Better regulation in the EU
Abstract

This collection of studies, prepared by the Policy Department C at the request of European Parliament's JURI Committee, indicates that better EU legislation and regulation can deliver gains to the European economy of over EUR 2,200 billion, while even selected sectorial legislation can deliver EUR 575 billion in case of free movement of goods and customs union, EUR 389 billion in case of free movement of services and EUR 177 billion in case of the Digital Single Market, annually.

At the same time delaying better legislation and regulation in the EU leads to an aggregate annual loss of EUR 319 billion just in the digital transformation area.

Experts indicate at an urgent need of new instruments for the EU better regulation agenda.

Better regulation in the EU
This document was requested by the European Parliament's Committee on Legal Affairs.

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BETTER REGULATION IN THE EU: IMPROVING QUALITY AND REDUCING DELAYS

Briefing requested by the JURI Committee (June 2022)

AUTHOR: Siôn Jones, Greta Dohler, Luke Pate (LE Europe)

KEY FINDINGS

There are very significant benefits from EU legislative initiatives – hundreds of billions of euros for major internal market initiatives. For example, free movement of goods - €386bn; Customs Union - €189bn; free movement of services – €389bn; Digital Single Market - €177 bn. There are potential gains to the European economy (EU-28) of over €2,200bn that can be achieved, if legislation advocated by the European Parliament were to be adopted in a series of EU policy areas.

Understanding the quantum of net benefits from previous and proposed legislative initiatives is vital in order to enable legislators to fully understand the implications of their decisions. Nevertheless, the work of the Regulatory Scrutiny Board suggests that there is significant room for improvement in the practical implementation of better regulation, in particular in relation to quantifying actual and potential benefits and costs of EU initiatives in ex post evaluation.

The very significant level of benefits from major EU legislative initiatives means that delays in putting legislation into action can mean very substantial costs in the form of delayed benefits. For example, typical legislative and transposition delays in putting digital transformation policies into action could lead to an aggregate cost of €319 billion in lost annual benefits. Further delays in the overall process, before and after the legislative process and transposition, are likely to be adding to this cost.

Recommendation: European Parliament should call on the European Commission and the Regulatory Scrutiny Board (RSB) to place additional focus on quantification for evaluation, as they have done for IAs. Full quantification is of key importance for evidence-based policy and for understanding of impacts of legislation. Further measures to encourage more quantification, should include ensuring that each IA includes a ‘monitoring and evaluation plan’ that sets out the data that need to be collected in order to meet evaluation objectives.

Recommendation: Given the key role of strategic decisions, a quantified evidence base should also inform political inputs at the strategic stages of decision-making, such as the development of Commission priorities and work programmes.

**Recommendation:** European Parliament together with European Commission should undertake further investigations of delays in the legislative process across a wider range of policy areas and of delays in other parts of the system (pre and post legislation). This would help to provide a baseline understanding of these issues which have significant implications for the policy benefits experienced by citizens, businesses and other EU stakeholders.

**Recommendation:** European Parliament should give consideration to: how the most costly delays can be addressed; how delays and their costs can be monitored and assessed on a regular basis; which institutional mechanism can be used to ensure clear responsibility for future monitoring, assessment and recommendations for action – should this be a part of the Court of Auditors performance audit responsibilities, for example.

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**The EU Better Regulation Ecosystem**

The Interinstitutional Agreement between the European Commission, the European Parliament and the Council of 2016 sets out the EU approach to better law-making, and draws on earlier work on better regulation.\(^1\) The approach recognises impact assessment (IA), ex post evaluation and stakeholder engagement as core elements of a high quality approach to law-making and regulation.

Better regulation works alongside the EU’s legislative procedures, in line with the Better Regulation Guidelines, most recently updated in November 2021.\(^2\)

As part of their recent review of regulatory practices, the OECD\(^3\) benchmarked jurisdictions on the basis of a number of criteria relating to better regulation including, in particular, practices relating to: ex ante IA; ex post evaluation; and inputs from stakeholders.

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\(^1\) Interinstitutional Agreement of 13 April 2016 on Better Law-Making.


As shown in Figure 3, the EU’s system of better regulation (OECD, 2021) performs strongly against the selected comparator jurisdictions. However, the OECD assessment is based on documented procedures and focuses on the structure and content of the regulatory system. There is less focus on the practical implementation of better regulation requirements. As illustrated in the next section, there is considerable scope for improving the way in which the requirements of the EU better regulation system are implemented.

**Practice of Better Regulation: Evidence from the Regulatory Scrutiny Board**

Initial rejection rates of IAs and evaluations by the RSB are high and have not declined in recent years

Overall, the trend in the numbers of IAs reviewed by the Regulatory Scrutiny Board (RSB) is declining over the period 2007 to 2020 (Figure 4). The cyclical pattern broadly matches the 5-yearly period for each Commission, with IAs submitted declining in the final year of a Commission (as in 2019). More recently, between 2015 and 2020, the Board saw a 40% increase in the number of IAs it was presented with (from 29 to 41), mainly related to Commission priorities for 2019-24. In most years in the period 2007 - 2020, the initial rejection rate is around 35% to 45%, with no sign of this improving over time.

For evaluations, the Board did not issue overall ratings before 2017 and so it is too early to assess trends. Case numbers are much lower than for IAs – in the range of 10 to 17 each year. Initial rejection rates are in the range of 25% to 40%, so similar to IAs.

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If the lack of improvement in initial rejection rates reflects a lack of improvement in the quality of submissions, then this is concerning. It could be consistent with increases in the quality of submissions if it is a consequence of increasing standards being applied by the RSB. However, the qualitative descriptions provided by the RSB in their Annual Report for 2020 (see Figure 5) do suggest that there is cause for concern and that the quality of initial drafts needs to be improved. They clearly have concerns about the quality of the IAs and evaluations that are submitted to them.

Figure 5: Examples of RSB Comments

<table>
<thead>
<tr>
<th>Comment</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;Quality of first submissions was not acceptable for most IAs&quot;</td>
<td>Regulatory Scrutiny Board (2020). Annual Report 2020.</td>
</tr>
<tr>
<td>&quot;lack of sufficient time to prepare assessments [IAs], given ambitious political deadlines&quot;</td>
<td>Impact Assessment Board (2015). 2014 Activity Statistics.</td>
</tr>
<tr>
<td>&quot;the weakest element for all IAs was the problem definition and use of evaluation&quot;</td>
<td></td>
</tr>
<tr>
<td>&quot;the quality of initial draft evaluations remained patchy&quot;</td>
<td></td>
</tr>
<tr>
<td>&quot;The Commission teams that design and produce the evaluation may not have the necessary capacity to evaluate properly&quot;</td>
<td></td>
</tr>
<tr>
<td>&quot;Operational departments may have an interest in the evaluated initiative, and this can impede a frank assessment of its potential flaws [in evaluations]&quot;</td>
<td></td>
</tr>
</tbody>
</table>

Quantification of costs and benefits in IAs and evaluations requires improvement

Quantification of costs and benefits contributes to better policy-making and in ex post evaluation it enables the verification of the size of benefits actually achieved through EU legislation. The importance of quantification is recognised by the RSB and they monitor the extent to which IAs quantify costs and benefits.

In 2020, only 23% of IAs first submitted to the RSB had fully quantified benefits and 29% had fully quantified costs. In addition, around half had partially quantified costs and around half had partially quantified benefits. The problem of insufficient quantification has been recognised for many years, with research relating to the Digital Single Market (DSM) in 2013, for example, showing that only 40% of a small sample (10) of DSM initiatives provided a useful degree of quantification.7

There is substantial external research on the costs and benefits of EU policies especially in the context of the internal market, and digitalisation means that more and more data are becoming available from a wide range of sources.8 The Commission Services should take advantage of these data sources. If they have insufficient time, or capacity, as suggested by the RSB, they need to use external expertise.

For evaluations, the RSB do not specifically monitor the extent of quantification though many of their comments on recent evaluations imply limited or inadequate use of evidence. They assessed data collection overall as “weak” at first submission. A brief LE Europe review of 13 evaluations and fitness checks scrutinised by the RSB in 2020 suggests that 31% had fully quantified costs and none had fully quantified benefits, with many citing problems with data availability. This suggests that quantification in the context of evaluation also requires improvement.

We **recommend** that the RSB places additional focus on quantification for evaluation, as they have done for IAs. Further measures that might encourage more quantification, could include ensuring that each IA includes a ‘monitoring and evaluation plan’\(^9\) that sets out the data that need to be collected, as part of project implementation, in order to meet evaluation objectives.

### Delays in delivering benefits through EU legislation

The enhanced performance-based policy cycle, developed in previous research for the IMCO committee, provides a structure within which to develop, assess, implement, monitor and evaluate policy.\(^10\) The enhanced performance-based policy cycle places greater emphasis on a strategic programming phase to policy development than the EU Better Regulation Guidelines.

![Figure 8: The enhanced performance-based policy cycle](image)

**Timely formulation of well designed high level strategies based on quantified evidence.**

The European Commission’s Better Regulation Guidelines require that the European Commission’s work should ‘focus on the Commission’s priorities as reflected in the President’s political guidelines and the Commission’s annual work programmes’. It appears however, that no assessment of potential impacts is required in the preparation of the President’s political guidelines or the Commission’s annual work programmes. High level strategies (‘strategic programmes’) and political agendas are an important part of the policy development process. They set the context in which many individual policy choices are made and research has suggested that the preliminary stages of decision-making strongly influence the final outcome. **We **recommend** that whilst political inputs are important at the strategic programming stage, a quantified evidence base is also an important input at this early stage. It should seek to inform the political inputs.**

### Delays in presenting and carrying out effective legislative initiatives

Developing effective policies - that properly consult stakeholders and make use of robust IAs - takes time. However, in some cases the timespan between recognising that there is a problem until any

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legislative action is implemented is very long, and means that the benefits of policy action are significantly delayed.

Delays can occur in some or all of the stages of the process illustrated in Figure 8 above. Two specific examples of long delays – the Single European Gateway and the Union Customs Code – are summarised in the boxes below. In both cases the European Parliament commissioned research from independent experts that suggested changes in policy and important benefits from reforms. Although the research had important impacts on the policies, they did not succeed in speeding up the overall policy implementation process.

Delays in customs reform

From the mid-1990s, there was ambition to modernise the Community Customs Code (CCC). By 2008, the Modernised Customs Code (MCC) came into force. But due to the adoption of the Lisbon Treaty and the development of a new electronic system for customs administration, the MCC was recast by the Commission in 2012. This led to serious delay, since the initial proposal was to delay application of the MCC by more than 7 years. At the time, research for IMCO anticipated that the MCC might not be fully implemented until 2020 or later. The MCC, renamed as the Union Customs Code (UCC) was adopted in 2013, but didn’t take effect until May 2016. The required electronic systems to deal with formalities are still not fully in place yet.

Figure 9: Timeline of Customs Reform

Notes: *See PwC Belgium et al, 2012. An update and discussion on customs reform was held at a workshop organised by the IMCO Committee in 2019.

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Delays in the legislative process have increased since the period 2001 – 2010

The Amsterdam Treaty called on the EU institutions to ensure that the co-decision procedure operates as efficiently as possible. Hence, there have been various efforts to speed up the average length of the EU legislative process, such as the trilogue meetings between representatives of the Parliament, the Council and the Commission.14

A review of the length of EU legislative processes for procedures within IT, telecommunications and data-processing shows that the average duration from adoption of a proposal by the European Commission to signature by the Parliament and President of the Council between 2016 and 2020 was 21 months (1.75 years). Thus, the minimum length of time between an initial policy action at the EU level and the earliest date on which legislative impact can be expected is almost 2 years. Moreover, the average length of the total legislative process appears to have increased since 2001 - 2010 (see Figure 11).

Between 2016 and 2020 the shortest 25% of all EU legislative processes over that period (16 processes in total) took on average 11.3 months from adoption of a proposal by the Commission to being signed. If this is assumed to be the fastest that legislation can be passed in the current context and reflects a legislative process without delays, then any legislative process that takes longer than this can be viewed as being delayed. On this basis, between 2016 and 2020, the average delay of the legislative process was 10 months, which is the longest average delay since 1990 - 2000.

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The first stage of the legislative process – from the adoption of a proposal by the European Commission until the European Parliament’s position at first reading – takes the longest, and has increased in duration. The later stages of the legislative process following the first reading are shorter, and becoming even shorter over time. The share of legislative processes within IT, telecommunications and data-processing that are adopted after the first reading has increased from 15% before 2000 to 81% since 2016. While fewer instruments undergo second or third readings, this has been outweighed by increases in the time until the Parliament’s position at first reading. Thus, it has not resulted in a decline in the overall duration of the legislative process.

Transposition of EU legislation into national legislation is associated with delays and errors

When a new directive is adopted, it always comes with a deadline by which Member States are required to adopt it into national law. These transposition deadlines can vary from a few months to several years. For the Single Market directives, the average transposition delay (any time beyond the transposition deadline) is usually between 6 and 12 months. However, it increased by 37% in 2019, from 8.4 months in 2018 to 11.5 months in 2019.

Legislative delays can be very costly

EU legislation generates high levels of benefits for EU citizens and businesses. The ‘Contribution to Growth’ exercise undertaken by the IMCO Committee of the European Parliament identified high levels

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of potential benefits from actions linked to completion of the Single Market (e.g. free movement of goods - €386bn; Customs Union - €189bn; free movement of services - €389bn).\textsuperscript{16}

Several studies have estimated the benefits of EU actions for the digital economy. Marcus et al. (2019) estimated annual benefits from completing the Digital Single Market (DSM) of €177bn.\textsuperscript{17} In their ‘Mapping the Cost of Non-Europe’ exercise, European Parliamentary Research Service (2019)\textsuperscript{18} estimated annual benefits of €178bn from completing the DSM, improving internet connectivity and enhanced cyber-security. The most recent analysis estimates the cost of non-Europe for digital transformation to be €315bn per year in 2021.\textsuperscript{19}

Mapping costs of non-Europe for 2019-2024 indicated that there are potential gains to the European economy (EU-28) of over €2,200bn that can be achieved, if legislation advocated by the European Parliament were to be adopted in a series of EU policy areas.\textsuperscript{20}

Whilst the legislative process is underway, the EU does not capture these annual benefits (this is known as the ‘cost of slow Europe’).\textsuperscript{21} Assuming benefits from the digital economy of €315bn per year and an average delay in the EU legislative process of 10 months, an estimate of the cost of slow Europe for the digital economy from the EU legislative process is €262bn.

