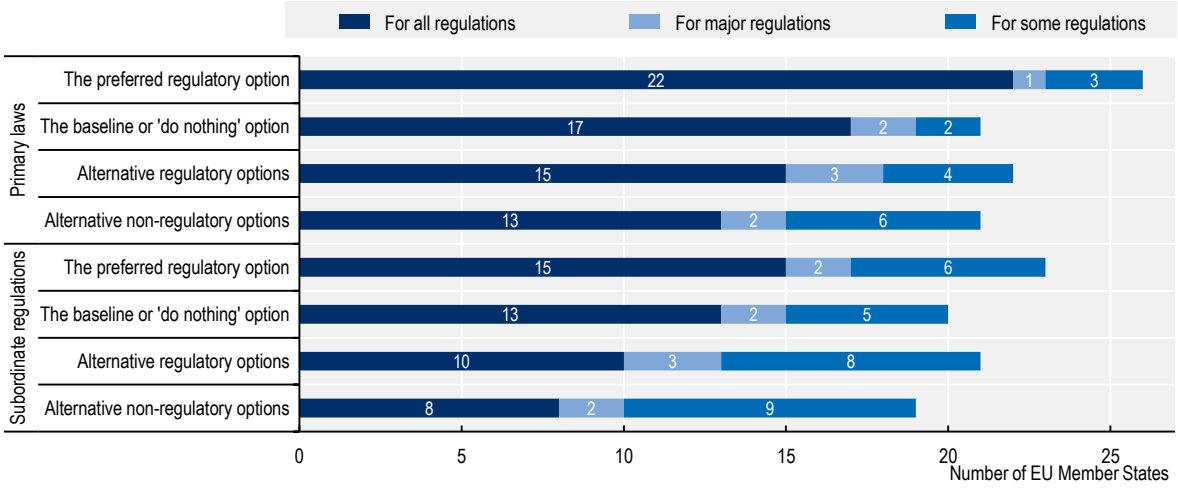
Considering all feasible options when potentially embarking on regulating is crucial to ensure that the broadest possible range of alternatives are genuinely considered by policy makers. This was recognised in the *OECD Recommendation* (2012[1]) and complemented by the *OECD RIA Best Practice Principles* (2020[2]) noting that RIA is more generally an iterative process. This is certainly the case for the consideration of alternative options, as options are gradually ruled out as more information on their potential impacts becomes available; or where stakeholders identify that certain options proposed are not feasible – and also the possibility that stakeholders may raise alternative options not considered by policy makers, as discussed in Chapter 2.

A majority of EU Member States systematically focus on identifying and analysing the preferred regulatory option (Figure 3.8). Identifying and assessing the impacts of the preferred regulatory option for at least some primary laws is almost universally required across the European Union and the results have not changed since 2017. Considering the baseline or 'do nothing' option (i.e. the status quo) also seems relatively well established as around 70% of EU Member States are systematically required to do so (Figure 3.8), although some EU Member States would benefit from systemising this practice more. The European Commission requires its policy makers to identify and assess the impacts of the preferred policy option as well as the impacts of the baseline or 'do nothing' option for major primary laws or subordinate regulations. In practice however, there is still scope for improvement as the Regulatory Scrutiny Board finds that the set of options analysed in RIA is not always complete. The European Commission's impact assessments tend to focus only on the preferred (political) choice, without including alternate ones supported by the main stakeholder groups (Regulatory Scrutiny Board, 2020[12]).

Alternative policy options,[2] both regulatory and non-regulatory ones, are less systematically assessed in EU Member States than in OECD member countries. Countries would benefit from systematically incorporating the assessment of non-regulatory options in their RIAs to avoid prejudging that regulatory intervention is warranted and to provide stakeholders with more information, in order to improve decision making. In the European Commission, the assessment of more than one alternative regulatory option and of one alternative non-regulatory option is mandatory for major primary laws and subordinate regulations. However, policy makers in approximately two-thirds of EU Member States are required to systematically identify and assess alternative regulatory options for primary laws (Figure 3.8), compared to 80% of OECD members (OECD, 2021[4]). This suggests that decision makers generally benefit from having information about alternative regulatory paths that could be taken to solve the policy problem at hand, albeit RIAs are slightly less likely to contain this information when compared with the preferred regulatory option. In

addition, just over half of EU Member States for primary laws – and less than two-fifths for subordinate regulations – have a requirement that proposals systematically identify and assess the impact of alternative non-regulatory options (Figure 3.8). Around 70% of OECD members for primary laws and just over half for subordinate regulations have similar requirements (OECD, 2021[4]). Results for both EU Member States and OECD member countries have experienced little change since 2017. The specific assessment of regulatory costs and benefits for the identified policy options is explored in the next section.

## Figure 3.8. Most EU Member States identify and assess the impacts of the preferred regulatory option, but fewer do so for non-regulatory options




Note: Data is based on 27 EU Member States.
Source: Indicators of Regulatory Policy and Governance (iREG) Survey 2021.

### *Types of impacts, costs and benefits assessed in EU Member States*

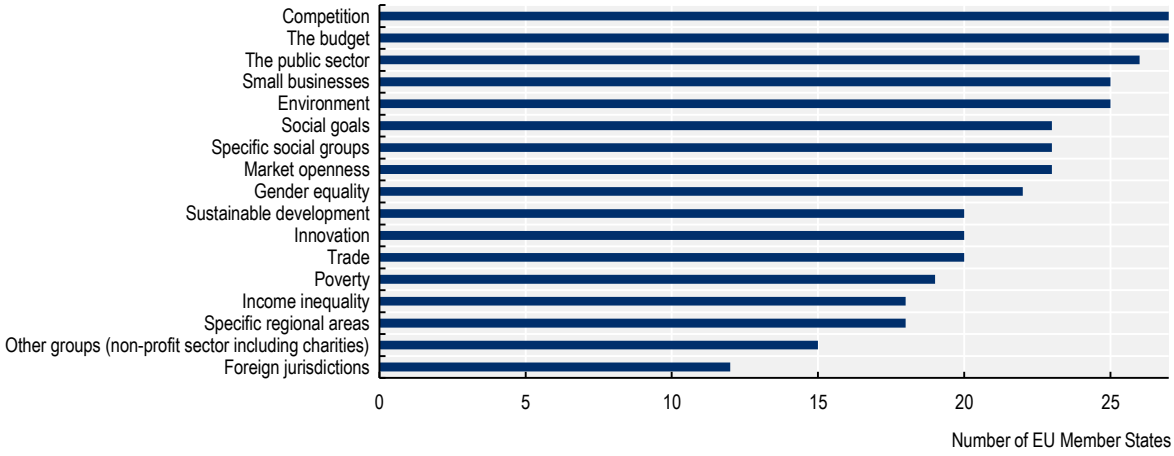
Overall, policy makers appear to focus more on economic impacts and on identifying and measuring regulatory costs than benefits, particularly for subordinate regulations. Only a minority of EU Member States quantify the costs and benefits of more than one policy option, suggesting that this detailed analysis tends to be limited to the option that policy makers prefer to take forward. In turn, this risks converting RIA into an analytical exercise that is used to justify an established policy choice instead of a process that is used to inform decision making.

The *OECD RIA Best Practice Principles* (OECD, 2020[2]) calls for policy makers to identify all relevant direct and important indirect costs as well as benefits. It is necessary for policy makers to go beyond direct economic impacts and assess various other types such as impacts on the environment, social impacts (jobs, public health, gender equality, poverty, inequalities and their reduction, working conditions, etc.), the Sustainable Development Goals, impacts on innovation, cross-border impacts and also second-round effects and unintended consequences, etc (OECD, 2020[2]). Wherever partial impact assessments are conducted separately, they should be integrated into one crosscutting integrated impact assessment. The European Commission requires RIAs to assess a broad range of economic, environmental, and social impacts in line with the proportionality principle. In addition though it also requires policy makers to consider issues relating to compliance and enforcement, distributional impacts, as well as identifying a process by which the objective of a regulatory proposal will be assessed.

Policy makers from EU Member States are generally required to assess the impacts of regulatory proposals on a large range of factors (Figure 3.9). Compared to the previous report (2019[5]), there continues to be a strong focus on analysing the economic impacts of regulatory proposals, with the effects

on competition and the budget being universally required to be assessed in all Member States. The regulatory impacts on the public sector, on small and medium-sized companies and on the environment are also commonly assessed amongst EU Member States. In line with the findings from the *Regulatory Policy Outlook* (2021[4]) for OECD member countries, the requirement to analyse regulatory impacts on foreign jurisdictions however remains the lowest amongst all assessments. If this trend continues, this may have consequences on the quality of RIA and may result in significant impacts (both positive and negative) being omitted from the analysis, as the magnitude of impacts on foreign jurisdictions will be expected to continue to grow in an ever increasingly interconnected world. This is particularly relevant in the context of the EU, where regional integration via different forms of international regulatory co-operation (IRC) is key to support the four liberties – i.e. free flow of people, goods, services and capital – as discussed in Chapter 1.

### Figure 3.9. EU Member States assess regulatory impacts in various areas




Note: Data is based on 27 EU Member States.
Source: Indicators of Regulatory Policy and Governance (iREG) Survey 2021.

Policy makers should assess the anticipated costs and benefits of a regulatory proposal in order to have an accurate picture of the total impacts of all policy options. RIAs are central to policy makers' decision-making, by helping to provide as much objective information as possible on the likely benefits and costs that would emerge if the available regulatory options are implemented. RIAs thus enable a more meaningful comparison of regulatory options and help policy makers identify which one is the most appropriate to resolve the policy issue at hand. It is therefore crucial to identify, direct costs (i.e. administrative, financial and capital costs), indirect costs (e.g. opportunity costs), as well as benefits for the preferred policy option but also for alternative policy options (OECD, 2020[2]).

The benefits of a regulatory proposal are particularly important to identify, as this provides information on whether the policy option will achieve its objectives as well as on who will gain from it and how. Any significant regulatory intervention is bound to result in costs due to the burdens that it introduces. Policy makers must therefore demonstrate that the benefits resulting from the proposal justify the costs and that it will have a positive net impact on society as a whole. In addition, a reduction in costs could be considered and calculated as part of the anticipated benefits from a policy, thus placing the assessment of the expected benefits at the centre of the assessment methodology.

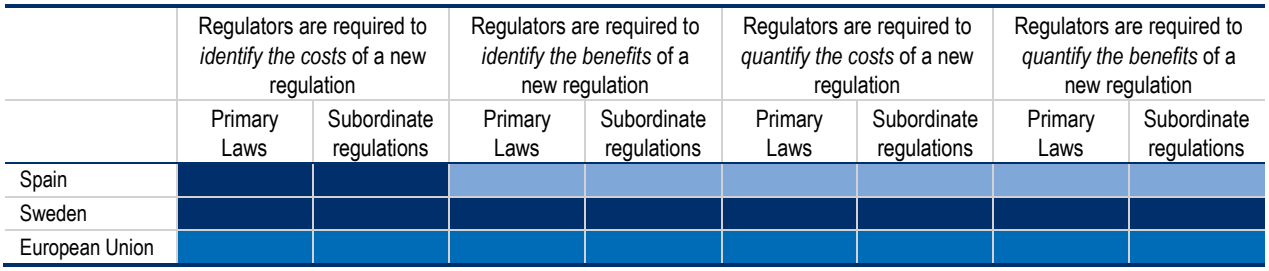
Quantitative estimation of the costs and benefits provide policy makers with crucial information on the extent of the impacts of the proposal, even if fully-fledged cost-benefit analysis is not proportionate or appropriate for all regulatory proposals. The *OECD RIA Best Practice Principles* (2020[2]) suggest that the goal of governments should lie in making quantitative estimation integral to a RIA as it not only helps

identify who may gain or lose from a regulatory proposal, it also provides a point of comparison to discern the costs and benefits arising from various policy options. This contributes to providing policy makers with sufficient evidence to choose which policy option to implement and helps demonstrate whether the benefits of introducing a new regulation justifies its costs.

Qualitative analysis can be informative, particularly when data is not available or reliable. EU Member States are more likely to identify the costs of new regulations over their benefits and put more emphasis on quantifying regulatory costs than benefits (Table 3.2). This trend was already highlighted in the previous edition of this report (2019[5]) and continues to be the case for a number of EU Member States. Almost all EU Member States have a requirement to identify the costs of primary laws, but less than three-quarters of EU Member States have a systematic requirement to identify the benefits. This gap further increases when it comes to quantification: 23 EU Member States require a systematic quantification of regulatory costs for primary laws, compared to 15 for quantification of benefits (Table 3.2). In contrast, policy makers in the European Commission face the same requirements for both regulatory costs and benefits, which must be assessed and quantified for both major primary laws and major subordinate regulations. Despite the importance of assessing benefits, a number of EU Member States continue to focus their analytical efforts on assessing and measuring regulatory costs without understanding the full benefits that may result from a policy proposal.

### Table 3.2. EU Member States are more commonly required to identify and quantify regulatory costs than benefits

| | Regulators are required to *identify the costs* of a new regulation | | Regulators are required to *identify the benefits* of a new regulation | | Regulators are required to *quantify the costs* of a new regulation | | Regulators are required to *quantify the benefits* of a new regulation | |
|---|---|---|---|---|---|---|---|---|
| | Primary Laws | Subordinate regulations | Primary Laws | Subordinate regulations | Primary Laws | Subordinate regulations | Primary Laws | Subordinate regulations |
| Austria | | | | | | | | |
| Belgium | | | | | | | | |
| Bulgaria | | | | | | | | |
| Croatia | | | | | | | | |
| Cyprus | | | | | | | | |
| Czech Republic | | | | | | | | |
| Denmark | | | | | | | | |
| Estonia | | | | | | | | |
| Finland | | | | | | | | |
| France | | | | | | | | |
| Germany | | | | | | | | |
| Greece | | | | | | | | |
| Hungary | | | | | | | | |
| Ireland | | | | | | | | |
| Italy | | | | | | | | |
| Latvia | | | | | | | | |
| Lithuania | | | | | | | | |
| Luxembourg | | | | | | | | |
| Malta | | | | | | | | |
| Netherlands | | | | | | | | |
| Poland | | | | | | | | |
| Portugal | | | | | | | | |
| Romania | | | | | | | | |
| Slovak Republic | | | | | | | | |
| Slovenia | | | | | | | | |



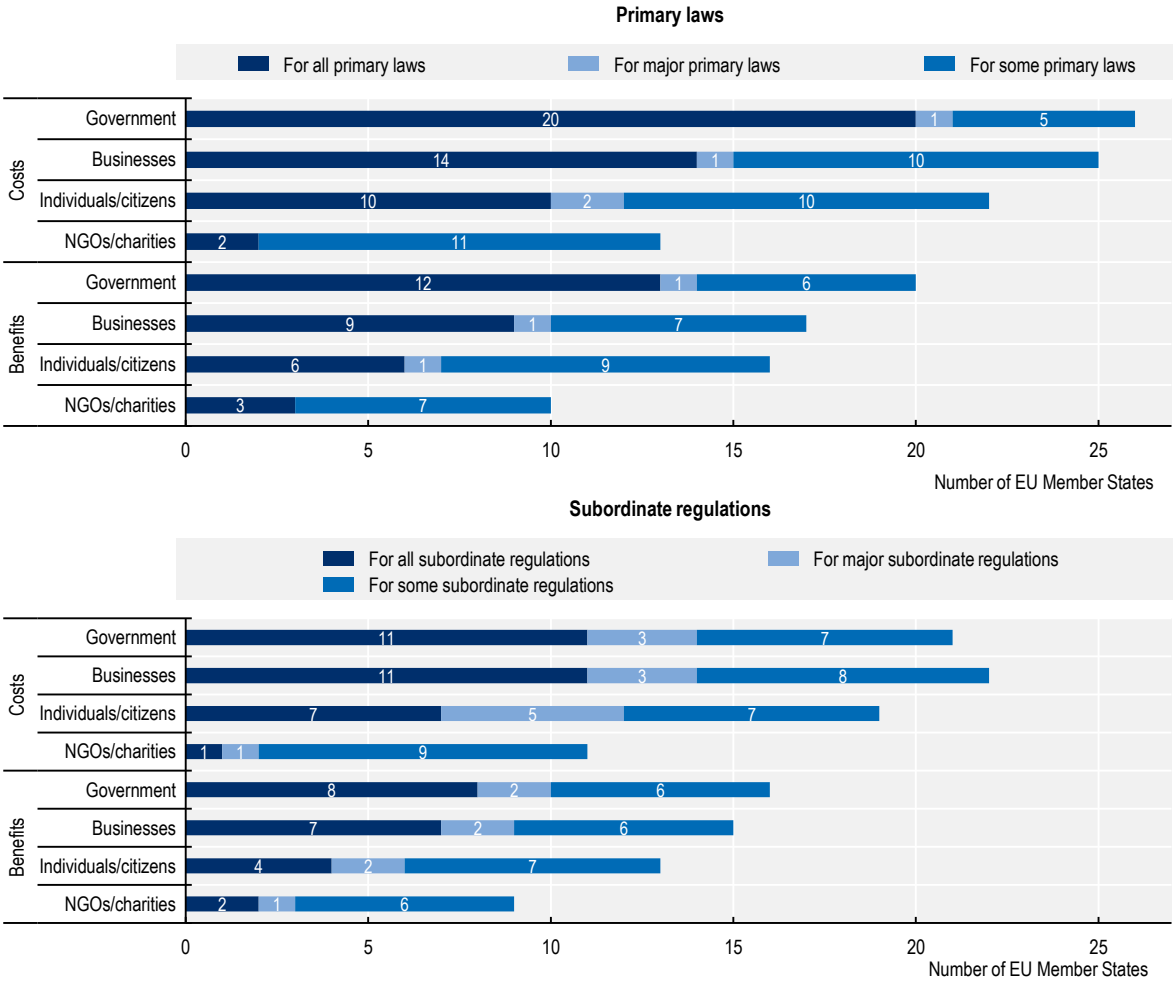

Note: Data is based on 27 EU Member States and the European Union.
Source: Indicators of Regulatory Policy and Governance (iREG) Survey 2021.