Additionally, there are also costs associated with transposition delays for EU directives. The average transposition delay between 2018 and 2019 was 11.5 months. The share of directives among all legislative processes within IT, telecommunications and dataprocessing between 2016 and 2020 was 19%. Applying the same estimate of €315bn per year as cost of delay, this results in a cost of transposition delay of €57bn. Summing the cost of slow Europe for the digital economy (€262bn) and the cost of transposition delay (€57bn), the total the cost of delay for the digital economy is €319bn.

**Further investigation of delays**

We have undertaken a preliminary investigation of delays in the system. Based on legislation in a limited policy area, this suggests that actions to complete legislative processes after the first European


\textsuperscript{19} European Parliamentary Research Service (2022). Digital Transformation: Cost of Non-Europe. DOI: 10.2861/409750


Parliament opinion are not reducing the overall duration of the legislative process as expected; and that a significant component of delays is outside (before and after) the legislative process.

We recommend further investigations of delays in the legislative process across a wider range of policy areas and of delays in other parts of the system (pre and post legislation). This would help to provide a baseline understanding of these issues which have significant implications for the policy benefits experienced by citizens, businesses and other EU stakeholders.

Once further information about current delays in the legislative process is available, we recommend that consideration be given to: how the most costly delays can be addressed; how delays and their costs can be monitored and assessed on a regular basis; which institutional mechanism can be used to ensure clear responsibility for future monitoring, assessment and recommendations for action – should this be a part of the Court of Auditors performance audit responsibilities, for example.
ASSESSMENT OF CURRENT INITIATIVES OF THE EUROPEAN COMMISSION ON BETTER REGULATION

In depth analysis requested by the JURI Committee
(June 2022)

AUTHOR: Andrea RENDA, Centre for European Policy Studies and European University Institute

Abstract

This in-depth analysis commissioned by the European Parliament’s Policy Department for Citizens’ Rights and Constitutional Affairs at the request of the JURI Committee, looks at the past and current developments in the EU better regulation agenda. The author finds that, despite important achievements that put the EU at the forefront in this field, many of the most ambitious reforms announced over the past few years are still far from complete. The in-depth analysis offers several policy recommendations.
EXECUTIVE SUMMARY

The EU better regulation strategy was launched two decades ago, and was accompanied by very high expectations. Since then, several features were introduced in terms of methodology, overall scope, and instruments, and today the EU can claim to have an extremely comprehensive better regulation system, as recognised i.a. by the OECD. Among the key ongoing trends in the EU, most noteworthy are a transition from the use of cost-benefit analysis towards multi-criteria analysis; a move from pure evidence-based towards evidence-informed and also foresight-based policies; the completion of the policy cycle with the introduction i.a. of ex post evaluations and fitness checks; the emergence of a strong (but still insufficiently supported) regulatory oversight body; the growing role of the European Parliament in the better regulation domain; and the slow and partial development of the better regulation agenda in the Member States.

This paper reviews existing trends and proposed solutions presented by the European Commission in its recent Communication on Better Regulation, “Joining Forces to Make Better Laws”. The author finds that the full implementation of the Inter-Institutional Agreement on Better Law-Making may be easier if the EU better regulation agenda completed its shift away from the use of cost-benefit analysis as key criterion to select the preferred option, towards a full mainstreaming of sustainability (i.a. the SDGs) and resilience. This does not imply that the Commission should refrain from quantifying impacts: to the contrary, whenever possible and appropriate impact assessments and ex post evaluations should be accompanied by quantitative estimates of impacts, to strengthen the evidence-based nature of EU policymaking. Moreover, the adoption of the One-In-One-Out rule should be made compatible with the EU’s ambitious agenda, and this requires a focus exclusively limited to “unnecessary costs”, i.e. costs that can be eliminated without compromising regulatory benefits, for example through codification or digitalisation. The author also observes that the proposed changes in stakeholder consultation can bring positive results in terms of lifting the burden on respondents, but are unlikely to solve the problem of representation; and that new EU better regulation agenda requires a better legal framework and guidance on experimental policymaking, as well as the use of new technologies in regulation. Finally, given the amount of measures adopted under emergency over the past two years, the European Commission should consider carrying out post-implementation reviews of rules that bypassed the ex ante impact assessment, in line with existing best practices in some OECD countries.

Against this backdrop, the current proposals go in the right direction, but fall short of realising the systemic transformation that the EU better regulation agenda needs, in order to remain a leading example of regulatory management at the global level. Future actions should, i.a., promote coherence between EU legislative initiatives and overarching goals (e.g. the twin transition, resilience and sustainability); make the Better Regulation Toolbox more accessible to Commission services; and create more visibility and interest around better regulation and the work of the RSB.
1. INTRODUCTION: TEN TRENDS OVER TWO DECADES OF EU BETTER REGULATION

KEY FINDINGS
The EU better regulation strategy was launched two decades ago, and was accompanied by very high expectations. Since then, several features were introduced in terms of methodology, overall scope, and instruments, and today the EU can claim to have an extremely comprehensive better regulation system, as recognised i.a. by the OECD.

Among the key ongoing trends in the EU, most noteworthy are a transition from the use of cost-benefit analysis towards multi-criteria analysis; a move from pure evidence-based towards evidence-informed and also foresight-based policies; the completion of the policy cycle with the introduction i.a. of ex post evaluations and fitness checks; the emergence of a strong (but still insufficiently supported) regulatory oversight body; the growing role of the European Parliament in the better regulation domain; and the slow and partial development of the better regulation agenda in the Member States.

Until the early 2000s, the European Commission did not adopt a whole-of-government approach to better regulation. There had been developments in this domain, especially the introduction of the Business Impact Assessment (BIA) introduced by the UK presidency in 1986; the SLIM project (Simplification of the Legislation on the Internal Market); the BEST (Business Environment Simplification Task Force) in 1997; and the creation of the Business Test Panel in 1998 (Renda 2006). Such a proliferation of initiatives, however, had not produced the desired cultural shift in the Commission services. It was only with the 2001 White Paper on European Governance, and the creation of a high-level advisory group in charge of drafting of an “action plan for better regulation” (the so-called ‘Mandelkern Group’) that a comprehensive, horizontal system for ensuring the quality of EU legislation was eventually introduced. The action plan on “simplifying and improving the regulatory environment” was eventually adopted in June 2002. The action plan led to the introduction i.a. of a fully-fledged system for the ex ante impact assessment of major new Commission initiatives, and of minimum standards for stakeholder consultation.

Since then, and even more after 2005, the Commission has embraced one of the most ambitious better regulation systems in the world. However, the early days featured at once ambition, courage and naïveté. On the one hand, the Mandelkern group ended up recommending the adoption of a system that was largely focused on the use of cost-benefit analysis when choosing the most desirable (read: efficient) policy alternative in ex ante impact assessments. This was largely due to the influence of existing models such as the U.S. Regulatory Impact Analysis, adopted in 1981 during the Reagan Administration; and the UK experience, which after an initial emphasis on compliance costs for businesses had eventually embraced fully fledged cost-benefit analysis in 1998, during the Blair years (Renda 2006). Despite clarifying that the European system would focus on the economic, social and environmental impacts of major new proposed policy initiatives, ultimately the Secretariat General has prioritised and endorsed the use of cost-benefit analysis, a methodology that allows the centre-of-government to control peripheral agencies and departments (in the case of the European Commission, the Directorate-Generals) (Posner 2001). Such methodology, typically reliant on the monetisation of both benefits and costs, is considered as a good choice for subordinate regulation, such as implementing and delegated acts, but too limited and insufficiently attentive to distributional impacts to be usefully applied to primary legislation. Following its introduction in 2003, the EU impact
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assessment system immediately faced the difficulty of adapting this methodological approach to ambitious far-reaching pieces of legislation such as the Services Directive, or the Policy Approach to Asylum among others; let alone non-binding policy initiatives such as White Papers or Communications (Renda 2018). However, policy leaders such as the European Commission’s Vice President Günther Verheugen continued to raise expectations as to the system’s ability to uncover the “full costs and benefits” of EU legislation.22

This methodology mismatch was, however, not the only “original sin” of the European Commission when launching the better regulation agenda. The scope and ambition of the system soon clashed with the lack of preparation and skills within Commission services, as well as the lack of a central oversight body in charge of quality assurance functions such as scrutinising draft impact assessments. Moreover, the ability of the Secretariat General to persuade the services to embrace the new system proved limited, and this in turn led to an enduring fragmentation inside the European Commission, which some DGs (e.g. Enterprise, later GROW) keen on focusing on simplification and the reduction of regulatory costs; and other DGs (namely Environment, but also Justice among others) remaining very reluctant to embrace quantification in general, and cost-benefit analysis in particular. Even more importantly, the European Commission initially declared that the ex ante impact assessment system was being introduced mostly for “in-house learning” purposes, rather than to strengthen the transparency and quality of EU legislation. Such an underlying motivation supported the choice not to publish draft impact assessments for consultation, which clashed with established good practices in other parts of the world. However, one year later the European Commission, the European Parliament and the Council signed an Inter-Institutional Agreement on Better Lawmaking, in which they acknowledged the “positive contribution of impact assessments in improving the quality of Community legislation” and committed to applying impact assessment not only to Commission (major) proposals, but also to major amendments tabled during the ordinary legislative procedure by both the Parliament and the Council.23 This, in turn, meant that the “in-house learning” purpose of impact assessments had been replaced by a focus on using impact assessments throughout the ordinary legislative procedure, to improve the quality of EU legislation.

Not surprisingly, in light of the above, the first years of implementation were rather painful, with impact assessments very often failing to fully serve their purpose inside EU institutions. Two decades down the road, several features of the EU better regulation system have changed, but many traces of the early days still remain.

At least ten main trends can be highlighted in this introductory section.

First, the original emphasis on cost-benefit analysis has been gradually replaced by a prevailing orientation towards using multi-criteria analysis, with the EU Better Regulation Guidelines specifying the need to test alternative options for specific impacts (e.g. impacts on SMEs), and finally culminating in the adoption of a Better Regulation Toolbox that counts, today as many as 69 different tools.24 Most of the Commission’s impact assessments end up comparing policy options through scorecard approaches, in which options are ranked in terms of their ability to achieve specific objectives, as well as based on a quali-quantitative assessment of their associated costs. The cost-

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benefit analysis approach, which normally ends up with the calculation of the net present value of each option, is not common in current Commission practice.

Second, and relatedly, the Commission’s approach to ex ante impact assessments has gradually shifted from an initial orientation towards efficiency, towards coherence and effectiveness as key criteria for identifying the preferable policy options. A distinctive trait of Commission impact assessments, in this respect, is the emphasis on the general and specific objectives of the intervention, and the appraisal of alternative policy options based on the extent to which options are likely to achieve those objectives. In principle, the “general objectives” should refer to the EU’s medium- to long-term goals, or at least high-level sectoral goals (e.g. the objectives of the Green Deal; the Twin Transition; the Digital Decade targets; the Sustainable Development Goals, etc.): however, as will be recalled below, the extent to which this is really occurring is debatable.

Third, the emphasis on coherence and effectiveness has become even more visible after 2010, when the Commission announced for the first time its intention to complete the policy cycle, by performing ex post evaluations of existing legislation alongside the ex ante assessment of new proposals. The so-called “evaluate first” rule, regularly applied in the Commission, often obliges services to perform ex post evaluations “back to back” with the ex ante assessments of future legislation. Ex post evaluations, from a methodological perspective, are based on five criteria, i.e. effectiveness, efficiency, relevance, coherence and EU added value. However, the lack of systematic quantification of impacts (only partly explainable with the gradual departure from cost-benefit analysis) prevents the Commission from using ex post evaluations also as a means to verify the estimates made in the original impact assessment (Jones, forthcoming). This, in turn, leads the Commission to miss an important policy learning opportunity.

Fourth, the menu of instruments in the hands of the European Commission has significantly expanded in the past two decades. Besides ex ante assessments and ex post evaluations, the Commission has launched new types of measurements, moving from an analysis of the flow of legislation, towards comprehensive measurements of the stock. Most notable instruments in this respect are the baseline measurement of administrative burdens, launched in 2007 and covering the 43 EU directives considered to be most burdensome for businesses, and culminated in a reported (though highly criticised) 33% reduction of administrative burdens in 2012; the consultation on the TOP10 most burdensome pieces of EU legislation for small and medium-sized enterprises conducted between October and December 2021; the launch of “fitness checks” to review the acquis in specific policy sectors; and a limited number of “cumulative cost assessments” that looked at how different EU rules affected the costs of market operators in specific industrial sectors. This trend includes the “one-in-one-out” rule, a form of regulatory offsetting that is being piloted since the second half of 2021 (see below for details), which may lead the European Commission to establish a systematic link between the flow (i.e. new proposals) and the stock of EU legislation (i.e. existing legislation).

Fifth, the first two decades of EU better regulation have marked the gradual realisation of the extreme importance of oversight, and in particular the need to establish a strong, independent regulatory oversight body. While at the outset the Commission was reluctant to establish such a body, since 2007 a decision was made to appoint an Impact Assessment Board (IAB), which started examining draft impact assessments and requesting integrations or even rejecting drafts when insufficiently complete. The IAB was later replaced by a more independent Regulatory Scrutiny Board (RSB), with seven members (four high-level Commission officials and three externally recruited), enhanced powers to accompany and monitor the policy cycle, yet unfortunately a very limited support staff. There is no doubt that the RSB has had a positive impact on the whole better regulation system in the European Commission, and the board has certainly performed its duties with utmost commitment and precision:
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at the same time, its visibility and resources, as well as its ability to engage with the academic community and homologous bodies in Member States and outside the EU, have remained limited.