The discrepancy between the requirements to assess regulatory costs and those to assess benefits is more prominent for subordinate regulations. Systematic identification of costs for subordinate regulations is required in approximately 85% of EU Member States and systematic identification of benefits in approximately 60% of them (Table 3.2). The same is true for the quantification of impacts for subordinate regulations: it is systematically required to quantify costs of subordinate regulations in 21 EU Member States but in only 10 EU Member States for benefits (Table 3.2). Many EU Member States therefore appear to have less stringent requirements for subordinate regulations than for primary laws, particularly regarding the identification and assessment of benefits for subordinate regulations.

Less than half of EU Member States quantify the costs and the benefits of more than one policy option, suggesting that policy makers are not provided with evidence on the impacts of alternative policy options. Costs and benefits should not be identified for the preferred policy option only, but should also be done for all policy alternatives in order to help policy makers identify the regulatory option that lead to the best societal outcomes. When it comes to the quantification of costs and benefits, 12 EU Member States quantify the costs of more than one policy option for primary laws, while 10 EU Member States quantify the benefits of more than one policy option. This suggests that a vast majority of EU Member States do not collect detailed evidence on the impact that alternative policy options might have. The European Commission quantifies both the costs and benefits of more than one policy option.

EU Member States appear to focus their analytical efforts on estimating the costs and benefits on governments and businesses, with fewer requirements to estimate the impacts on citizens and on NGOs or charities (Figure 3.10). A similar trend is observed amongst OECD member countries. The impact on NGOs and charities seem to be rarely assessed in this type of analysis: If EU Member States have the requirement to quantify costs and benefits of a regulatory proposal on NGOs and charities, it is usually only required for some laws and regulations (Figure 3.10). Additionally, and in line with the above findings, costs are quantified across all interest groups more often than benefits and such estimation and less systematically required for subordinate regulations than for primary laws. In contrast, the European Commission mandates that the costs and benefits for citizens, businesses, public administrations, NGOs/charities and for the European Union be quantified for major legislative proposals. Focusing the analysis exclusively on the impacts of one or two societal actors may point to a weakness of EU Member States' RIA systems. Indeed, this may present a risk that the analysis – and thus the developed regulatory proposal – is biased towards the impacts one of a limited number of parties and may fail to understand how other key members of society are affected and how such impacts could be mitigated if necessary.

## Figure 3.10. Requirements to quantify costs and benefits of new regulations are more common for government and businesses than for individuals and NGOs




Note: Data is based on 27 EU Member States.
Source: Indicators of Regulatory Policy and Governance (iREG) Survey 2021.

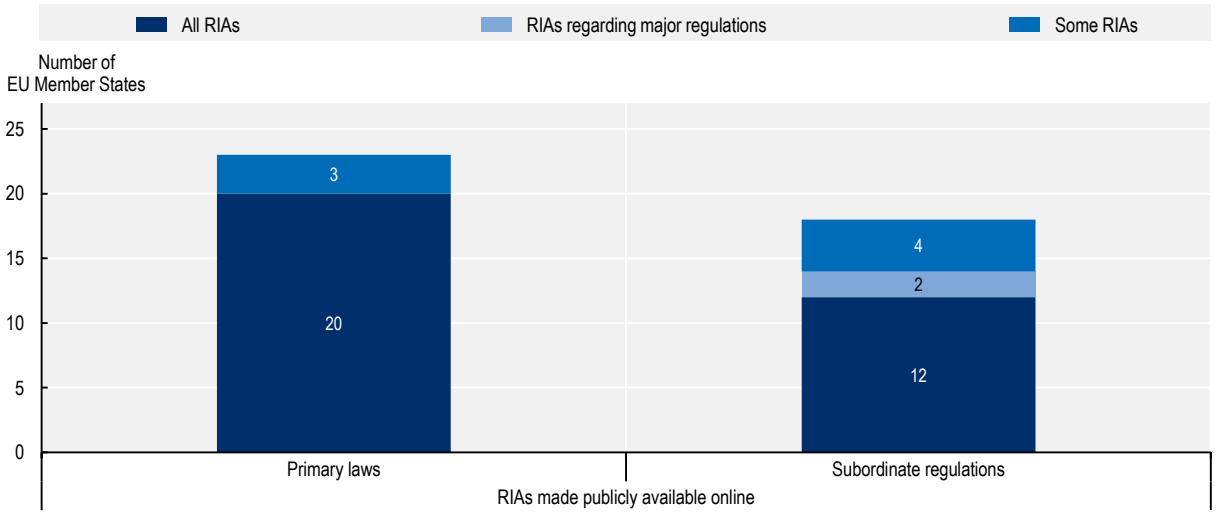
### *Transparency of RIA procedure in EU Member States*

Governments have to ensure transparency of decision making to enable public scrutiny of the RIA process. Transparency is a core feature of the *2012 Recommendation*, with Principle 4.4 stating that "RIA should as far as possible be made publically available along with regulatory proposals" (OECD, 2012, p. 13[1]). Consultation on the draft RIA document is particularly useful since it can focus on the data used, the alternative options selected, the criteria applied for comparing options, and the overall quality of analysis to select a preferred policy option (OECD, 2020[2]). In addition, a transparent decision making process helps ensure that citizens and businesses feel included in the policy making process, accept regulatory decisions and, ultimately, trust their government (OECD, 2018[6]).

RIA practices for EU Member States are more transparent when it comes to laws that are approved by parliament than for those that are approved by the government. The majority of EU Member States make all RIAs regarding primary laws publicly available whilst only half of EU Member States make RIAs regarding subordinate regulations systematically publicly available (Figure 3.11). The majority of EU Member States that make RIAs publicly available publish them on central registries, whilst some also make

RIAs publicly available on ministry websites but this practice is less common. Making RIAs publicly available facilitates access to information for citizens and businesses and improves the transparency of decision-making processes.

### Figure 3.11. The majority of EU Member States publish their RIAs online




Note: Data is based on 27 EU Member States.
Source: Indicators of Regulatory Policy and Governance (iREG) Survey 2021.

The discrepancy in transparency between primary laws and subordinate regulations is unsurprising but can point to a weakness in EU Member States' regulatory systems. Primary laws are, by definition, adopted by Parliaments and thus subject to parliamentary debates. Members of Parliaments request a wide-range of information, prompting policy makers to publish policy documents, including RIAs, to potentially be scrutinised in open parliamentary debate. Policy makers thus have strong incentives to ensure that the RIAs for primary law proposals are transparent and publicly available. In contrast, subordinate regulations are adopted by a range of institutions in the executive and may not be subject to open debate. There may thus be less direct consequences for policy makers if the RIAs are not published and thus less incentives to do so.

The *RIA Best Practice Principles* (OECD, 2020[2]) call for transparency and clear communication of the results of RIA. RIAs should not only be made publicly available, they should also be written in a clear and understandable manner that maintains a reasonable level of simplicity and conciseness. In addition, it is important to ensure that the level of analytical rigour is at least commensurate with the anticipated impacts resulting from the regulatory proposals and that the RIA is not written in a way that obscures important information or that distorts the assessment to support a particular policy (OECD, 2020[2]).

## Requirements and practices regarding RIA for the negotiation of EU directives and regulations and for the transposition of EU directives

EU Member States should be informed about the *domestic* impacts of a proposed EU regulation or directive when they engage in the negotiation stage. Many countries are however under no obligation to conduct a domestic RIA to define a negotiating position, although it is worth noting that some undertake such analysis in practice even if they are not required to do so. The short timing between the publication of the European Commission's impact assessment and the beginning of the negotiation can impede the development of

suitable analysis to inform the domestic negotiation position. EU Member States can use the impact assessment produced and published by the European Commission and which provides complementary evidence on the legislative proposal. Many EU Member States report sometimes using the European Commission's impact assessment during the negotiation phase but there is scope for them to do so more systematically.

Regulatory impact assessments are more systematically required to be undertaken during the transposition of EU directives than during the negotiation stage. EU Member States generally understand the importance of assessing the impact of EU directives on domestic citizens and businesses, as almost all countries are required to undertake this analysis at the time of transposition and have the same requirements and processes in place as for legislation originating nationally. Few EU Member States however report assessing the impacts resulting from any additional national provisions added to the directive, suggesting that, if decision-makers do engage in gold plating, they may not systematically understand the impacts that these impose on their citizens and businesses. Finally, evidence from the European Commission's impact assessment appears to not be systematically used during the transposition phase, despite the fact that it includes evidence on the types and range of impacts that EU Member States can collectively expect to encounter when implementing a directive.

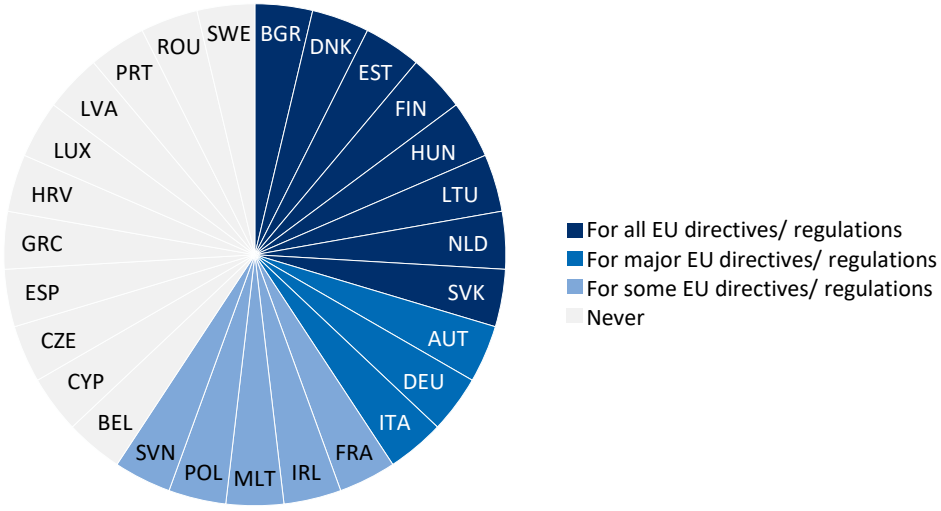
### *The use of RIAs by EU Member States to inform the negotiation of proposed EU directives and regulations*

EU Member States should ground their amendments of proposed EU directives and regulations during the negotiation phase on evidence and on an understanding of the anticipated impacts in individual countries. EU Member States can directly amend proposed EU directives or regulations during the negotiations undertaken by the European Parliament and the Council of the European Union. Given that negotiation can result in substantial changes to a proposal before it becomes an EU legislative act, EU Member States ought to prepare evidence on the impacts of the proposed legislation on their individual countries and use it in the debate. This is particularly important for EU regulations as these are directly applicable and binding in their entirety without being transposed into Member States' national law. The negotiation stage is thus crucial as, once regulations are adopted, EU Member States do not have another opportunity to amend them. Impact analysis is a critical tool to use in the context of negotiation as they can help EU Member States base their arguments on evidence and to alleviate any information deficiencies faced when countries commence negotiation.

The analysis at this stage of the legislative process does not necessarily have to be as detailed as the RIAs produced when developing domestic legislation or as impact assessments produced by the European Commission. Member States however ought to undertake proportionately lite analysis that would provide them with some evidence on the types and potential scope of the regulatory impacts on the domestic economy, businesses, and citizens, during the negotiations.

Despite the gains from analysing the domestic impacts of a proposed EU regulation or directive ahead of the negotiation, many EU Member States are under no obligation to conduct RIA to define a negotiating position and evaluate the potential policy impacts at the early stages of a European Commission proposal. This suggests that EU Member States' negotiation positions are not systematically informed by analysis and may fail to consider how the European Commission's proposals may affect their citizens and businesses. In fact, just over half of the EU Member States have a requirement to carry out RIA to define the negotiating position for the development of at least some EU directives and regulations (Figure 3.12), with the **Netherlands** having newly introduced this requirement since 2017. Carrying out domestic impact analysis is particularly relevant when the original impact assessment of the European Commission does not necessarily include an assessment of the impacts on individual countries.

## Figure 3.12. A significant number of EU Member States do not have a requirement to conduct RIA to define the negotiating position for the development of EU directives and regulations




Note: Data is based on 27 EU Member States.
Source: Indicators of Regulatory Policy and Governance (iREG) Survey 2021.

Five of the EU Member States that have requirements to carry out RIA to inform the negotiating position for EU regulations report to have the same RIA requirements as for regulations originating domestically. These EU Member States are **Estonia**, **Hungary, Italy**, **Lithuania** and **Malta**. Most of the EU Member States report to have different RIA requirements for domestic legislation than for laws initiated by the European Commission. Examples of practices of EU Member States when undertaking analysis to inform the negotiation of EU legislative proposals are explored in Box 3.8.

Some EU Member States consider it important to use evidence to inform the negotiation stage, even though they are not formally required to do so. This is, for example, the case of **Croatia**, **Latvia** and **Sweden**, which all have procedures in place to include some assessment of domestic impacts in the negotiation stage. Member States undertaking a RIA without being formally required to do so demonstrates the value of assessing the impacts of EU legislative proposals ahead of the negotiation. The practices followed by some of these Member States are included in Box 3.8.

### Box 3.8. Some EU Member States have specific analytical practices to inform the negotiating position of EU legislative proposals

There are no formal requirement in **Croatia** to conduct RIA in the process of drafting the national negotiating positions, however it is encouraged to indicate whether the EU legislation will have national legal and financial consequences. The depth and scope of the analysis depends on the capacities of the ministries responsible for the policy area affected by the EU legislative proposal.

In **Finland**, ministries are encouraged to conduct impact assessment at the time when the European Commission is preparing a new initiative. This is particularly relevant for political files of special interest for Finland. Within 6 weeks upon approval by the European Commission of its proposal and the related notification, the Government (ministries) must submit so-called “U” or “E” Letters to national Parliament to inform it about the new European Commission initiative and the Government stance on it; and to seek the formal mandate to negotiate / deliberate at the EU level. The Letter includes a basic, short

RIA. This is not sophisticated as it basically points out the most relevant of the proposal and of the European Commission's impact assessment.

The domestic RIA in **Italy** provides evidence to support the activity of the government and its representatives in the relevant Council formations. The Italian RIA starts within 30 days from the publication of the European Commission's Work Programme. This RIA should look at domestic effects and types of impacts that have not been considered by the European Commission but may be relevant for Italy. It is then part of the normal dialogue between the Member State and the EU institutions.

In **Poland**, the preliminary positions with elements of RIA are prepared obligatorily by the relevant ministries following the publication of the draft legislative act. The positions must be approved by the Committee for European Affairs operating on behalf of the Council of Ministers. In addition, the draft government positions are also reviewed by the relevant parliamentary committee. This acts as a preliminary verification of the impact assessment proposed by the Government.

The European Commission's proposal is distributed to the Permanent Mission of the **Slovak Republic** to the EU, to all Slovak Central Authorities and to the Parliament Office. A primary decision is made by the Ministry of Foreign Affairs together with the Government Office on the basis of the responsibility for given Working Group of the Council of the European Union. A Preliminary Opinion on the European Commission's proposal is then prepared within four weeks upon availability of the Slovak official text. The Preliminary Opinion may be "regular" (for the more important proposals) or a lower level one (non-legislative materials). Regular Preliminary Opinion includes information on the Draft Act, its content and goals, type and time frame of the approval process for given Draft Act in the EU, subsidiarity and proportionality assessment, analytical Impact Assessment for the Slovak Republic regarding the political, economic, legislative, social and environmental impacts.

In **Sweden**, to inform the National Parliament, the *Riksdag*, about an upcoming EU legislative, a document is drafted that includes information on the impacts of the proposed regulation, including the estimated impacts on the budget.

Source: Indicators of Regulatory Policy and Governance (iREG) Survey 2021 and Radaelli et al (unpublished[13]), Extending the OECD indicators of Regulatory Policy and Governance (iREG) to all EU Member States of the European Union.

EU Member States use various methods to identify European Commission legislative proposals that will undergo a domestic RIA. The identification of laws that will be subject to RIA is predominantly based on proportionality, and particularly on the significance of their impacts in general, their impacts on national and EU budgets, or their non-budgetary domestic impacts. For example, in **Germany,** European Commission proposals have to fulfil two conditions (i.e. the double condition) to be subject to a domestic RIA at the time of the negotiation. First, the threshold of EUR 35 million of expected compliance costs across the EU as per the RIA of the European Commission has to be met. The second condition is fulfilled if there is insufficient information on the proposal already available, e.g. via studies carried out in Germany. When the double condition is met, an impact assessment covering the compliance costs for German businesses is carried out by the competent department (Radaelli, Dunlop and Allio, unpublished[13]). In **Estonia**, a preliminary impact assessment is done for all EU directives and regulations. If the preliminary impact assessment identifies significant impacts, a full RIA is ordered and financed by the Government. EU proposals that have a significant impact in **Malta** are required to undergo specific analysis: In order to determine whether a RIA should be carried out at the negotiation stage, the significance of the regulatory impacts is considered. In addition, the number of individuals and businesses affected by the regulation, and matters of strategic national importance (e.g. the protection of national competitive advantages) are considered when evaluating the significance of an EU legislative proposal on Malta.