Sixth, the initial steps in the better regulation field were made by the Commission alone, and the implementation of the 2003 inter-institutional agreement on better lawmaking was very slow and incomplete. Since 2012, the European Parliament has set up a dedicated structure, later incorporated in the European Parliamentary Research Service, to increase its capacity in scrutinising legislative proposals, as well as performing ex post evaluations and even engaging in foresight. While this gradually led the EPRS to play an important role in the EU better regulation system, the original commitment to carry out the impact assessment of major amendments to Commission proposals (nested in the 2003 Inter-institutional agreement, and later renewed in the 2016 inter-institutional agreement on better lawmaking) was replaced by other activities, such as the assessment of European Commission’s impact assessments, ex post evaluations and implementation assessments, as well as by a very prolific production of studies on the “EU added value” and the “Cost of non-Europe” in specific policy domains. Against this backdrop, the Council, despite some attempts, has not significantly stepped up its production of impact assessments or ex post evaluations in support of the legislative process. As a result, today Commission proposals are scrutinised along the way by the European Parliament, but as they are amended during the ordinary legislative procedure, their prospective impact is not updated to reflect the amendments tabled by the other institutions, let alone the ones achieved during trilogues.

Seventh, the European Commission has remarkably expanded its use of stakeholder consultation throughout the years. The strengthening of the minimum standards for consultation (extended i.a. to twelve weeks of duration), the publication of inception impact assessments subject to a short consultation period, and the introduction of a consultation process at the end of the Commission’s work on legislative proposals multiplied the possibilities for stakeholders to have their voice heard during the period in which the Commission’s work traditionally became akin to a “black box”. The creation of the REFIT platform in 2015 institutionalised the representation of Member States and stakeholders in the better regulation system, leading to a new channel for tabling proposals to the Commission, especially in the context of the REFIT agenda, mostly devoted to legislative simplification and the reduction of administrative burdens. With the von der Leyen Commission, the REFIT platform was relabelled “Fit for Future” (F4F) platform, and its mandate was expanded beyond simplification, to encompass also opportunities provided by digitalisation and the innovation-friendliness and future-proofing of EU legislation.

Eighth, the uptake of the better regulation agenda in Member States has been patchy and extremely heterogeneous. This was confirmed by a project jointly launched by the OECD and the European Commission, which looked at developments in 15 Member States between 2008 and 2011. While the situation has not significantly changed since then, some Member States have taken action to strengthen their ability to monitor the stock and the flow of regulation. These notably include countries with a deep vocation towards the simplification of legislation and the reduction of regulatory costs, such as the Netherlands and Germany, who grouped with like-minded administrations to form a network called RegWatchEurope, mostly oriented at exchanging good practices on the reduction of administrative burdens and regulatory budgeting, and now counting eight participants (including the UK). It also includes a few Member States (in particular Denmark), which decided to abandon rigid forms of cost reduction to reorient their better regulation system towards the Sustainable

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26  https://www.regwatcheurope.eu/
Development Goals (see box 1). In most Member States, however, the better regulation agenda is under-developed, or tied to very formalistic mechanisms such as the Standard Cost Model for the measurement of administrative burdens.

Ninth, the European Commission has tried to improve its ability to engage in anticipatory, as well as flexible and innovation-friendly regulation by strengthening its focus on innovation, as well as adopting new initiatives in the domain of foresight and horizon scanning, as well as “future-proofing” policy options. The emphasis on resilience brought about by the Covid-19 pandemic has also prompted the European Parliament to start considering new tools such as the stress-testing of legislation for resilience (Fernandes and Heflich 2022). However, the integration between foresight and tools such as impact assessment and ex post evaluation seems to be in its infancy. The Commission Joint Research Centre and the Directorate-General for Research and Innovation both engage in substantial foresight activities, but examples of how these scenarios have been incorporated in the baseline options of impact assessments are still lacking. Furthermore, the introduction of an “innovation principle” in the EU better regulation toolbox, including a focus on innovation impacts of legislation, innovation deals and foresight, led to disappointing results so far (Simonelli and Renda 2019).

Last, the better regulation agenda has climbed some steps in the European Commission’s hierarchy, and since 2015 is firmly in the hands of a Vice President of the European Commission with an ad hoc mandate (Frans Timmermans in the Juncker Commission, maroš Šefčovič in the von der Leyen one). This sends a strong signal on the need to ensure coherence across Commission services, and a general orientation of the better regulation agenda towards the achievement of the EU’s political goals. Needless to say, the pandemic and the recent new economic, security and geopolitical emergency caused by Russia’s invasion of Ukraine have made it very difficult for the EU better regulation agenda to keep the pace of fast-tracked, often almost instantaneous decisions that had to be adopted. The result of this unforeseen streak of emergencies was a gradual shift towards a narrative of resilience, as well as new goals such as strategic autonomy, which were the subject i.a. of the Strategic Foresight Report adopted by the Commission last year (Cagnin et al. 2021).

As a result of these trends, today the EU can claim to have adopted an extremely ambitious, comprehensive better regulation system, which stands out as one of the most sophisticated in the world. At the same time, the system still suffers from a general proliferation of overall goals, with too many “north stars” resulting in a lack of clear direction. Moreover, most of the trends described above, from the greater political salience to the focus on innovation, the involvement of other institutions and Member States, and the opening up of the better regulation agenda to stakeholders, appear far from complete. There seems to be at least partial awareness of this issue in the European Commission, as testified by the launch of several new initiatives in the latest Communication on Better Regulation, released in April 2021.
2. CURRENT INITIATIVES TO IMPROVE THE BETTER REGULATION SYSTEM

KEY FINDINGS

- The full implementation of the Inter-Institutional Agreement on Better Law-Making may be easier if the EU better regulation agenda completed its shift away from the use of cost-benefit analysis as key criterion to select the preferred option.
- Despite the Commission’s stated intention and announced initiatives, the full mainstreaming of sustainability (i.a. the SDGs) and resilience in the better regulation agenda would require much more radical innovation at all phases of the policy cycle.
- The adoption of the One-In-One-Out rule can be compatible with the EU’s ambitious agenda only if it focuses exclusively on unnecessary costs.
- The proposed changes in stakeholder consultation can bring positive results in terms of lifting the burden on respondents, but are unlikely to solve the problem of representation.
- A better legal framework and guidance are needed on experimental policymaking as well as the use of new technologies in regulation.
- The Commission should consider carrying out post-implementation reviews of rules that bypassed the ex ante impact assessment stage due to situations of urgency or emergency.

Since the inception of the von der Leyen Commission, action was announced on each of the ten main areas mentioned in the previous section. The Communication “Joining Forces to Make Better Laws”, in defining the Commission’s better regulation system as “one of the most advanced regulatory approaches in the world”, outlines a series of possible reforms, which would potentially improve on almost all the trends and challenges outlined above, in the introductory section; and would contribute to the new goals emerged over the past two years, including the need to ensure that policies support the recovery and resilience of the EU, as well as the twin (green and digital) transition.

2.1. Reviving the Inter-institutional Agreement on Better Law-Making

The Commission reiterated its call to the European Parliament and the Council to “live up to the commitments in the Interinstitutional Agreement on Better Law-Making”, and thereby assess and document the anticipated impacts of their amendments. This step, which as already mentioned can be traced back to the 2003 Inter-Institutional Agreement, may require a stronger “political dialogue”. However, after two decades and in view of the emerging trends in the EU better regulation agenda, it is difficult to imagine that the realisation of the original commitments may be achieved any time soon; at the same time, whether living up to these commitments would be a meaningful step is increasingly questionable today, and may warrant a renewed reflection, if not a fresh start. The reasons for this assessment include the following:

- As already mentioned, while the European Parliament has made substantial progress in its handling of better regulation tools, this has not gone in the direction of a systematic ex ante appraisal of the prospective impact of amendments. The reason for this would need to be investigated more in-depth inside EU institutions: from the perspective of an external observer, there seem to be at least two important reasons why the Parliament took a different direction. The first is due to the timing of amendments: for important legislative files, different Parliamentary committees work on their amendments in parallel, and only at the end of the Parliament’s work...
plenary amendments are selected and voted upon: this leaves very little time to process such amendments, which result from political compromise, through a structured impact assessment. The second reason is that the political work of the Parliament very often responds to criteria and rationales that do not lend themselves easily to the technical application of assessment frameworks such as cost-benefit analysis: accordingly, a clearer shift towards multi-criteria analysis based on the extent to which proposals and amendments help the EU achieve its long-term goals may help the Parliament and the Commission “speak the same language” when working on legislative dossiers. Such shift, as explained in more depth below, is currently far from evident, despite the Commission’s stated intention to mainstream the Sustainable Development Goals in its better regulation agenda.

• The capacity to carry out impact assessments in the Council is still very limited, and this too may be related to two main reasons. First, progress on better regulation in Member States is still patchy and often focusing on a subset of the tools used by the European Commission (e.g. cost reduction), and this provides little support to Ministers when discussing the prospective impacts of legislative proposals (very few Member States, notably Germany, provide delegates with reports on the prospective impacts of proposals under discussion). Second, the political compromises struck in the Council often follow a very different logic than the one the Commission adopts in impact assessments, and this is far from surprising: as a matter of fact, it is very difficult to find examples of countries in which the impact assessment system was successfully implemented in parliaments, or at the highest level of government.

• The practice of addressing competing stances on important files in trilogues, often dictated by the need to speed up the legislative process, hardly fits a scenario in which all institutions work simultaneously on impact assessments. And the traditional slogan in the better regulation domain, i.e. that impact assessments should inform political decisions without replacing them, does not necessarily lead to imposing such commitment on all institutions. This, of course, does not mean that institutions such as the European Parliament or the Council should not motivate or justify why they are tabling specific amendments: but whether they should do it by adapting to the Commission’s system, or whether the latter should adapt to the ultimate logic of EU decision-making and inform inter-institutional dialogues, is an issue that is seldom addressed in the political debate.

2.2. Mainstreaming resilience and sustainability

These considerations point at another area, where the Commission identifies possible improvements: the mainstreaming of resilience and sustainability in the better regulation agenda. More specifically, the Commission wishes to ensure that “every legislative proposal contributes to the 2030 sustainable development agenda”; and to “ensure that the ‘do no significant harm’ principle is applied across all policies in line with the European Green Deal oath”. At the same time, the Commission aims at incorporating resilience in the better regulation system by strengthening the use of tools such as strategic foresight.

These commitments are to be welcomed, as they align the better regulation agenda with the long-term goals of the EU, and notably with the need for a greener, more digital and resilient society. However, at least two main problems may be worthy of enhanced attention. First, the alignment and mainstreaming announced by the European Commission require that a clear “north star” is established: at the moment, and also as a result of the proposed changes, the better regulation agenda would need to serve a multitude of purposes, sometimes leaning towards the SDGs, sometimes towards the twin (just) transition, sometimes towards resilience, at times towards maximising net
benefits, and sometimes towards reducing regulatory cost. The proliferation of (often incompatible) goals does not contribute to clarity, and may dilute the coherence and effectiveness goals that appear to be central in the EU better regulation agenda. This problem is evident also in other domains of EU legislation, such as the emerging industrial strategy (Renda 2021).

Second, if such a paradigm shift is to be achieved, then the reforms needed to implement it in practice would need to be much more ambitious and far-reaching than the ones proposed in the Communication on “Joining Forces to make better laws”. A good example is Denmark’s announced shift towards the SDGs in its better regulation agenda, reported in Box 1.
Box 1: The Danish better regulation agenda and the SDGs

In Denmark, following the new guidelines issued on 3 June 2021, each ministry, in proposing new government bills, must carry out a screening in relation to any consequences for the SDGs and the 169 sub-goals. The Ministry of Finance supports the ministries in the screening process. If a bill is deemed to have relevant and significant consequences on the SDGs, a separate ad hoc section must be included in the general comments on the bill. The assessment of the consequences for the SDGs consists of three steps, which are the starting point for all impact assessments: an initial assessment (screening), a scoping exercise, and a final assessment and dissemination.

**Step 1 - Initial assessment (screening).** A screening is carried out to assess whether the bill concerns issues that are covered by one or more of the SDGs. It can e.g. be a bill that concerns health and well-being (SDG 3), education (SDG 4) or the climate (SDG 13). In their contributions to the legislative program, the line ministries state their immediate bid for whether the individual bills relate to themes covered by the world goals, and whether the proposals are deemed to have relevant and significant consequences for the achievement of the world goals. The Ministry of Finance reviews the contributions to the bill and, if necessary, enters into a dialogue with the line ministries regarding their assessment of which bills are immediately considered to have relevant and significant consequences for the fulfilment of the global goals. When the line ministries - possibly after dialogue with Ministry of Finance - have identified the bills that are immediately considered to have consequences for the achievement of the world goals, a more detailed assessment of the consequences of these bills must be made (step 2).

**Step 2 – Scoping.** The Ministry of Foreign Affairs conducts a more detailed assessment of the bills that relate to areas covered by the SDGs, with a view to selecting the bills that have significant and relevant consequences for the fulfilment of the world goals in a Danish context. It depends on a concrete assessment whether the consequences of a bill must be considered significant and relevant. In assessing materiality, particular emphasis should be placed on the extent of the consequences. The greater the consequences, the more important it is to assess the impacts. In relation to relevance, it is noted that several sub-goals state objectives that Denmark already meets, and which today are primarily of relevance to developing countries. The Leave no one behind agenda can be highlighted if it is deemed to be relevant and significant in connection with the assessment of a sub-goal. Finally, there may be concrete grounds for assessing the consequences for global development and developing countries if they can be assessed without major difficulties and assessed as relevant and significant. In the assessment, the ministry should uncover the immediate consequences for the sub-goals (in the short term). The long-term consequences can be elucidated if they can be assessed without major difficulties, and it is possible to give a reliable picture of this. Importantly, only the direct consequences of a bill must be analysed. The indirect consequences can be elucidated if they can be assessed without major difficulties.

If the line ministry concludes that a bill has significant and relevant consequences for the achievement of the SDGs, an actual impact assessment must be prepared, which is included in the comments on the bill (step 3).

**Step 3 - Final assessment and dissemination (assessment).** In bills that have significant and relevant consequences for the achievement of the SDGs, a separate point in this regard is included in the general comments on the bill. The point must briefly describe how the bill is expected to affect the relevant sub-objective or objectives. Normally, the analysis is qualitative, but where possible a quantitative assessment is also included.
The impact assessment of the SDGs is placed as the last item before the mandatory impact assessments (ie before the item on economic impact and implementation impact on the public sector). The title of the section is entitled “Consequences for the achievement of the UN’s world goals”. It is noted that in some areas there will be a thematic coincidence between the SDGs and existing points in the bill. Bills contain e.g. already today mandatory points on climate consequences and environmental and natural consequences, just as, where relevant, a separate point on gender equality consequences is already included today. In such cases, the section on the SDGs may be limited to a remark that the bill is assessed to have positive or negative consequences for the fulfilment of a specified sub-goal, as well as a reference to the item where the topic is discussed in more detail.

If a bill is not considered to have significant and relevant consequences, this must not be stated in the comments.


2.2.1. Mainstreaming sustainability in impact assessment

It can be useful to imagine how full mainstreaming of the SDGs could work in the European Commission’s impact assessment system. Figure 1 below shows a stylised description of the regulatory governance cycle developed by the OECD (2011). In the cycle, administrations wishing to introduce new regulation perform an ex ante regulatory impact analysis, comparing alternative policy options for the achievement of a given objective, or the solution to a given market or regulatory failure; in carrying out this activity, administrations often are asked to carry out stakeholder consultation, commission external studies, and consult other institutions (e.g. competition authorities) to obtain an opinion on specific impacts. The administration is then called to regularly monitor the impacts of the regulation at hand and evaluating ex post whether there is a need for reform. In this constant cycle of ex ante RIA and ex post evaluation, administrations must coordinate, cooperate, consult stakeholders and other institutions, and communicate internally and to the public the process and results of their activities.

Figure 1 – The “regulatory governance cycle”

Source: OECD (2011)
The changes that will be needed in order to fully complete the mainstreaming include the following.

- During the *agenda-setting* phase, regulatory oversight bodies such as the RSB and other institutions in charge of legislative planning should assess the legislative proposals that have a significant potential impact on sustainability and its related sub-goals. They could also use the information on the urgency of tackling specific aspects of sustainability and the possible inter-linkages between sustainability indicators, in order to potentially flag the most systemically important proposals. When presenting the legislative work plan for the following period, the European Commission could develop a “heat map”, showing the sustainability areas and indicators that are most affected by the proposals to be tabled. The heat map can also become a communication tool, as well as a monitoring tool, which can flag areas that are less directly addressed by the action of the government.

- In *ex ante impact assessments*, the following changes would be needed:
  - The problem definition should not only reflect the need to address market failures or regulatory failures, but rather the need to achieve one or more of the targets through proactive policy action in specific areas. Ideally, impact assessments should identify the SDGs that are critically affected by the problem identified, as well as those indirectly affected, and justify intervention on the basis of a dynamic, prospective analysis of how the identified problem would evolve absent government intervention. A so-called “heat map” of the targets that are directly/indirectly and positively/negatively affected by the problem identified would be a very valuable instrument in the early phases of the *ex ante* impact assessment process.
  - When defining the *general objectives* of the proposal, the Commission services must refer to the SDGs that will be primarily affected, and the ones that will be only marginally affected, by the proposed policy. Ideally, every new legislative proposal should be justified in terms of its contribution to the SDG agenda. The specific objectives should then refer to the individual targets that will be affected by the proposal, whenever the need to achieve those targets is the underlying motivation for the initiative.
  - Any *public consultation* conducted on draft impact assessments should contain specific questions related to the targets, to help the administration collect more accurate and complete information on the possible impacts of alternative policy options. This implies, i.a. that a dedicated section is included in the consultation document, covering the possible impact of the proposed action, and calling for evidence on such impact.
  - The methodology currently used to compare alternative policy options would need significant adjustments to reflect the renewed focus on long-term goals. This involves in particular the transition from standard cost-benefit analysis, which mostly aims at economic efficiency, towards multi-criteria analysis based in adequate indicators and methods. Here too, different levels of ambition are possible. A relatively minor change would be that the Commission maintains its analysis of the costs and benefits of alternative policy options, but then ranks them also based on their effectiveness in contributing to the SDGs; more ambitious changes would imply the use of a more structured multi-criteria analysis, a structured set of weights to be given to different positive or negative policy impacts; or directly a non-linear social welfare function, which reflects the need to account for inequality and welfare distribution when dealing with policy evaluation, and could be used at least as a sensitivity analysis tool. Another possibility would consist in applying the same “SDG Synergies” approach used to prioritise specific goals to assess the impact of alternative policy options on the level of urgency,
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interlinkages and overall distance from the frontier. This approach could also offer an interesting perspective for the European Parliament and the Council, in choosing among alternatives.

- The choice of monitoring and evaluation indicators would need to be more directly related to the expected progress towards specified targets. As a general rule, the Monitoring and Evaluation section of the impact assessment should always contain a reference to sustainability indicators: this would be logical and coherent, since the objectives of the proposed policy measure also refer to the sustainability agenda.

- The ultimate stage of using better regulation as a tool of policy coherence for sustainable development would be reached if annual or six-monthly reporting on the state of advancement towards sustainability goals was used as a benchmark to prioritise certain impacts over others and guide the administration in navigating uncertainty whenever trade-offs emerge among different policy goals.

2.2.2. A new frontier: incorporating resilience and well-being in the regulatory cycle

Ensuring that resilience features more prominently in the better regulation agenda would require another set of reforms, which are sketched below.

*Step 1. Further strengthen the use of foresight, science advice and communication.* As mentioned, the von der Leyen Commission has brought together foresight and better regulation under the portfolio of the Vice-President for Interinstitutional Relations and Foresight. This is a welcome move that should, however, be complemented with measures aimed at making more use of foresight and horizon scanning results in various steps of the better regulation system. However, translating the findings of foresight exercises into daily policy practice is far from straightforward, and is complicated by the fact that investing in resilience “before the event” is unlikely to be a popular decision with citizens: collective bounded rationality typically leads to “hyperbolic discounting”, or the systematic downplaying of low-probability events. This tendency, already strong in most governments, is further exacerbated by deteriorating trust in science (already before the pandemic), and also by the fact that policies are crafted and adopted in the attempt to minimize costs, and thereby often eliminate any redundancy or excess capacity in the name of efficiency (see below). Governments that speak the “less is more” language, just as businesses that pursue cost advantages in global supply chains, are unlikely to take into account resilience to a full extent. One way to promote resilience-oriented investments would be to strengthen science-based advice to policymakers, both “before” and “after the event”. In many legal systems, including the EU, existing bodies devoted to scientific advice have proven to be unable to help policymakers when the pandemic started to emerge.

*Step 2. Stress-test policies periodically to check their resilience.* The need to embed stress-testing of policies in the policy cycle, in the form of regular interim evaluations, was already felt by policymakers in the aftermath of the financial crisis of 2007-2008, and later with the Fukushima nuclear disaster in 2011. Stress-testing of policies should, in the post-pandemic age, be made a key step in the ongoing monitoring and evaluation of the legislative and regulatory stock (Fernandes and Heflich 2022). This implies that, rather than merely evaluating the prospective impacts of new policies (or spending programmes) at the proposal stage, and performing ex post evaluation a few years down the road, governments perform interim evaluations that incorporate resilience-related questions during intermediate steps of the policy cycle. Alternatively, a more systemic approach to testing the resilience of entire policy domains of a critical nature (e.g. financial markets; the agrifood chain) could be adopted. Such an approach (which would echo the early experience of the European Commission
with the so-called “fitness checks”, which however did not incorporate resilience-oriented analysis) could perhaps provide a clearer view of the robustness of entire legislative corpora. As of today, the practice of policy evaluation and regulatory oversight does not incorporate, in any country, suitable instruments for the analysis of systemic resilience. Future research and public sector training should be oriented towards using enhanced simulation (e.g. “digital twins”; general equilibrium models) to perform resilience testing of existing rules and policies. These implies a rather new set of skills, which future policymakers will need to develop. The European Parliament has launched a study on the possible stress-testing of EU policies for resilience, which may lead to interesting developments (Fernandes and Heflich 2022).

Step 3. Embed resilience (or the lack thereof) in the problem definition phase. The theory and practice of policy evaluation has traditionally emphasised problem definition as one of the most important phases of the whole better regulation toolkit, and in particular the ex ante impact assessment phase. However, when governments define the problem and thereby justify legislation or regulation, they are typically constrained by the need to identify either a market failure, or a regulatory failure. In other words, the mainstream approach to ex ante impact analysis does not contemplate acting to improve systemic resilience. This, coupled with the absence of foresight and stress-testing techniques, leaves policymakers practically without arguments backing any proactive legislative proposal aimed at remediing a lack of resilience observed in the system, or in a specific part thereof. Addressing this problem requires that better regulation guidelines recommend that governments contemplate acting to address a resilience-related problem. Importantly, resilience-related problems will often clash with the overarching criterion currently used to decide on the desirability of a given public policy, i.e. economic efficiency in the sense of the maximisation of net benefits (see next step). The quest for resilience-oriented public policy can become even more frustrating in the presence of badly designed “regulatory offsetting” mechanisms, or regulatory budgeting, especially since these mechanisms oblige administrations to identify one or more regulatory provisions to repeal or drastically simplify, whenever they want to propose new regulation. Such an approach, unless carefully designed, can encourage governments to slim down the regulatory stock to the essential, potentially removing resilience-enhancing provisions. As the European Commission recently announced that it will start adopting regulatory offsetting (“one-in-one-out”), as well as foresight, the compatibility of such an approach with a resilience-oriented mindset will be put to the test.

Step 4. Mainstream resilience in multi-criteria analysis. Alongside sustainability goals, future multi-criteria assessment of alternative policy options may have to incorporate specific resilience-oriented criteria, perhaps drawing on the work of the JRC on the resilience dashboard. This, too, may require a departure from standard cost-benefit analysis (CBA): difficulties in translating risk into monetary values often leads to an under-representation of risk in CBA frameworks; CBA, in its most classical form, ignores distributional impacts, which places decisionmakers in a position of virtual indifference between solutions that enhance resilience by catering for all potential systemic weaknesses, and solutions that focus on concentrating benefits in the hands of the few; and finally, several other reasons stand between the use of CBA and the objective of resilience, including methodological individualism, as well as the equation of income with well-being. More generally, the use of CBA is incompatible with resilience since it is fundamentally a “bottom-up” exercise, in which benefits from public policies can only be justified as such when they are expressed, either implicitly or explicitly, in terms of the willingness to pay of citizens for impacts triggered by policy reform.

Step 5. Consider resilience in the selection and analysis of policy alternatives. One lesson learnt from the first two years of COVID-19 pandemic is that decentralised, redundant governance models appear to be more able to absorb shocks than more centralised ones. Observing the different resilience
characteristics of alternative modes of governance is not common in the daily practice of policymakers. However, **shifting towards a more resilience-oriented approach might make the consideration of alternative (more decentralised) governance options more compelling.** Guidance on this aspect is currently missing in the Better Regulation Toolbox, and not a feature of the mix of competencies requested for the members of the regulatory Scrutiny Board.

### 2.2.3. Towards a renewed policy cycle?

Figure 2 below summarises the way in which the steps described above would contribute to the EU policy cycle, using the traditional view of the regulatory governance cycle adopted by the OECD. When reading the Communication on “Joining Forces to Make Better Law”, it emerges that the Commission has made important steps towards introducing some of these new features, but several other steps are still missing. These include, broadly speaking, the definition of sustainability and resilience as motivations for intervening (agenda-setting); and the repurposing of assessment, monitoring and evaluation tools related to both the stock and the flow of legislation, to embrace a “beyond CBA” approach that closely echoes the Commission’s current move towards a “beyond GDP” approach in public policymaking.

Figure 2 – A resilience- and sustainability-oriented regulatory governance cycle

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**2.3. Simplifying EU legislation and the “one-in-one-out” rule**

Another proposed set of reforms announced by the European Commission include the adoption of measures to ensure the reduction of regulatory costs, and the management of the costs associated with the whole regulatory stock. These include the empowerment of the EU SME envoy to help screen EU initiatives and identify where the impact on SMEs requires special attention; the launch of the Fit for Future Platform, and most notably the announcement of the piloting of a regulatory budgeting system known as “one-in-one-out” (OIOO). While the impact of the first two measures is hard to assess, and only time and implementation will provide evidence that they were helpful, some comments can be provided on the OIOO system.
The European Commission (the institutions that initiates new legislative and regulatory proposals) has traditionally been very reluctant to introduce such a rule (Renda et al. 2019). This is understandable, also since the Commission has limited control of what its co-legislators, the Parliament and the Council, do in terms of introducing costly amendments on its proposals; and since regulatory costs can also depend on the way in which EU Member States transpose and implement legislation (especially in the case of so-called gold-plating or double banking practices). In 2019, however, the newly elected President von der Leyen, announced her intention to introduce the OIOO principle “to cut red tape”.27 The Communication on “Joining Forces to Make Better Laws” (European Commission 2021) announced that the Commission will “strengthen the burden reduction effort further through a ‘one in, one out’ approach whereby, when introducing new burdens, we systematically and proactively seek to reduce burdens imposed by existing legislation” (European Commission 2021). The OIOO approach will now complement the REFIT program by helping the European Commission pay special attention to cumulative costs for individuals and businesses in a given policy area and by covering new initiatives.

The OIOO approach presented by the Commission is still rather vague, but the following features are already defined: for every new legislative initiative generating administrative burdens, the Commission services will need to identity one or more provisions to modify or repeal, such that the cost increase would be offset. The system allows no trading: offsets normally have to be found in the same policy area; however, if it is not possible to find an ‘out’ in the same area, the Commission can decide to take the ‘out’ from a different policy area). Moreover, the OIOO rule will be not applied mechanically, and will allow for some flexibility. The Commission states that “if an ‘out’ cannot be identified in the same year’s work programme, it will be reported in the next year”. In general, the Commission will report on the annual implementation of the OIOO approach in its Annual Burden Survey, towards the end of the solar year. Moreover, if there is political will to regulate, but it is not possible to identify an offset in the same area, the Commission can decide to exempt the regulation from the OIOO approach.