A minority of EU Member States have analytical guidance used specifically for the negotiation phase. In total, 11 EU Member States report having specific guidance available to government officials for conducting RIA to inform the national negotiating position for the development of EU legislation. In most cases, such guidance is included within the main domestic RIA guideline document although there are some countries where this guideline is separate and specifically directed at officials preparing the negotiation position of EU directives or regulations.

All EU Member States reported carrying out RIAs to inform the development of domestic regulations but in contrast, only around two-thirds reported carrying out RIAs in practice during the development or adoption of EU directives and regulations. This suggests that countries have relevant tools required for carrying out an impact assessment in practice but that such instruments may not be utilised as systematically for laws originating from the EU. Further research and comprehensive data – particularly around the timing difficulties experienced between the publication of the proposal and the start of the negotiation (see below) – is necessary to assess the EU Member States' actual practices regarding the use of impact assessment during the development and negotiation of EU directives and regulations.

The timing between the publication of the European Commission's impact assessment and the beginning of the negotiation can make it difficult for EU Member States to undertake an analysis of domestic impacts. The main difficulties countries report on the interface between the EU and the national processes is the length of time it would take for EU Member States to analyse and quantify the domestic impacts of the EU regulation. Even though the assessment of expected impacts of proposed regulations is crucial in order to carry out evidence-based and well-informed decisions, conducting a more in-depth analysis may not be always possible at the negotiation stage. Time is a variable that is affected by administrative challenges, i.e. how EU affairs are processed with their own deadlines (Radaelli, Dunlop and Allio, unpublished[13]). The deadlines may or may not allow for time invested in in-depth RIA and stakeholder engagement. Evidence provided by some EU Member States suggests that the issue of timing creates friction in the system – there are instances where analytical time to produce quantification of costs or subject RIA content to stakeholder scrutiny is inconsistent with political timing. In addition, it may often be the case that the nature of an EU proposal is uncertain, which makes it difficult to undertake analysis. The inability to carry out RIA can, for example, lead to difficulties optimising future burdens, and the timing pressures may also generate analytical capacity gaps (Radaelli, Dunlop and Allio, unpublished[13]).

### *The majority of EU Member States could better use the European Commission's impact assessments to inform their negotiating position*

EU Member States are able and ought to use the information provided in the European Commission's impact assessment as a starting point for making their own analysis and to improve the evidence that is brought to the negotiation table. Using the information provided in the European Commission's impact assessments is an especially relevant "low-hanging fruit" for the EU Member States that do not undertake their own analysis, as this may be the only source of evidence that they can use when developing their negotiating position. The European Commission's impact assessments are a functional and published resource that EU Member States can easily use and that is available several weeks in advance of the negotiation. Whilst they generally do not provide evidence on the impact of the proposed legislation on individual Member States, the European Commission's impact assessments contain comprehensive and robust information on the objectives and on the types of impacts likely to result from the proposed directive and regulation. Further information on the content of the European Commission's impact assessment is provided in Box 3.9.

### Box 3.9. The European Commission's impact assessment

Impact assessments are required for all of the European Commission's initiatives when the expected economic, environmental or social impacts of EU action are likely to be significant and there are available options. The lead European Commission service should establish as early as possible in the European Commissions' internal political validation process whether a RIA is required. Once a decision has been made that a proposal will be prepared, the European Commission publishes a call for evidence in which it is makes clear whether the proposal will be subject to an impact assessment. The call for evidence document presents an outline of the policy problem, an initial mapping of the policy options as well as preliminary assessment of expected impacts. Where no impact assessment is prepared, this is made clear in the call for evidence, which nonetheless provides key elements of the analysis that will be subject to feedback from stakeholders.

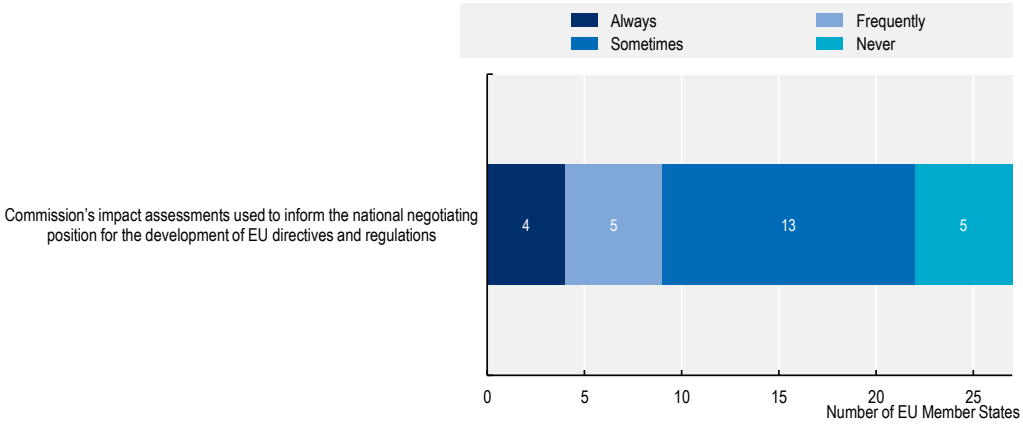
The public feedback period on the Call for evidence document and the public consultation (see Chapter 2), contributes to the impact assessment process, including data collection, public and stakeholder consultations, expert hearings and/or seeking additional scientific evidence. The results of the impact analysis will be summarised in an impact assessment report and sent to the Regulatory Scrutiny Board (RSB) for a quality assurance review. Following potential revisions of the impact assessment and based on a positive opinion from the RSB, the RIA is subject to internal consultation between the European Commission's departments together with the legal proposal. Once a regulatory proposal has been adopted by the College of Commissioners, the proposal – accompanied by the impact assessment as well as the opinions of the Regulatory Scrutiny Board – will be published online for feedback and sent to the co-legislators for the negotiation of the European Commission's proposals.

Source: European Commission (2021[3]), *Better Regulation Toolbox,* https://ec.europa.eu/info/sites/default/files/br_toolbox-nov_2021_en_0.pdf.

Many EU Member States understand the importance of using the European Commission's impact assessment during the negotiation phase but there is scope for doing it more systematically. Over 80 percent of EU Member States have reported using the European Commission's impact assessment as input to inform their national negotiating position for the development of EU directives and regulations, although few report doing so systematically (Figure 3.13). There is however no evidence that the European Commission's impact assessment is used at all in several EU Member States, such as **Greece**, **Portugal**, and **Spain**, even though they are not required to prepare a domestic RIA for the negotiation. This suggests that some EU Member States do not systematically arrive at the negotiation table with more complete information, which could potentially lead to poor representation of the interests of their citizens. Using the results of domestically carried out RIA as well as those carried out by the European Commission can help countries form a comprehensive negotiating position to inform better decisions by taking into account robust and available information on the impacts of a proposed regulation.

Anecdotal evidence from several EU Member States suggests that they recognise the European Commission's impact assessment as a relevant source of qualitative information about a proposed directive or regulation. Member States however note that the European Commission's impact assessment cannot and does not provide a sufficiently accurate picture of the regulatory impacts that could be expected at the national level. As such, the European Commission's impact assessment is often an initial starting point to inform more specific domestic analysis. Some EU Member States suggested more clarity regarding which impacts result from the specific provisions in the proposed directive or regulation to help them in developing their own analysis and to inform their negotiation position.

## Figure 3.13. A majority of EU Member States use the European Commission's impact assessments during negotiation but few do so systematically




Note: Data is based on 27 EU Member States.
Source: Indicators of Regulatory Policy and Governance (iREG) Survey 2021.

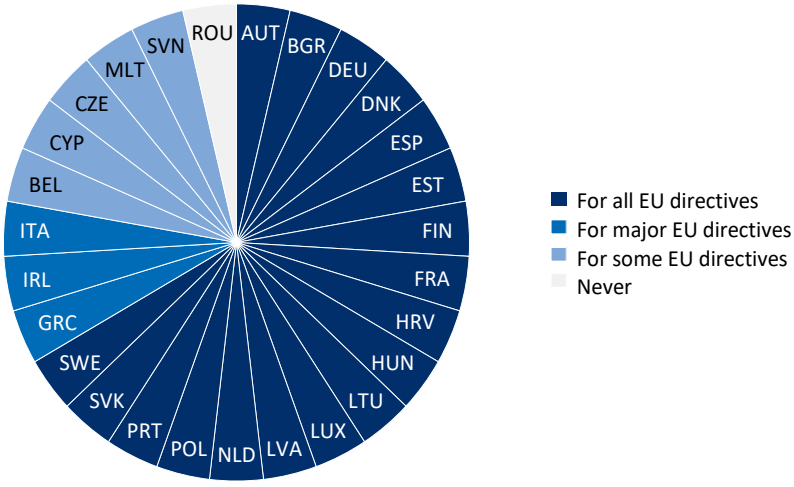
### *The use of RIA to inform the transposition of EU directives*

Transposition is the process that individual EU Member States undertake to incorporate adopted EU directives into national law. Unlike regulations, which are directly applicable to all EU Member States and binding in their entirety, directives offer flexibility to choose the method and form of implementation into national law. Transposition is the very last step of the EU legislative process for directives and takes place after the adopted policy is published in the Official Journal of the EU. EU Member States are bound by the terms of the directive as to the result to be achieved and the deadline by which transposition should take place (European Parliament, 2018[14]). They can however use the transposition process to add national provisions that go beyond the actual requirements set-out in the directive.