While the features of the system place it in line with the best international practice, there is reason to believe that the Commission could have made additional efforts to ensure that the OIOO rule is not implemented to the detriment of its ambitious regulatory agenda, especially considering the Green Deal and the Digital Decade programmes. In a recent report, I have explained in detail how emphasis on “unnecessary costs” (i.e. costs that can be reduced without impinging on the benefits, for example through digitalization, codification, consolidation of legislation) would be absolutely necessary to accommodate a rule that, otherwise, could work against the legitimate ambition of the Commission to regulate for the twin transition. Such focus, however, remains only in the title of the relevant section in the Communication “Join Forces to Make Better Laws”; the text does not make any reference to this concept, and this appears to be a major issue for a rule that is surrounded by fierce criticism especially among civil society organisations.

2.4. Improving consultation and communication with stakeholders

One important area in which the Commission wants to improve the better regulation agenda is stakeholder consultation. Evidence of “consultation fatigue”, especially with the proliferation of new proposals tabled by the von der Leyen Commission during its first two years in office, led the Commission to attempt to simplify the procedures, and streamline its communication channels with stakeholders. Key initiatives include the consolidation of public consultations on the same initiative into a single ‘call for evidence’, to be published on the “Have Your Say” web portal with a 12-week

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deadline for responding. Calls for evidence will bring together two previously separate consultation instruments, i.e. the consultation on roadmaps/inception impact assessments, and public consultations based on questionnaires. The Commission also announced that, in case of “back to back” ex post evaluations and ex ante impact assessments, it plans to consult only once, thereby reducing the burden for respondents. To further ease such burden, it will try to improve the structure, content and language of questionnaires, striving for an optimal balance between open and closed questions. Respondents will also see their submission explicitly considered by the Commission, in a summary report that will be published within eight weeks from the end of the consultation period. Finally, the Commission announced more transparency-oriented measures, including openly available repositories of models such as MIDAS, developed by the JRC.

All in all, these appear to be rather minor adjustments to a system that, as already explained, is already extremely comprehensive. However, the Commission could have taken more ambitious steps to explain how it plans to collect data and evidence and use it in impact assessments and ex post evaluations: at the moment, no explicit data quality standards apply in the European Commission, even if important work seems to be underway at Eurostat to support the use of data in EU policymaking. Understanding what data were used, and how, is key for stakeholders to be able to validate the findings of the Commission. Moreover, the hope is that the calls for evidence will be published on draft documents (the roadmaps, or inception IAs), which are sufficiently complete, so that the main elements of the impact assessments are already sufficiently visible. Otherwise, it would be very complicated for stakeholders to meaningfully comment on an emerging initiative. In practice, what has happened is that stakeholders end up submitting their opinions to communications of White Papers, even before they comment on roadmaps or inception IAs. At the same time, since 2015 consultation is also available after the adoption of the Commission proposal: the usefulness of this additional step, potentially very important if coordinated with the work of the European Parliament, has not been subject to sufficient debate over the past years.

Finally, the proposed adjustments to the stakeholder consultation process, while welcome and meaningful, will not necessarily address the issue of under- or over-representation of specific stakeholders. The Commission should, in this respect, explain what strategy it will follow to ensure that those organisations and communities that are minorised and systematically under-represented “have their say” on an equal footing with powerful business associations and political groups. Simply promoting the Have Your Say portal may not be sufficient in this respect; at a minimum, the Commission should explain how it plans to avoid what often appears as an “availability bias”, i.e. the tendency to consider the average results of all submissions, without adequately distinguishing between specific groups, and considering the different resources and ability of specific groups to make their voice heard. Besides, it may consider using existing and innovative means of consulting citizens and specific groups, from focus groups to dedicated workshops and even interactive digital tools that aim at promoting empathy across citizens or societal groups.

2.5. What is missing?

The proposed initiatives appear guided by an intention to fine-tune, rather than fundamentally overhaul, the better regulation agenda in the European Commission. In many respects, this is logical as the perception inside the Commission (and as explicitly stated in the Communication) is that the system is already a world-class example of better regulation agenda. At the same time, there are at least four dimensions (in addition to the ones mentioned above) that the proposed initiatives do not fully tackle, and which would warrant attention in the coming years.
First, the Commission should explicitly tackle the issue of decisions adopted under emergency, by adopting measures that go beyond the mere presentation of the rationale for intervention within 3 months from adoption. The problem has become more entrenched in the EU better regulation agenda, and started even before the Covid-19 pandemic, for example with the adoption of ad hoc simplified formats during the negotiations for the multiannual financial framework 2021-2027. With the invasion of Ukraine, and the still enduring pandemic, the cases in which the Commission will be faced with emergency decisions to adopt may become almost a “new normal”. One possible solution could be the introduction of the possibility, for the Commission, to expedite a post-implementation review (PIR) of adopted decisions, which would replace the ex ante impact assessment but would still enable the possibility to gather evidence, at a slightly later stage, related to the prospective impact of recently adopted legislative initiatives. Such a possibility already existing in a fistful of OECD countries including i.a. Australia, where a PIR is required for major regulations with substantial impact on the economy, within two years from the implementation, whenever (i) the regulation has been introduced, removed, or significantly changed without an ex ante impact assessment; (ii) the Prime Minister granted an exemption from the impact assessment requirements when the regulation was first introduced; or (iii) an agency sufficiently diverges from best practices in their preparation of an ex ante impact assessment (OECD 2018).

Second, the Commission should clarify how it intends to use scientific advice and data in support of regulation. Besides foresight, already addressed in the previous sections, the many scientific advice mechanisms available to the European Commission, coupled with enhanced data availability from Eurostat, could significantly aid the drafting of comprehensive ex ante impact assessment. At the moment, however, the Joint Research Centre, I.D.E.A., the Science Advice for Policy by European Academies (SAPEA) and the Group of Scientific Advisors could provide important inputs into the shaping of the EU agenda, and some of them are increasingly geared towards serving that role in the context of the EU better regulation agenda. Taking stock of how these groups and bodies have performed during the pandemic would be a good starting point for devising solutions in this important domain. In addition, important inputs such as the Foresight Report (this year, dedicated to Strategic Autonomy) and the institution of a Strategic Compass in the domains of security and defence can further contribute to the definition of the problem, as well as of the general and specific objectives of specific new legislative initiatives.

Third, despite the plethora of tools available to Commission services in the Toolbox, the use of experimental policymaking in the form of regulatory sandboxes and similar instruments remain orphan of a general framework at the EU level, which would allow Member States to engage in experimental policymaking. As it stands, Tool #69 on “Emerging Methods and Policy Instruments”, however laudable, risks providing only a theoretical opportunity for Commission policymakers, rooted in the possibility to include provisions for sandboxes in the legislative texts, rather than engaging in experimentation themselves, or relying on a structured process of experimentation in Member States while proposals are still in the making.

Fourth, and relatedly, the cases in which the Commission will have to rely on regulatory approaches that make use of technological solutions and specific technical standardisation processes are likely to become more recurrent in the practice of regulation. Solutions such as RegTech and SupTech options, as well as reliance on algorithmic inspections (in legislation such as the Digital Services Act or the Digital Markets Act, and the Artificial intelligence Act) require guidance and ad hoc skills. Moreover, complementing principles-based legislation with technical standards is becoming almost inevitable in the EU digital acquis, as seen in the latest yearly Commission annual Work Programme on Standardisation for 2022, which features important initiatives related to the Data
Act (regulation of smart contracts) and the AI Act (on Auditing of AI systems). Guidance on this aspect, and on the pros and cons of adopting more or less prescriptive legislation, to be coupled with delegated acts and/or technical standardisation, would be welcome.
3. CONCLUDING REMARKS: THE WAY FORWARD

KEY FINDINGS
The EU better regulation system is certainly very sophisticated. However, the recently announced initiatives of the European Commission in the field of better regulation appear insufficiently ambitious, since they:

- Insufficiently mainstream sustainability and resilience in the better regulation system;
- Lack clarity on the focus of the One-In-One-Out rule and its relation with the EU’s proactive regulatory agenda;
- Do not take steps to make the Better Regulation Toolbox more accessible to Commission services;
- Do not introduce a clear legal framework for experimental policymaking;
- Do not provide guidance on how data and new technologies can be used in regulation, monitoring and oversight.
- Do not create more visibility and interest around better regulation and the work of the RSB. One possible change going forward, to be subject to further discussion, could be the appointment of a Chair of the RSB recruited from outside the Commission.

This Study has explored the main ongoing trends and recent initiatives in the EU better regulation agenda. While consolidated and well-established, the agenda would require more courageous steps to ensure that it becomes the engine of the realisation of the EU’s long-term vision of resilience and sustainability, rather than a technical exercise disconnected from the policy priorities. At the moment, despite clear evidence of steps in the direction of coherence with EU priorities, the agenda remains halfway between systems originally conceived for purely technical decisions (the United States), and a system that backs ambitious policies and regulatory agendas with evidence and tools for monitoring and oversight.

The main recommendations that emerge from this analysis can be summarised as follows:

- **Insufficient mainstreaming of resilience and sustainability.** The Commission should make additional steps to fully mainstream its long-term goals into the ex ante impact assessment and ex post evaluation tools. This requires a series of changes, which may not necessarily be incremental, but may also mark a clearer change of direction for an institution willing to move away from a growth-based logic, towards a new compass for policymaking. The future of the Inter-institutional Agreement on Better Lawmaking may be linked to a clearer shift towards multi-criteria analysis focused on EU long-term goals, which may greatly help the Parliament and the Council in their contribution to the shaping of new policies.

- **Lack of clarity on One-In-One-Out.** It is essential that the European Commission provides guidance to its services on the notion of unnecessary costs, in a way that reconciles the legitimate goal of reducing costs with the EU priorities, linked to sustainability and resilience.

- **Improve accessibility of the Better Regulation Toolbox.** The toolbox is becoming longer and more complex at every update, to the extent that its user-friendliness for services can be questioned. Focusing more clearly on key decisions on how to approach specific problems and turning the toolbox into an interactive, user-friendly guide, may offer services an easier and more informative access to this very valuable repository of tools.
• **Experimental regulation is still largely undefined and lacks a legal framework.** A general experimentation clause, coupled with a suitable governance for defining the key features of experiments, coordinating national initiatives and sharing best practices, could greatly benefit the practice of adaptive regulation in Europe.

• **Foresight does not yet translate into a coherent approach to the baseline.** The move towards more integrated foresight is as challenging as it is laudable. The key additional steps would be to define ways for Commission services to integrate strategic foresight (i) in the definition of objectives in ex ante impact assessments; (ii) in the definition of the baseline, by inspiring common or at least coherent baseline options across the Commission; and (iii) in the approach to the “relevance” criterion in ex post evaluations.

• There is a need for **greater guidance and oversight of how data and new technologies** (e.g. AI) can be used in support of better regulation, in particular for what concerns new approaches to regulation (e.g. SupTech) and the possible role of technical standards as complements to regulation.

• The establishment of the Regulatory Scrutiny Board has certainly been a positive step, with a small but cohesive group of experts performing their function with great commitment. That said, the RSB has not been able to achieve the level of visibility and engagement with the outside community (in particular, academia) that similar bodies (e.g OIRA in the United States) have managed to achieve over the past decades. Its ability of “speaking truth to power”, as well as tabling innovative approaches to known and unknown problems, has remained constrained by its institutional design, which in turn condemned the better regulation agenda, despite its crucial importance, to remain rather hidden in the debate on the governance of the EU. One possibility to step up the importance and contribution of the RSB, in addition to hiring technical support staff, could be the **appointment of one of the external members (normally, academics or expert practitioners) as chair of the RSB**, and tilt the internal balance towards a majority (4-3) of external experts.

Table 1 below contains a summary of the outstanding problems in the EU better regulation agenda, the solutions proposed by the Commission, and the recommendations formulated in this Study.
Table 1: Summary of main issues, solutions and recommendations

<table>
<thead>
<tr>
<th>Key issue/need</th>
<th>Commission’s proposed initiatives</th>
<th>Recommendations in this paper</th>
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| **Fully implementing the Inter-Institutional Agreement on Better Law-Making** | - Commission urged the Parliament and Council to document the effect of their amendments in terms of anticipated impacts.  
- Member States should provide the Commission with feedback on its estimates of the benefits and costs associated with specific pieces of legislation after they have implemented them. | - Departing from cost-benefit analysis may facilitate the dialogue between the three institutions involved in the ordinary legislative procedure  
- Member States could usefully contribute to a dialogue based on sustainability and resilience, by offering analysis related to territorial impacts |
| **Embracing the EU sustainability agenda**                                        | - Commission will identify relevant SDGs for each proposal and examine how the initiative will support their achievement.  
- Links to the SDGs will be included throughout evaluations and impact assessments. | - Measure and prioritise SDGs (or related goals, e.g. Green Deal targets) at the agenda-setting phase; and identify synergies between SDGs/targets  
- Embed SDGs in the problem definition and in the general and specific objectives  
- Publish a “heat map” on SDGs to the inception IA  
- Specific modules and questions on the SDGs to stakeholder consultation  
- Compare alternative policy options in terms of their impact on the SDGs (multi-criteria analysis)  
- Monitor and evaluate adopted pieces of legislation in terms of their progress on the relevant SDGs |
| **Embracing the resilience agenda**                                              | - Integrating Strategic Foresight in policymaking  
- Future-proofing EU policies through strategic and science-based foresight | - Strengthen and integrate scientific advice  
- Foresight and horizon scanning results should contribute to a common or at least coherent baseline for all Commission proposals  
- List the need to strengthen resilience as a motivation to intervene with policy measures  
- Embed resilience in the problem definition  
- Compare options, where relevant, in terms of their impacts on indicators of resilience (multi-criteria analysis)  
- Stress-test policies based on their resilience (“relevance” criterion in interim evaluations) |
### Better regulation in the EU

<table>
<thead>
<tr>
<th>Issue</th>
<th>Proposed Solutions</th>
<th>Notes</th>
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| **Expansion of tools to simplify the regulatory stock and reduce administrative burdens** | - Launch of the “one-in-one-out” system  
- Fit For Future platform | - Need to focus the “one-in-one-out” system on unnecessary costs |
| **Lack of impact assessment for decisions adopted under emergency**   | - Publish the rationale within 3 months                                           | - A post-implementation review within two years of implementation |
| **Focusing on innovation, regulatory sandboxes and foresight**       | - Fit for Future platform  
- New Tool#69 in the Toolbox                                                      | - A clear legal framework and guidance to Member States on experimental policymaking  
- Guidance on how to regulate by using new technologies (e.g. SupTech)  
- The Toolbox should become an interactive atlas, easier to consult for civil servants |
| **Stronger regulatory oversight board**                               | None                                                                             | - Consider appointing a highly reputed Chair that is external to the Commission services |

Source: Author
REFERENCES


THE WAY FORWARD FOR BETTER REGULATION IN THE EU – BETTER FOCUS, SYNERGIES, DATA AND TECHNOLOGY

In depth analysis requested by the JURI Committee (August 2022)

AUTHOR: Giovanni SARTOR, European University Institute of Florence; University of Bologna

Abstract

This in-depth analysis, commissioned by the European Parliament’s Policy Department for Citizens’ Rights and Constitutional Affairs at the request of the JURI Committee, looks at the use of data for the purpose of regulatory assessment/evaluation. The author finds that data is needed to support evidence-based regulation, that information technologies, and in particular AI, can enable a more extensive and beneficial use of data, and that the use of data in ex-post evaluations can improve the regulatory process. The in-depth analysis offers policy recommendations.
EXECUTIVE SUMMARY

The accelerated growth of data has been counterbalanced by the development of technologies for storing and processing data in such a way as to enable efficient use of vast resources. Moreover, thanks to artificial intelligence and data-analytics such vast datasets can be exploited to extract useful information. Governments, at all levels, must improve their ability to access data that are relevant to defining and implementing policies, and to process such data as needed.

The efficient and effective use of data in the public sector requires governments to engage in data governance, i.e., to design data policies, implement them, adopt appropriate regulations, involve actors with the requisite skills, create a data infrastructure, and define technical architectures. Data are essential to anticipatory governance, as they support forecasting, foresight, policy design and policy evaluation.

Figure 1: Data governance in the public sector

The collection/generation, curation and processing of data involves costs, as well as benefits. Costs may be reduced by reusing and repurposing the data. In particular, data collected for the purpose of implementing a policy can be reused for the purpose of evaluating the policy and possibly reforming it.

Computing techniques can be applied to (big) data to do descriptive, predictive and prescriptive analytics. Thanks to AI (machine learning), the very models used for this purpose can be automatically learnt (partially or totally) from vast datasets. Through prediction and simulation, the effects of regulations can be anticipated and assessed.

Technologies to support drafting of legislation can be woven into synergy with technologies to assess/evaluate outcomes. Different approaches may be adopted for regulatory assessment, which make different informational demands. More inclusive multi-criteria approaches for assessing regulatory impacts, such as the UN sustainable development goals, require additional data.
To make data-collection cost effective and sustainable, it is necessary to design data collection and creation policies under which data are automatically produced as a side effect of administrative processes, resulting from the actions by governments and citizens. Private companies have excelled at collecting data in providing services. The same should apply to governments. Data protection and ethical issues pertaining to data collection should be considered from the very start, so that the data processing respects data subjects' right and meet their factual and normative expectations. Risk reduction measures should be adopted, in accordance with the principles of data protection by design and by default (Art. 25 GDPR), with a particular emphasis on the anonymisation or pseudonymisation of data.

The uncertainty of ex-ante assessment, even when carried out by relying on the best methodologies and on adequate datasets, underscores the significance of both interim monitoring and ex-post evaluation. Interim monitoring and ex-post evaluation provide evidence of the outcomes, support democratic dialogue with evidence, contribute to government's accountability toward elected assemblies, such as the European Parliament.

The traditional policy cycle is characterized by evaluations happening at the very end of policymaking. It should now be possible to take advantage of instantaneous or near-instantaneous data processing, so that evaluation results become available the very moment data arrives. Rather than being a neatly defined step at the end of the policy cycle, the evaluation of policies could take place continuously, opening permanent possibilities of reiteration, reassessment, and consideration.

Interim monitoring and ex-post evaluation enable legislators to control the effectiveness and efficacy of the measures proposed, assessed, and implemented by executive branch. Thus, they contribute to ensuring the accountability of towards elective bodies. Parliamentary committees and units should place themselves at the apex of the accountability structure and make efforts to be widely known as the prime location and focus of ex post legislative evaluation, so that information, research and analysis is submitted to them as a matter of routine.

Given the importance of regulatory assessments and evaluations for the EU Parliament, the JURI Committee should consider setting up a permanent Working Group on Better Regulation, to ensure a more active and persistent critical involvement by the Parliament. The Working Group should systematically contribute to identifying shortcomings and proposing improvements, with a special focus on data practices and corresponding technologies, and with the support of academic and research institutions.
Table 1: Policy recommendations

<table>
<thead>
<tr>
<th>Policy recommendations:</th>
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<tbody>
<tr>
<td>1. The public sector should catch up with the private sectors in the capacity to collect and use data.</td>
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<td>2. Better and larger datasets should support the policy cycle, for the purpose of forecasting, foresight, policy design, assessment, and evaluation.</td>
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<td>3. The cost and benefits of data collection, curation and use should be considered, and addressed by adopting cost-effective solutions, also involving the reuse and repurposing of data. The statistical processing meant to provide aggregate information should be distinguished from the processing of personal data meant to provide individualised outcomes.</td>
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<tr>
<td>4. The opportunities offered by AI for collecting and interpreting data, extracting aggregate information though analytics, and exploring scenarios and possible developments through simulation, should be exploited.</td>
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<td>5. The need to support multicriteria evaluations with appropriate data, according to methods such as the UN sustainable development goals, should be considered. Quantitative metrics should be used whenever possible, consistently with the nature of the data and the goals pursued.</td>
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<td>6. Compliance with law and ethics should be ensured, as to uphold the rule of law, respect citizens’ rights, and foster trust.</td>
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<tr>
<td>7. Predictions should be matched against reality through monitoring and evaluation. An ex-post evaluation should accompany every ex-ante regulatory assessment, making it possible to adjust policies, in a process that contributes to democratic debate and makes for greater government accountability.</td>
</tr>
<tr>
<td>8. To expand and facilitate the role of the European Parliament in participating in the Better Regulation process and in contributing to its improvement and reform, the JURI Committee should consider setting up a Working Group on Better Regulation.</td>
</tr>
<tr>
<td>9. A platform involving academic and research institutions could be created, with the task to identify strength and weaknesses of the Better Regulation process, and propose methodologies and technologies to make it more effective.</td>
</tr>
</tbody>
</table>
1. DATA IN THE PUBLIC SECTOR

KEY FINDINGS

The accelerated growth of data has been counterbalanced by the development of technologies for storing and processing data in such a way as to enable an efficient use of vast resources. Moreover, thanks to artificial intelligence and data-analytics such vast datasets can be exploited to extract information. Governments, at all levels, need to improve their ability to access data that are relevant to defining and implementing policies, and to process such data as needed. The combination of AI and Big Data could improve government’s performance across different dimensions such as detecting social issues, predicting the effect of policies through analysis and simulation, and supporting the tailored decision of individual cases. Much progress in the efficiency and effectiveness of public action can be achieved through a lawful and ethical use of data in the public sector.

It is well known that in the recent years we have witnessed veritably a “data deluge.” The amount of data that is available, has increased at an accelerated pace, as human life has transferred online, and most economic, administrative and social processes are computer mediated. At the same time the cost of data storage and processing has shrunk significantly. More data have been stored in the last few years than in all humankind’s pre-computer history.

Figure 2: The growth of the datasphere

The data deluge has indeed been countered by the development of technologies for the storage and processing of data that enable the efficient use of such vast resources. Moreover, thanks to artificial intelligence and data-analytics such vast datasets can be exploited to extract useful information. Artificial intelligence can indeed gain aggregate information from vast data sets, even when such data are characterized by the features usually associated with Big Data: high volume, variety in format and content and fast-paced change. Big Data sets can also be used to train AI systems, i.e., to build predictive models, which provide fresh inferences (predictions) when applied to specific cases, both in the private economy (e.g., for targeted advertising) and in the public sector (e.g., to detect unlawful behaviour).

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1 Source: Data Age 2025, sponsored by Seagate with data from IDC Global DataSphere, Nov 2018.
Arguably, the public sector has lagged behind the private sector in adopting data-intensive technologies.\(^2\) In particular, the private sector has excelled in collecting transaction data, registered when providing services. Online services are indeed characterised by a double flow of information: individuals receive information and services, and, at the same time providers automatically observe, verify, and analyse all transactions, using every character typed or link clicked.\(^3\) The vast amounts of data collected by the private sector raises a number of concerns which cannot be considered here, in particular with regard to the violations of privacy and data protection, the manipulation of individual users/consumers, the impacts on the public sphere (e.g., the spread of fake news and extreme opinions), and the competitive advantages of controllers of Big Data resource. Together with these worries we need to consider the advantages that data resources offer to private companies, with regard to both the aggregate information they can extract from such data (e.g., as when looking to anticipate future demand and other economic trends) and the opportunity to personalise performance toward individual users/consumers. Public sector bodies are less ready not only to collect transactional data, but also to use the data they have for analytical and predictive purposes. It has been indeed observed that

*In the classic Weberian model of bureaucracy, data are compressed within files, available for checking individual pieces of information, but generating no usable data for analytics. This characteristic of governments’ information architecture persisted into the era of computerization, with a lack of usable data remaining a feature of the “legacy systems” of many governments.*\(^4\)

In the era of Big Data and AI, governments, at all levels, must improve their ability to access data that are relevant to defining and implementing policies, and to process such data as needed. The combination of AI and Big Data should improve governments’ performance across different dimensions such as detecting social issues, anticipating the effect of possible policies through analysis and simulation, and supporting decision-making in individual cases.\(^5\)

The collection of data by the public sector raises important concerns: privacy, data protection and freedoms are at risk when data about individuals and groups are used for purposes of surveillance, control and manipulation. Even when data are collected for valuable purposes, there is always the possibility that they are reused in ways inconsistent with a democratic society (so-called function creep). However, even though the prospect of a surveillance state raises well-justified worries, within a democratic society vast progress can be achieved through a lawful and ethical use of data in the public sector, by ensuring not only data protection, but also transparency and trust.

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\(^3\) Varian (2020).
\(^4\) Margetts (2022).
2. DATA IN THE POLICY CYCLE

KEY FINDINGS

An efficient and effective use of data in the public sector requires that governments design and implement data policies, adopt appropriate regulations, involve actors with the requisite skills, create a data infrastructure, and define technical architectures for it. There is a synergy to be had between the data produced when planning, delivering, and evaluating a policy, since such data can be reused at subsequent stages of the policy cycle. Data are essential to anticipatory governance, as they support forecasting and foresight as well as policy design and evaluation.

Data should be recognised as a key strategic asset for the public sector, with its value defined and its impact measured. Consequently, active efforts are needed to remove barriers to managing, sharing, and re-using data, and data should be used to transform the design, delivery and monitoring of public policies and services. A data-driven public sector —in the sense that it relies heavily on data in predicting forecasting needs, shaping the delivery of services, and understanding and responding to change— is indeed considered a key dimension of the digital government strategy, as shown in Figure 2.

Figure 3: Data in digital government

The efficient and effective use of data in the public sector should not be taken for granted. It requires, as shown in Figure 3, a governance structure that includes the ability to design a data policy, implement it, adopt appropriate regulations, involve actors with the requisite skills, create a data infrastructure, and define technical architectures for it.

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6 OECD (2019d, 8).
7 Source: OECD (2019d, 13)
In 2017 the Economist ran an article describing information as the new oil, the idea being that data is a highly valuable asset which fundamentally powers the economy; this idea has since become a trope. However, information is relevantly different from oil (and from other natural resources): it is non-rival, and indeed its value tends to grow with use (by different users) and with increased links (with other items of information), while it tends to decrease over time (hence, the importance of acquiring new information and verifying and updating old one). Moreover, it is not depletable; on the contrary new valuable information can be generated by processing existing information. The features of information as an asset also tend to change as technologies evolve. It has been argued that additional data might have negative utility, because of information overload. However, in the context of Big Data and AI, while it can still be argued that information often has a decreasing marginal utility (as the size of a data set increases, additional items contribute less to higher performance), technological solutions may enable the scalability of data resources, so that every new data item can profitably be integrated with existing ones, and contribute to better performance.

Figure 4 shows the process for collecting and using data in such a way as to maximise their value for the public sector. This process starts with collecting and generating data and proceeds by storing and securing such data, curating, and distributing them, and finally using them to extract information and define and implement policies, which may require further data to be collected or generated, so that the cycle may start over.
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Figure 5: The government data cycle

A broad picture of the use of data in the public sector is presented in Figure 5, which shows how data should be used for connected and mutually reinforcing purposes: anticipating changes, forecasting needs, and designing policies. Matching needs (anticipating and planning) requires adequate information, implementing policies (delivery), requires further data but also provides opportunities for data collection, assessing the policy on the basis of its implementation (evaluation and monitoring) provides information that can be used to improve both the implementation of the policy and the design of new or revised policies.

Figure 6: The use of data in the public section

11 van Ooijen et al. (2019, 11).
12 OECD (2019d, 88).
The top box in Figure 5 is concerned with what may be called "anticipatory governance", in a broad sense, namely the

*systematic efforts to consider the future in order to inform policy decisions today. In this context, governments respond proactively rather than reactively, based on knowledge and evidence rather than experience and protocol".  

It is important to distinguish the different data driven activities listed in Figure 5:

- **Forecasting** (which includes anticipating change) is meant to predict the future, namely, to use existing data and trends to try to predict the most likely developments and outcomes, so as to anticipate “societal, economic or natural developments that are likely to occur in the future.”

- **Imagining futures**, also referred to as foresight, is instead meant to identify scenarios, i.e., it “systematically explores multiple plausible versions of how the future could be different from expected, and then uses them to make policies more prepared and agile today.”

- **Designing policies**, rather than forecasting the independent evolution of society, requires predicting what differences a policy would make, by identifying the expected causal effects of a regulatory intervention. It also requires comparing these effects with the effects of alternative options. This aspect is the focus of the ex-ante assessment of regulatory impacts.

- **Evaluating policies**, requires engaging with actual causation, i.e., determining the causes why certain state of affairs took place or failed to take place, and in particular assessing the extent to which a policy produced or failed to produce its intended outcomes or produced some side effects (perhaps unwanted).