It is important for EU Member States to assess the impacts that the directive, in its final adopted form, will have on the domestic economy and society. As mentioned earlier in the chapter, the original impact assessment of the European Commission does not necessarily include an assessment of the impacts on individual countries. In addition, the European Commission's analysis is drafted before the directive is amended by the Council of the European Union and by the European Parliament during the readings and negotiation of the legislative proposal and, as discussed in Chapter 1, the impacts of such amendments are not systematically assessed by the other two EU institutions. The directive adopted may thus differ from the one originally developed by the European Commission and, as a result, the European Commission's original impact assessment may no longer fully reflect the resultant directive.

Requirements to assess the domestic impacts of directives when they are transposed into domestic law are well established across EU Member States. Almost all countries have formal requirements to conduct RIA when transposing at least some EU directives into domestic laws and this has not changed since 2017. In fact, more than three-quarters of EU Member States systematically require RIAs to be carried out during the transposition stage of EU directives (Figure 3.14). Only **Romania** does not require RIA to be carried out during the transposition of EU directives, as EU directives are explicitly exempted from RIAs at the transposition stage (Article 6 of Government Decision No. 561/2009).

## Figure 3.14. Most EU Member States systematically require RIAs to be carried out when transposing EU directives into national law

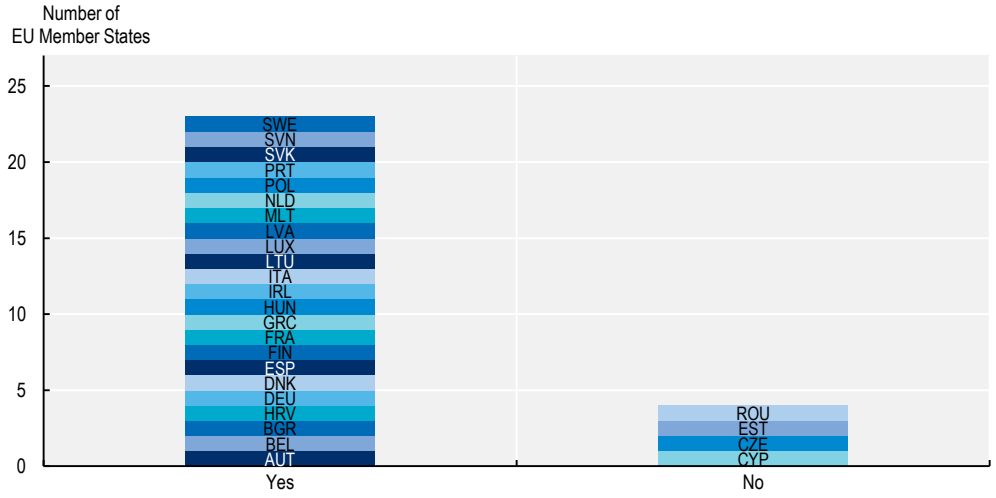



Note: Data is based on 27 EU Member States.
Source: Indicators of Regulatory Policy and Governance (iREG) Survey 2021.

When EU Member States assess the domestic impacts of directives, they usually follow the same processes as when analysing the impacts of their respective domestic proposals. In fact, the vast majority of EU Member States have the same RIA requirements for transposing EU directives as for laws originating domestically and there have been no changes since 2017 (Figure 3.15). As transposing EU directives involves amending existing or developing new domestic regulations, the transposition in EU Member States almost always goes through the same legislative process as laws originating domestically. As such, it is understandable and logical that the RIA requirements for laws originating at the EU level are identical to those originating domestically. The depth of the analysis in some sections may differ as policy makers have less flexibility to improve the policy when transposing EU directives (OECD, 2020[8]). For example, the assessment of the baseline 'do nothing' options or of alternative non-regulatory options may be less in-depth for RIAs accompanying EU legislative proposals because the decision to regulate has already been made. When fewer policy options or instruments are available, even if the impacts may be quite significant, policy makers have less flexibility to improve a policy at this stage. Despite this, governments should be mindful that EU directives or other supranational instruments might still have a degree of flexibility in their implementation (OECD, 2020[8]).

**Cyprus**, the **Czech Republic** and **Estonia** are the only EU Member States that have a requirement to undertake RIA for EU directives and where the RIA process is slightly different from that of regulations originating domestically. In **Cyprus**, policy makers have a different RIA questionnaire for transposing EU directives and the RIA procedure differs slightly. In the **Czech Republic**, policy makers are excepted from carrying out RIAs when there is no discretion on how to implement the EU legislative act and when no additional provisions going beyond the requirements of the EU directives are added by the Czech Government. In **Estonia**, it is not mandatory to compose a legislative intent document, i.e. an early-stage roadmap, for legislations that transpose EU directives. Examples of RIA practices for the transposition of EU directives in a sample of EU Member States is provided in Box 3.10.

## Figure 3.15. Almost all EU Member States have the same RIA requirements for transposed EU directives as for domestic regulations




Note: Data is based on 27 EU Member States.
Source: Indicators of Regulatory Policy and Governance (iREG) Survey 2021.

### Box 3.10. Examples of RIA practices at transposition stage

The RIA process in **Estonia** kicks off when the deliberations of the Council of the European Union are close to adopting a legal text. The responsibility lies with the Department of Justice and the Government Office. The process follows a series of steps that are carried out by default, meaning that there are no thresholds or exceptions.

In **Denmark**, the Danish Business Regulation Forum advises the government on the implementation of new business-oriented EU legislative acts by commenting on the relevant ministry's Implementation Plan. The responsible ministry must prepare Implementation Plans for all EU legislation (directives, regulations, implementing legislation and delegated acts) that have consequences for business and that must be implemented in Danish law. The Implementation Plan must be drawn-up immediately after the adoption of the legislative act and its publication in the Official Journal of the European Union. In their implementation scheme, the ministries have to explain how they have taken the recommendations from the DBRF into account or why it has chosen not to do so.

In **Finland**, the decision-making process during the transposition stage of EU legislation follows the same procedural steps as legislative initiatives originating domestically. While the RIA follows the standard procedure and format, it takes the European Commission's impact assessment as a starting point. Therefore, the RIA is to a certain extent less elaborated and comprehensive than a RIA on a domestically originated laws, since for example, the problem definition is already defined by the requirement to transpose an EU directive, or directly implement a regulation. On the other hand, the RIA is more elaborated than the impact assessment accompanying the EU Letter

The **Italian** government prepares an annual bill (the "*european delegation law*") that contains the provisions of legislative delegations necessary for the transposition of the directives and other acts of the European Union into Italian law with further legislative decree. This bill contains an appendix with all the legislative decree. Each legislative decree contains the national impact assessment. There is no difference between RIAs of EU legislation and other RIAs. The RIAs of EU legislation are carried out by individual departments and Ministries. They are scrutinized by the central RIA unit which could provide

a negative opinion. In that case the opinion is integrated in the documents supporting the final decision of Council of Ministries.

The process in **Poland** is equal to the legislative process of domestic originated drafts acts. The leading ministry submits the application for the introduction of the draft act to the Government Work Plan. The RIA should be attached to that application.

The responsibility for transposition in **Slovak Republic** is allocated by the Government Office. Key stakeholders are consulted during the commenting procedure on the preliminary position which is available at the Slov-lex portal. Relevant European Commission regulations (mainly of higher importance) are subject to impact assessment during the preliminary commenting procedure governed by the Ministry of Economy of the Slovak Republic. The impact on public finances, budget, and businesses, social and environmental impact must be indicated in the "preliminary position" paper.

Source: Indicators of Regulatory Policy and Governance (iREG) Survey 2021 and Radaelli et al (unpublished[13]), Extending the OECD indicators of Regulatory Policy and Governance (iREG) to all EU Member States of the European Union.

Eight EU Member States have reported having specific guidance for conducting RIA to inform the transposition of EU directives. In most cases, such guidance is included within the main domestic RIA guideline document, with only a small sub-section discussing RIAs for the transposition of EU directives. A notable exception is **Cyprus**, where the RIA questionnaire for EU legislation differs slightly from the one for domestic legislation. The country thus has an additional and separate guideline to inform officials drafting legislation and accompanying impact assessments.

EU Member States generally assess the impacts of EU legislation on national economies and societies once the legislation is adopted instead of during the negotiation when it can still be amended. Comparing the number of EU Member States with requirements to carry out RIA to inform the negotiation (Figure 3.12) versus those with a requirement to carry out RIA during transposition (Figure 3.14) suggests that countries use RIAs at a later stage in the legislative process. This issue was highlighted in the previous edition of this report (OECD, 2019[5]) and has not evolved since. The flexibility offered by directives is limited, as the requirements and provisions from the EU directive are already set and Member States are under strict obligations to implement them. The fact that domestic impact assessments are more systematically undertaken once the EU legislative text is adopted raises concerns on the capacity of EU Member States to ground the negotiation and ensuing amendments of EU directives on solid evidence regarding the regulatory impact on *domestic* citizens and businesses. Further evidence and data would be necessary to fully understand why the EU Member States do not have as stringent RIA requirements and practices for negotiations as for transposition and what are some of the factors that drive this discrepancy.

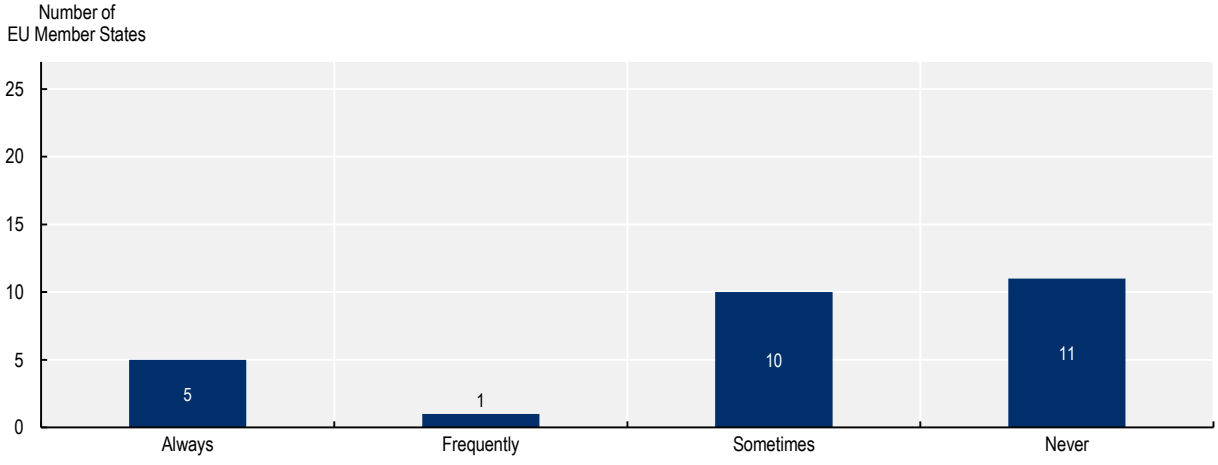
### *Requirements to assess gold plating*

Gold plating is a term specifically used in the European Union to describe over-implementation of a directive through the imposition of national provisions going beyond the actual requirements established by the directive. EU directives set minimum requirements that EU Member States must implement in order to safeguard the Single Market and the level playing field across the Union (European Commission, 2021[10]). Directives also allow EU Member States to choose how to meet the objectives set out, adapting their approach to their own institutional and administrative cultures (OECD, 2009[15]). EU Member States thus sometimes introduce additional provisions that are not directly prescribed by the directive. These can go beyond the requirements set out in the directive, which can result in extra impacts and burdens to citizens and businesses (OECD, 2009[15]).

When EU Member States engage in gold plating, they ought to analyse the impacts ensuing from the national provisions added. Given that provisions are added at the discretion of each EU Member State, the impacts introduced are not considered in the European Commission's impact assessments. In addition, divergence in implementation of EU directives, unless justified, can have important consequences for businesses, particularly those that operate in multiple EU Member States. It is thus crucial that, where gold plating occurs, EU Member States concerned identify and assess the impacts that these will have on its citizens and businesses. Special attention should be given to the additional provisions added at the national level, which ought to be transparently outlined and subject to an individual and specific assessment. This analysis is necessary for EU Member States to make informed decisions about whether such provisions and their impacts are essential to the efficiency of the transposed policy. In addition, there is scope and motivation for EU Member States to undertake this analysis, given that they must report how they transpose directives and may also indicate which national measures go beyond the requirements of EU directives (European Commission, 2021[10]), which is currently not systematically done.

Few EU Member States report assessing the additional impacts that national provisions added to EU directives through gold plating impose on domestic citizens and businesses. Six EU Member States report to systematically conduct specific assessments of potential provisions added at the national level going beyond the requirements set out in the EU directives (Figure 3.16). A further 10 EU Member States report to sometimes conduct gold plating assessments (Figure 3.16). This suggests that whilst almost all EU Member States are required to undertake RIA when transposing EU directives, few systematically conduct a specific assessment of the impacts resulting from any additional provisions. The RIAs undertaken during transposition thus appear to analyse the aggregated regulatory impacts, i.e. cumulating those imposed by the EU and those additionally levied by the respective individual EU Member State, without differentiating the impacts resulting from the directive and those resulting from the domestically added provisions. Indeed, out of the 16 EU Member States reporting to at least sometimes assess gold plating, only nine report assessing the marginal impact that the gold plating provisions have had. In other words, only nine EU Member States distinguish between impacts stemming from the EU requirements versus those resulting from additional national implementation measures in their RIAs. Since 2017, **Finland** has updated its RIA guidelines to now require a specific gold plating assessment, whilst **Slovenia** has reported no longer doing such assessment in 2020. More information of some of the practices of EU Member States related to gold plating are explored in Box 3.11.

## Figure 3.16. Approximately two-fifths of EU Member States report that they never conduct specific assessments to estimate the impacts of gold plating EU directives




Note: Data is based on 27 EU Member States.
Source: Indicators of Regulatory Policy and Governance (iREG) Survey 2021.

### Box 3.11. Gold plating practices across EU Member States

When transposing EU directives in **Czech Republic**, the draft regulation is checked by the Department of Compatibility with EU Law at the Office of the Government that also issues its opinions for the consideration of the Government Legislative Council (LRV). Additionally, there are several provisions in the RIA Guidelines that specifically require regulators to assess the compatibility with the EU law. Moreover, there are several methodological guidelines, such as Methodical Instructions for Fulfilment of Legislative Obligations arising from the Czech Republic's Membership in the EU or Methodical Tool for Prevention of Excessive Regulatory Burden in the Implementation of EU Law that encourage regulators to assess unnecessary measures going beyond the EU requirements as well as to avoid gold plating.

In **Denmark**, the Danish Business Regulation Forum advises a Government Committee on the implementation of EU-legislation and operates within a framework of five principles for good implementation to minimize gold plating in business regulation. The five principles are:

1. National regulation should as a general rule not go further than the minimal requirements in European legislative acts;
2. Danish businesses should not be disadvantaged compared to international competitors, and therefore the implementation should not be more burdensome than expected in comparable EU countries;
3. Flexibility and the exemptions in EU legislative acts should be used;
4. When possible and meaningful, EU legislative acts should be implemented through alternatives to regulation;
5. Burdensome EU legislative acts should commence latest possible with the national common commencement dates taken into consideration.

The process of transposition in **Estonia** is not particularly concerned with gold plating issues. This is not because the matter is not relevant. It is because all gold plating issues are examined at the routine stage of co-ordinating on draft legislation, of any type. The main tool adopted is the zero bureaucracy project.

In 2017, **France** directed an inter-agency mission to identify national transposition measures that deviate from the directive's minimum requirements and that may have penalised business competitiveness, employment purchasing power, or efficiency of public services. Out of the 137 directives identified by the mission as having a transposition gap with a penalising effect, in-depth analysis highlighted that 40 legislative measures no longer constituted over-transposition in view of the subsequently introduced directives.

There is a requirement to assess gold plating in the joint rules of procedure of the Federal Government of **Germany**. Enforcement is a matter left to the Länder and, for certain matters, to the local authorities. The German government provides comprehensive information on compliance costs – including those coming directly from the European legislative proposal. When there is gold plating in the domestic regulation that accompany a wider EU directive, the government applies the one-in-one-out rule.

All initiatives that transpose and implement EU acts in **Italy** should not go beyond what is necessary for the delivery of the minimum level envisaged by the EU legislative act. There is a requirement to be explicit when, in exceptional circumstances, implementation goes beyond the standards envisaged by the EU. These circumstances must be empirically supported and evidenced in the RIA.

In the **Netherlands**, an IAK-analysis is generally required and conducted to inform the development of regulations for all primary laws and subordinate regulations. The detail of the answers to the impact assessment questions must be proportional. Therefore, the analysis can vary per proposal, depending, for example, on the nature of the proposal, the scope and extent of the expected impacts of a proposed regulation. Instruction 9.4 of the Drafting instructions for regulation contains the general provision that implies that no other rules are included in the implementation regulation than necessary for implementation – a separate RIA for added provisions at the national level is therefore not required.