All the activities just mentioned require appropriate data, and on this basis, they produce new aggregate information for policy makers, which information can be used for further activities. In particular the ex-post evaluation is a key aspect of anticipatory governance, since its outputs can direct forecasting, foresight and policy design. In particular, with regard to legislation, an ex-post evaluation of the real impacts of legislative acts is strongly needed for the purpose of improving anticipatory governance, and specifically, ex ante assessments.

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13 OECD (2019d, 90).
14 OECD (2019d, 90).
16 Halpern (2016).
3. **THE COSTS AND BENEFITS OF DATA**

**KEY FINDINGS**

The collection/generation, curation and processing of data involves costs, as well as benefits. The costs can be avoided or reduced by reusing and repurposing the data. In particular, data collected for the purpose of implementing a policy can be reused (at no collection cost) for the purpose of evaluating the policy and possibly reforming it. The use of data must comply with law and ethics, in such a way as to respect the rule of law, align with the collective and individual good, and contribute to fostering citizens’ trust, which in turn facilitates the collection and reuse of data.

When considering the use of data by government it is important to stress that the collection/generation, curation, and processing of data involves costs, along with benefits (see Figure 6). A cost-benefit analysis also applies to the data, since the cost of data-related activities is an aspect of the larger cost of designing and implementing a policy. However, in considering the cost of collecting data for the purpose of the assessment of a legislative policy, it is important to stress the possibility of reusing and repurposing the data. In particular, data collected for the purpose of implementing a policy can be reused (at no collection cost) for the purpose of evaluating the policy and possibly reforming it. In particular, data collected while implementing a regulation are a key asset in evaluating that regulation.

Figure 7:13 The data-value cycle

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As a final, but most important, consideration, it must be stressed that the use of data must comply with law and ethics. Among the legal requirements, a key role is played by data protection law (including the GDPR, the ePrivacy Regulation, the Directive on data protection and the law enforcement), as well as the new emerging data laws (including by the proposed Data governance act and Data act, which

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OECD (2019d, 77).
also address the reuse of publicly collected data by private companies, and access to privately collected data by public administrations.\(^\text{19}\)

Going beyond legal requirements, we need to consider that data ethics, which indicates moral values to be respected and pursued when engaging with data and corresponding morally adequate conducts, being characterised as the branch of ethics that:

\textit{studies and evaluates moral problems related to data (including generation, recording, curation, processing, dissemination, sharing and use), algorithms (including artificial intelligence, artificial agents, machine learning and robots) and corresponding practices (including responsible innovation, programming, hacking and professional codes), in order to formulate and support morally good solutions (e.g., right conducts or right values)}\(^\text{20}\)

Lawfulness and morality in the management of public data are valuable in upholding the rule of law and achieving a fit between governmental action and social good. Moreover, they help to engender citizens’ trust and their support of policies, which in turn facilitate the collection and reuse of data.\(^\text{21}\)

\(^{19}\) On access to data, see recently Mayer-Schoenberger (2022).

\(^{20}\) Floridi and Taddeo (2016).

\(^{21}\) OCDE (2019d, Ch. 4).
4. NEW PROSPECTS FOR THE USES OF DATA THROUGH BIG DATA AND AI

KEY FINDINGS

Computing techniques can be applied to (big) data for the purpose of descriptive, predictive and prescriptive analytics. Thanks to AI (machine learning), the models used for analytics can be automatically learnt from vast datasets. AI is already helping government detect issues, predict phenomena, and simulate social dynamics. Consequently, it can contribute to improving policy-making and service delivery. AI-based prediction and simulation can increase our ability to anticipate the effects of new regulations.

Today we have a range of computing techniques that can be applied to (big) data for analytics, i.e., for extracting insights. Indeed, analytics has been defined as “the extensive use of data, statistical and quantitative analysis, explanatory and predictive models, and fact-based management to drive decisions and actions”, and the following aspects of it are distinguished:

- **Descriptive analytics** (also called business intelligence or performance reporting) provides access to historical and current data. It delivers the ability to alert, explore, and report using both internal and external data from a variety of sources.

- **Predictive analytics** uses quantitative techniques (e.g., propensity, segmentation, network analysis and econometric forecasting) and technologies (such as models and rule-based systems) to predict the future on the basis of past data.

- **Prescriptive analytics** uses a variety of quantitative techniques (such as optimization) and technologies (e.g., models, machine learning and recommendation engines) to specify optimal behaviours and actions.22

In recent times AI has indeed become a key instrument for analytics. Through machine learning descriptive, predictive, or prescriptive models can be (partially or totally) learnt automatically from vast datasets. It has been claimed that leading organisations “are rapidly making a strategic shift toward cognitive technologies in general, and machine learning in particular”, this being the only feasible option if they are “to handle the amount of data they have at their disposal and to create the personalized, rapidly-adapting models they need”23 It is worth pointing out that the terminology pertaining to analytics and prediction is not used consistently. In some cases, all activities engaged in inferring information from data, are called predictions.24 Here the term “prediction” is used to refer only to inferences made about the future.

Analytics, and in particular AI-based analytics is mostly deployed by companies in the private sector, and in particular by tech companies, but analytics can also be used by the public sector, for valuable purposes.25 In recent years there has indeed been much interest in government’s use of data science and AI.26 A 2020 study on AI in the US federal government found that nearly half of the agencies studied

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22 Davenport and Harris (2017, 30).
23 Davenport and Harris (2017, 18).
25 An application to corruption and fraud risk assessments is presented in OCDE (2019a).
26 Margetts and Dorobantu (2019)
had experimented with AI and related machine learning tools. Among the AI application listed, are the following: the extraction of information from textual reports on adverse drugs events; the analysis of consumer complaints, the processing of worker injury narratives.

It has been claimed that, more generally, AI can contribute to improve policymaking and service delivery, by helping government to perform three key tasks, namely, detection, prediction, and simulation.

The detection task is concerned with understanding societal and economic behaviors, trends, and patterns as a precondition for gauging public policy accordingly. An important concern is with detecting unlawful or anyway unwanted behaviour, where AI is already supporting the task of identifying tax frauds, money laudering, and terrorism threats. The use of Big Data and AI for detection purposes can play a useful role, but it should be applied fairly across the population, with appropriate caution and careful human assessment of potentially unlawful cases identified by the machine. A most significant instance of abusive deployment of AI has recently emerged in the Netherlands, where a large-scale project aimed at automatically detecting welfare frauds has led to a vast number of people being wrongfully deprived of benefits and subject to fines, and certain groups being subjected to unfair treatment.

Prediction is concerned with anticipating individual events or aggregate phenomena. Examples exist of government using AI to predict aggregate demands, in settings such as schools, prisons, or childcare facilities, or to anticipate the spread of disease, or again to categorise and aggregate criminal complaints. Worries have been raised about applying prediction to individuals, a practice which is widespread in the private sector —e.g., in health care, the insurance industry, credit scoring, and job recruitment— but which has some controversial applications also in the public sector, e.g., in assessing recidivism, in predictive policing, or in identifying families at risk of violence or neglect of children. Less problematic is the use of prediction to anticipate aggregate phenomena. Such aggregate predictions may concern future conditions (e.g., economic, and social trends), or the outcomes of policies. In the latter case, the expected outcomes of alternative interventions have to be determined, which calls for a causal analysis. Predictions of both social conditions and outcomes of policies may be needed for the ex-ante impact assessment of regulations, the first ones providing the context for the second.

Automated prediction can rely on different models, e.g., on econometrics or statistics, possibly supplemented by machine learning. The current excitement about AI should not make us forget that all models are fallible, and that more traditional statistical-optimisation models can often outperform AI approaches.

A distinct development —made possible by the availability of vast computer resources and appropriate computational techniques— is computer simulation.

Governments need ways of testing out interventions before they are implemented to understand their likely effects, especially those of costly new initiatives, major shifts in resource allocation, or cost-cutting regimes aimed at saving public resources. In the past, the only option for trying out initiatives was by running field experiments: randomized trials in which the intervention is applied to a “treatment group” and the results are compared with a “control group.” But such trials are expensive and take a long time, challenge notions of public equity, and sometimes are just not possible due to attrition or ethical constraints. In contrast, the availability of large-scale

28 Margetts (2022).
29 Heikkila (2022).
transactional data, and innovative combinations of agent computing and machine learning, allow the simulation of interventions so unintended consequences can be explored without causing harm.\textsuperscript{30}

Social simulation relies an agent-based modelling, rather than on analytical formalisation through mathematical equations.\textsuperscript{31} Agent-based models are in principle experimental: the model specifies the features and behaviour of individual agents, so that the aggregate dynamic of the system emerges through the interactions of such agents. For instance, to anticipate patterns of road traffic, the behaviour of each vehicle (given its kind, ownership, etc.) may be algorithmically specified, along with the features of the environment (places, roads, etc.) in which the vehicles are operating. The traffic (with congestions, accidents, etc.) will result by the interactions of the individual vehicles. Similarly, by creating digital agents that will behave in certain ways when trading with one another, it is possible to investigate the dynamics of markets.
An interesting idea, related to the concept of simulation, is that of "digital twin", i.e., a virtual representation of a physical or social entity, which is constantly linked to that entity through dataflows. As defined by IBM:

>a digital twin is a virtual representation of an object or system that spans its lifecycle, is updated from real-time data, and uses simulation, machine learning and reasoning to help decision-making

The idea of a digital twin originates in engineering (initially in space-engineering) but has since been expanded to cover not only technological devices, but also buildings, factories, cities, and other systems. The digital twin is used to anticipate problems of the corresponding real system, and to test potential solutions before implementing them in the real world. It has been argued that AI and Big Data technology can enable us to create digital twins not only of physical systems, but also of social and socio-technical systems, i.e., societal twins. Such models could be used to proactively determine how social systems may respond to future contingencies, identify future issues, and evaluate possible interventions, such as the enactment of new regulations.

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32 Fuller et al (2020).
5. DATA AND ASSESSMENT / EVALUATION METHODOLOGIES

In this section and in the next one, we will focus on the deployment of data in ex-ante assessments and ex-post evaluations of regulatory initiatives.

As a preliminary observation, we need to consider that information technologies can be used in law-making to manage legal sources, supporting their drafting and retrieval. This includes:

- the digital management of legal sources to support drafting, amendments, consolidation, referencing, the annotation of documents with metadata, and the production of electronic versions;
- the insertion of semantic information within legal sources, to support retrieval and support consistency in drafting;
- the computable modelling of legal documents to test for logical consistency and completeness, as well as to test their application in real/hypothetical cases, check alignment between different texts (e.g., EU and national laws), and detect transposition issues;
- the use of machine learning to analyse regulatory documents, assess their terminological consistence, evaluate their language, and identify related documents, including administrative and judicial decisions.

Here we will not consider these application domains, but rather only focus on assessment of policies. However, synergies between drafting support and impact assessment/evaluation should be developed in the future and exploited to the benefit of both.

It must be considered that regulatory assessment may rely on different approaches, which make different informational demands.

A popular model is cost-benefit analysis, which measures the potential benefits (advantages) of a measure under consideration against its potential losses (disadvantages). Benefits and losses are quantified by numbers expresses in the same unit, usually corresponding to a common currency (e.g., euros or dollars). These quantities—the measure of the overall benefit or loss at stake—are often determined by referring to the individuals’ willingness to pay in order to gain a benefit or their willingness to accept payment in exchange for a loss, while also taking into account the probability that such a benefit or loss should take place. By summing up all expected benefits and subtracting all expected losses, for all individuals, we come up with a single number that indicates the overall merit of the

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35 On legal analytics, see Ashley (2017). On computer support to legislative drafting, see Palmirani et al (2022).
the measure being considered, which can be compared with a corresponding number assigned to each of the alternatives under consideration.36

Cost-benefit analysis is a powerful approach, which has the advantage of providing comparable numerical outcomes for all options under consideration. However, in many domains it encounters difficulties, pertaining to the possibility of operationalizing it, as well as to some normative issues. In particular, cost-benefit analysis makes informational demands —collecting data on willingness to pay or accept, for all the individuals concerned— that cannot be directly met, making it necessary to rely on proxies. Further issues pertain to the fact that cost-benefit analysis tends to disregard the distribution of benefits and costs between different individuals and groups (it just consider their sum total), and tends to under- or mis-appreciate collective goods as well as the goods that cannot be assigned a meaningful monetary value (such as human life, or respect of fundamental rights).37 Thus, it is generally understood that cost-benefit analysis can contribute to the appreciation of certain policies, with regard to some of their impacts, but in many cases cannot provide an overall evaluation.

Alternative/complementary, less demanding criteria for assessing legislative measures consist in least cost analysis and cost effectiveness analysis. Least cost analysis looks only at costs, in order to select the alternative option that entails the lowest cost; thus, it does not adequately address those cases in which a measure having higher costs would deliver greater benefit (the greater benefit fully justifying the higher costs). Cost-effectiveness analysis consider the relation between units of benefit and units of expense (e.g., dividing the number of lives saved by the euro amount needed for healthcare measures); thus it does not adequately address cases in which a measure having a broader scope would provide a greater overall net benefit (benefit-cost), even though a more restricted measure might have greater cost effectiveness (compare vaccinating all individuals, rather than only those at greater risk, during a pandemic).38

In multicriteria decision making the achievement of different objectives is separately considered, such as the contribution a policy can make to GDP, to the environment, or to individual rights, possibly using different methods and scales to measure such impacts. In such cases, in order to determine what measure is preferable, all things considered, a further evaluation is required, whenever, as it often happens, one measure is more favourable under some criteria and less favourable under some others in comparison with other measures (e.g., a regulatory option is more protective of certain individual rights, such as privacy, and more costly for companies). Thus, in such cases it needs to be determined whether the advantages of one measure in certain regards (e.g., privacy rights) are more or less important than the advantages of the alternative measure in other regards (e.g., cost reduction for companies). Thus, a human assessment may be needed to establish what measure (what package of benefits and losses) is preferable overall, or a calculation has to be defined that transforms each benefit or loss into a common currency (units of utility, or “utils”, dollars, euros, etc.), or that otherwise makes it possible to compare alternative measures.39

Multicriteria decision making appears to have been adopted in EU regulatory assessments, at least for the most significant regulations. For instance, the impact assessment for the Digital Services Act40 separately considers economic impacts, social impacts, impacts on fundamental rights, and

37 Hansson (2010)
38 For a discussion of different approaches to regulatory assessment, see Renda (2015). For some critical considerations, see Micklitz (2022).
39 A vast set of approaches to multicriteria decision-making exist. For a seminal contribution see Keeney and Raiffa (1993); for a recent account Ishizaka and Nemery (2013).
environmental impacts, further detailing such impacts, attempting to quantify some of them (in particular, economic and environmental impacts).