Draft acts transposing EU legislation in **Poland** sent to stakeholders and interministerial consultation should be accompanied by several documents including a so-called "reverse compliance table" that provides a tabular summary of the draft provisions of the Act, which go beyond the implementation, together with an explanation of the necessity of including them within the project. The Ministry of Foreign Affairs in its opinion on conformity of the draft law with the EU law consider possible instances of gold plating.

The issue of gold plating is not considered as a great concern in **Slovak Republic** if correctly justified. That said, the gold plating initiative is being carried out by the Ministry of Economy of the Slovak Republic. The assessment on gold plating is made by the proposing authority. Should it conclude that there is gold plating in the new draft regulation, the authority is obliged to explain the reasons for such gold plating in a Reasoned Report accompanying the draft regulation in the national approval process.

In 2019, the *Riksdag* (Parliament) in **Sweden** called the government to work to ensure that EU directives are implemented in Swedish legislation in a manner that does not impair companies' competitiveness. A starting point should be that EU directives be introduced at a minimum level in the national legislation. When there is cause to exceed the minimum level, the impact on companies should be clearly accounted for and reported.

Source: Indicators of Regulatory Policy and Governance (iREG) Survey 2021; Radaelli et al (unpublished[13]), Extending the OECD indicators of Regulatory Policy and Governance (iREG) to all EU Member States of the European Union; Sveriges Riksdag (2019[16]), Beslut EU-direktiv bör inte försämra företagens konkurrenskraft (NU7), https://www.riksdagen.se/sv/dokument-lagar/arende/betankande/naringspolitik_h601nu7.

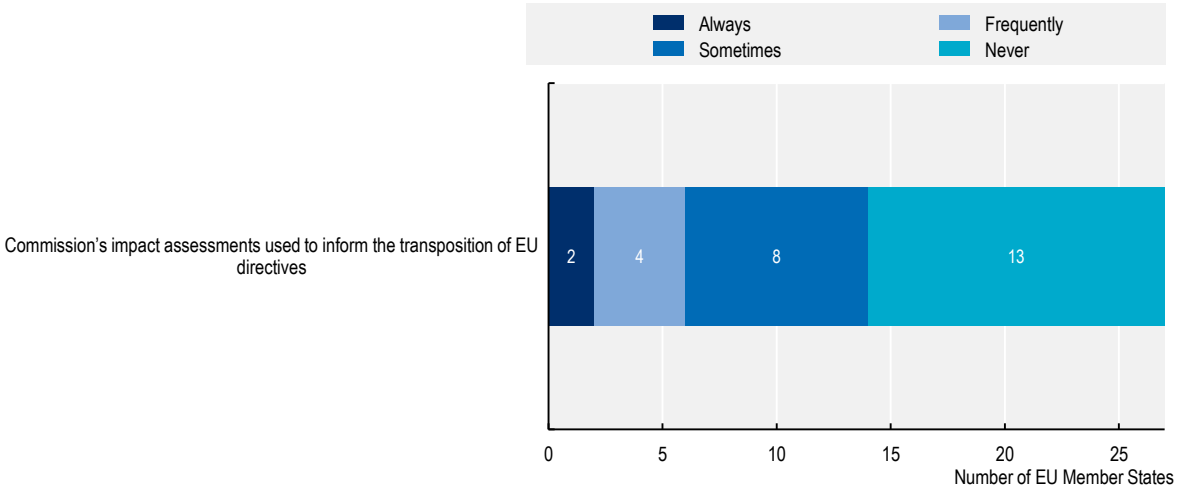
### *A minority of EU Member States report using the European Commission's impact assessments to inform transposition of EU directives*

EU Member States could use the European Commission's impact assessments when assessing the domestic impacts of the adopted directive, as they continue to provide helpful information and evidence to the domestic policy maker in charge of transposing the EU directive. There is value in using the European Commission's impact assessment as a source of information when EU Member States are assessing the impact that a directive has on the domestic economy and society. Whilst the European Commission's impact assessments provide evidence aggregated at the EU level, they still contain crucial information on the types of costs and benefits that EU Member States collectively can expect to face. This information can be a solid starting point for EU Member States to build on when developing their own assessment of the domestic impacts.

Approximately half of EU Member States report to use the results of the European Commission's impacts assessment to inform the transposition of EU directives (Figure 3.17). Generally, Member States occasionally use the results of Commission's impact assessment, rather than on a systematic basis (Figure 3.17). Only **Malta** and **Poland** report to always use the results of Commission's RIA to inform their transposition of EU laws. For example, in **Malta**, the results of Commission's analysis and findings are used in comparing with Malta's national situation and to provide options for strategic direction and assist

regulators with the implementation of EU laws. In **Poland**, the draft legislative act and staff working documents are used to assess the impact on the national economy.

### Figure 3.17. Only six EU Member States report systematically using the European Commission's impact assessments to inform the transposition of EU directives




Note: Data is based on 27 EU Member States.
Source: Indicators of Regulatory Policy and Governance (iREG) Survey 2021.

### *Use of "foreign" data in EU Member States' RIA*

Policy makers do not operate in silos, particularly in the context of the European Union, and thus need to collaborate with their counterparts in other EU Member States when developing domestic legislation and when transposing EU directives. Collaborating with parties outside national boundaries is an essential feature of embedding international regulatory co-operation (IRC) in domestic rule making, as highlighted in the *OECD Best Practice Principles on International Regulatory Co-operation* (OECD, 2021[17]).

Collaboration and evidence exchange with other EU Member States can be a relevant practice during the development, negotiation, or transposition of EU legislative acts. Member States would benefit from sharing information on the impacts of EU legislation, as it would allow them to learn from each other, improve their impact assessments and better inform their decision making. Particularly in light of the often-limited time before negotiation takes place, short deadlines might prompt EU Member States to partner to collect or to utilise evidence from one another when preparing their national position in the negotiation phase or when shaping the transposition of EU directives (Radaelli, Dunlop and Allio, unpublished[13]). Similarly, EU Member States can use other Member States' RIAs to supplement their own analysis in addition to the European Commission's, when transposing EU directives and into domestic laws.

EU Member States report not engaging systematically with each other despite the potential gains from collaboration during the negotiation and transposition of EU legislative acts. Four EU Member States – **Denmark**, **Germany**, **Latvia**, and **Malta** – report having systematic mechanisms in place for sharing or exchanging information and evidence on potential impacts of EU directives and regulations with other EU Member States and the European Commission. More information on their practices concerning information exchange with regards to EU legislative acts is provided in Box 3.12. Only six EU Member States report using information from the RIA conducted by other EU Member States when transposing a directive and this appears to be done on an ad-hoc basis.

### Box 3.12. Examples of EU Member States with systematic mechanisms for sharing or exchanging evidence on EU legislative acts

**Latvian** regulators systematically engage with other EU Member States at the European Union Council and European Commission working group meetings during which EU Member States exchange their views. Counsellors exchange with each other possible implications for the legal systems. Furthermore, for the Ministries of Justice there is a network which allows exchanges among ministries about various legal system issues including potential impacts of EU legislation.

**Malta** engages with other EU Member States on the base of ad-hoc mechanisms. In particular, Maltese regulators engage with like-minded EU Member States to push and advocate for its interests in line with those of other EU Member States.

In **Germany**, the impact of all new regulations of EU law is required to be assessed. Information and evidence on the potential impacts of EU directives and regulations is informally shared with other Member States and with the European Commission during the negotiation of the proposed act through the interactions in various working groups.

According to the **Danish** Guidelines on Legal Quality it is required that line ministries assess the impacts of proposed regulations on foreign jurisdictions. In particular, if the proposed legislation has a significant impact on other Nordic countries it is required that the impacts on these countries are evaluated and that they are described in detail in the comments. With respect to the implementation of EU directives, where appropriate, the relevant Ministry of Industry must ensure that the comments on a legislative proposal include a description of the legislation in other Nordic countries.

Source: Indicators of Regulatory Policy and Governance (iREG) Survey 2021.

It is noteworthy that beyond EU Member States' well-established practice regarding RIA to inform the transposition of EU directives, 11 EU Member States have a requirement in place to conduct a RIA when adopting international instruments beyond EU law. This may be a useful experience for EU Member States more broadly to learn from to conduct RIA to assess the benefits and costs of following non-EU international instruments, particularly when these are non-binding and several parallel instruments exist on the same subject (OECD, 2021[17]). In so doing, they could verify if the international instrument was already the subject of an IA by the international organisation or another member thereof, to draw on it as useful evidence (OECD, 2021[18]). Nevertheless, if the instrument is binding and its implementation is mandatory, it may be more relevant to conduct the assessment before the adoption of the instruments to consider alternative options.

## Notes

[1] Basic Law for the Federal Republic of Germany (1949), available at: http://www.gesetze-im-internet.de/englisch_gg/englisch_gg.html#p0111.

[2] See Box 2.5 on pages 25 and 26 of the *OECD Best Practice Principles for Regulatory Policy: Regulatory Impact Assessment* (2020[2]) for a typology of policy alternatives to "command-and-control" regulations

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