In Figure 8, a summary assessment of three options is presented: (1) baseline, limited measures against illegal activities, (2) full harmonization, and (3) asymmetric measures and EU governance. The chosen one is the third option.

Clearly, making a comprehensive assessment of a policy having such a vast set of different potential impacts by monetising all inputs on individuals according to a cost-benefit analysis seems unfeasible, aside from raising the previously mentioned normative issues.

Recently an increasing interest has been taken in the UN’s Sustainable Development Goals, which consist of seventeen goals—(1) no poverty; (2) zero hunger; (3) good health and well-being; (4) quality education; (5) gender equality; (6) clean water and sanitation; (7) affordable and clean energy; (8) decent work and economic growth; (9) industry, innovation, and infrastructure; (10) reduced inequalities; (11) sustainable cities and communities; (12) responsible consumption and production; (13) climate action; (14) life below water; (15) life on land; (16) peace, justice, and strong institutions; and (17) partnerships for these goals. The Sustainable Development Goals framework also provides targets for each goal and indicators for the achievement of the goals. While methods have been proposed for computing the merit of policies relative to this framework, this is a challenging task, given the diversity of the goals and the multiple indicators on which basis they are quantified.41

In a recent Report on Better Regulation,42 the European Parliament supports a broad and inclusive approach to impact assessments and evaluations:43

[The Parliament] welcomes the Commission’s intention to improve the analysis and reporting of proposals’ impacts, for example on competitiveness and SMEs, territoriality, sustainability, equality, subsidiarity and proportionality, which could also help identify gaps, needs and opportunities, as well as help discover existing risks and trends, and therefore contribute to defining policy priorities and devising strategic planning with a long-term perspective, especially in the least developed countries and with regard to achieving the sustainable development goals (SDGs);

41 For a proposal, see Guerrero and Castaneda (2020).
43 For a critical discussion on methods for regulatory assessment in the EU, see Renda (2022), for an analysis of some shortcomings and delays, see Sion et al (2022).
Figure 9: The ex-ante assessment of the impacts of the Digital Services Act\textsuperscript{44}

<table>
<thead>
<tr>
<th></th>
<th>Effectiveness</th>
<th>Efficiency</th>
<th>Coherence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Costs</td>
<td>Benefits</td>
</tr>
<tr>
<td>Baseline</td>
<td>~</td>
<td>~</td>
<td>~</td>
</tr>
<tr>
<td>Option 1</td>
<td>+</td>
<td>&gt;</td>
<td>+</td>
</tr>
<tr>
<td>Option 2</td>
<td>++</td>
<td>&gt;&gt;</td>
<td>++</td>
</tr>
<tr>
<td>Option 3: Sub-option 3.A</td>
<td>+++</td>
<td>&gt;&gt;&gt;</td>
<td>+++</td>
</tr>
<tr>
<td>Option 3: Sub-option 3.B</td>
<td>+++</td>
<td>&gt;&gt;&gt;&gt;</td>
<td>++++</td>
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</tbody>
</table>

\textsuperscript{44} From European Commission (2020, 67-8).

Figure 14. The top-level outcome of the ex-ante assessment of the Digital Services Act.\textsuperscript{45}

<table>
<thead>
<tr>
<th>Economic impacts</th>
<th>Baseline</th>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functioning of the Internal Market and competition</td>
<td>~</td>
<td>+</td>
<td>++</td>
<td>+++</td>
</tr>
<tr>
<td>Costs and administrative burdens on digital services</td>
<td>~</td>
<td>&gt;</td>
<td>&gt;&gt;</td>
<td>&gt;\textsuperscript{137} / &gt;&gt;\textsuperscript{138}</td>
</tr>
<tr>
<td>Competitiveness, innovation, and investment</td>
<td>~</td>
<td>+</td>
<td>++</td>
<td>+++</td>
</tr>
<tr>
<td>Costs for public authorities</td>
<td>~</td>
<td>&gt;</td>
<td>&gt;&gt;</td>
<td>&gt;&gt;&gt;</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Social impacts</th>
<th>Baseline</th>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Online safety</td>
<td>~</td>
<td>+</td>
<td>++</td>
<td>+++</td>
</tr>
<tr>
<td>Enforcement and supervision by authorities</td>
<td>~</td>
<td>+</td>
<td>++</td>
<td>+++</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fundamental and rights (as laid down in the EU Charter)</th>
<th>Baseline</th>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom of expression (Art 11)</td>
<td>~</td>
<td>+</td>
<td>++</td>
<td>+++</td>
</tr>
<tr>
<td>Non-discrimination, equality, dignity (Art 21, 23, 1)</td>
<td>~</td>
<td>+</td>
<td>++</td>
<td>+++</td>
</tr>
<tr>
<td>Private life and privacy of communications (Art 7)</td>
<td>~</td>
<td>+</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Personal data protection (Article 8)</td>
<td>~</td>
<td>~</td>
<td>~</td>
<td>~</td>
</tr>
<tr>
<td>Rights of the child (Art 24)</td>
<td>~</td>
<td>+</td>
<td>++</td>
<td>+++</td>
</tr>
<tr>
<td>Right to property (Art 17)</td>
<td>~</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Freedom to conduct a business (Art 16)</td>
<td>~</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>User redress</td>
<td>~</td>
<td>+</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Overall</td>
<td>~</td>
<td>+</td>
<td>++</td>
<td>+++</td>
</tr>
</tbody>
</table>

\textsuperscript{45} From European Commission (2020, 67).

\textsuperscript{137} / \textsuperscript{138} For the sake of simplicity, the table omits more detailed cost and benefit assessments.
6. THE COLLECTION AND REUSE OF DATA

KEY FINDINGS

To make data-collection cost-effective and sustainable, data collection and creation policies need to be designed in such a way that new data are automatically produced as a side effect of administrative processes. The use of data in regulatory assessment and evaluation is in principle concerned with aggregate data, so that input data may in most cases be anonymous or at least pseudonymous, and the output data consists in aggregate, non-personal information. Thus, it seems that this processing belongs with the concept of statistical processing under the GDPR.

As noted, in the context of AI and Big Data new opportunities are available for ex-ante assessments and ex post evaluations of the merits of regulations. To this end, however, large datasets have to be made available, which requires expanding the data collection process. AI itself can contribute to this process, for instance by analysing and interpreting data inputs, e.g., by extracting data out of natural language reports (e.g., on accidents, or complaints). AI can then be used to mine for information, build models, test hypotheses, and develop what-if analyses and simulations.

To make data-collection cost effective and sustainable it is necessary to design data collection and creation policies, under which data are automatically produced as a side effect of administrative processes, resulting from the actions by public administrations and citizens. As noted, private companies have excelled at collecting data in providing services. The same should apply to governments. Data protection and ethical issues pertaining to data collection should be considered from the very start, so that the data processing respects data subjects’ right and meets their factual and normative expectations. Risk reduction measures should be adopted, in accordance with the principles of data protection by design and by default (Art. 25 GDPR), with particular emphasis on the anonymisation or pseudonymisation of data.

The use of data for the purpose of regulatory assessment and evaluation is in principle concerned with aggregate data, so that the input data may in most cases be anonymous or at least pseudonymous, and the output should in any event consists in aggregate, non-personal information. Thus, it seems this processing should fall in the concept of statistical processing which, according to Recital 162 of GDPR, requires that the result of the processing “is not personal data, but aggregate data, and that this result or the personal data are not used in support of measures or decisions regarding any particular natural person”. Note that personal data collected for other purposes can, in principle, be reused for statistical processing (Art. 5 (1) (b) GDPR).

The reuse of data for regulatory assessment/evaluation should indeed be encouraged, within the framework provided by the Data Governance Act and the Data Act. Relevant data can also be obtained through tools originally designed for use by individuals.

An example would be a diverted use of Claudette, an AI tool meant to enable individuals and consumer associations to assess the legality and fairness of online terms of service and data protection policies.\(^{46}\) The systems has been applied to a large set of data protection policies collected by crawling websites

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\(^{46}\) Lippi et al (2019).
before and after the enactment of GDPR. By automatically comparing such policies it has been possible to determine to what extent GDPR stimulated changes, and to assess whether such changes went in the direction of enhancing data protection (fewer unlawful clauses).

The European Parliament, in its Report on Better Regulation, has stressed the importance of making impact assessments for all legislative proposals and the need of providing adequate resources.

[The Parliament] calls on the Commission to perform impact assessments on all legislative proposals [...] calls for a sufficient amount of time and resources to be allocated to impact assessments in order to ensure their quality [...] calls for impact assessments to be published immediately upon their completion, and not only when the policy proposal is presented, thus ensuring greater transparency on how EU decisions are taken; acknowledges that the effective implementation of better regulation and, in particular, of the ex-ante impact assessments will require an appropriate level of resources; urges the Commission to allocate the appropriate means in this regard. 47

7. COMPLEXITY AND UNCERTAINTY IN ASSESSING AND EVALUATING IMPACTS

KEY FINDINGS

Even when impact assessments rely on advanced statistical or AI methods, they remain highly conjectural, since they involve predicting behavioural changes and further direct and indirect effects of such changes. The uncertainty of ex-ante assessments, even when based on the best methodologies and on adequate datasets, underscores the need for interim monitoring and ex-post evaluation. Both are needed to check the extent to which ex-ante predictions are confirmed or rather contradicted by subsequent facts, as well as the extent to which unexpected side-effects emerge. Ex-post monitoring and evaluation provide evidence of real outcomes, supports democratic dialogue with evidence, and contributes to making governments accountable toward elected assemblies, such as the European Parliament.

The assessment of impacts —even when relying on advanced statistical, computational, and AI methods— remains highly conjectural. This is due to the combination of different issues, such as the availability of data, the complexity of the regulated social contexts, the difficulty of causal analyses. As shown in the previous sections, the optimal assessment of regulations requires a vast amount of data, which may not always be available. Even when sufficient data are available, pervasive uncertainties may persist, since the assessment of regulatory impacts requires us to specifically determine what differences a legislative measure will make. Hence the need of identifying causal connections, rather than merely detecting correlations and projecting them into the future.

Figure 10 shows the complexity of the evaluations involved in ex ante regulatory assessment. Uncertainty is due to a need to estimate to what extent a regulation will prompt behavioural change and what further outcomes this would trigger in society, interacting with multiple further influences, within evolving and complex social contexts.

These uncertainties should not be underestimated, and consequently, we should keep in mind that ex-ante assessments are only conjectural. In some cases, uncertainty can be treated mathematically, since we can assign probabilities to the occurrence of future events, but there are also cases in which uncertainty also covers these very probabilities, i.e., we do not know what likelihood there is that a future event will happen. This is often the case where the impact of new factors has to be assessed (e.g., technological innovations), or when complexities are involved (as in many ecological and social contexts). In such cases quantities should only be assigned in full awareness of their uncertainty (and of the fact that the uncertainty will inevitably spread to the implications of such quantities).

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48 Hansson (2016).
The uncertainty of ex-ante assessment, even when made by relying on the best methodologies and on adequate datasets, make it necessary to emphasise the significance of both interim monitoring and ex-post evaluation. Both are meant to check the extent to which the ex-ante predictions are verified or contradicted by subsequent facts, as well as the extent to which unexpected side-effects have emerged. Thus, monitoring and evaluation can provide evidence for corresponding adjustments and revisions of policies. More generally, through monitoring and evaluation, policymakers can be held to account for the real (rather than the expected) outcome of their policies, and the very process of ex ante assessment (the data collected, the methodology used, etc.) can be subject to critical examination.

It has been argued that, while the traditional policy cycle is characterized by evaluations happening at the very end of policymaking, it should now be possible to “take advantage of instantaneous or near-instantaneous data processing”, so that “evaluation results become available the very moment data arrives.” Rather than being a neatly defined step at the end of the policy cycle, the evaluation of policies could take place continuously, opening permanent possibilities of reiteration, reassessment, and consideration.

On the other hand, it has also been claimed that policy evaluation should not be confused with monitoring. Monitoring consists in continuously checking implementation in relation to an agreed schedule. It involves the systematic collection of data on specified indicators to give management and the main stakeholders a sense of the progress and achievement of the objectives and of the delivery of outputs and outcomes. On the contrary, evaluation involves a deliberate and responsible “looping back” into the regulatory cycle.

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49 Coglianese (2012, 11).
51 Allio (2015, 193).
It seems to us that both monitoring and evaluation are valuable ways to retrospectively assess policies and provide useful feedback: they can be optimally integrated by using the information extracted through monitoring as input in evaluation, while using evaluation to assess how well the monitoring is working and whether it ought to be expanded.

The ex-post monitoring/evaluation, while being complementary to the ex-ante assessment, is grounded on specific reasons.

In the first place, interim monitoring and ex-post evaluation provide evidence of the real outcomes of regulative measures. Given the uncertainty inherent in social predictions, these outcomes may differ, in size and kind, from those predicted through ex-ante assessment, even when the latter has adopted appropriate methodologies. Thus, it may be necessary to fine-tune, tailor and complement such measures, in order to better achieve their intended goals and prevent or mitigate unwanted side-effects. It has also been observed that the systematic use of ex-post evaluations can engender in decision-makers an aptitude for openness and learning:

*carrying out retrospective evaluation and analysis is helpful in keeping an open mind as it encourages an ongoing learning from experience and stimulates efforts to adapt future policy as a result. Putting in place mechanisms to gather, and apply, new insights set an expectation that lessons will be learnt, and new insights gained.* \(^{52}\)

Secondly, ex post monitoring and evaluation play an important role in the democratic debate. They enable civil society to scrutinise the real outcomes of the policy process and check whether government goals have been achieved and whether public resources have been effectively managed. The availability of data on the impact of policies can improve the democratic dialogue, making it less ideological and more evidence-based.

Thirdly, when ex-ante assessments of legislative proposals are entrusted to governments (in the EU, to the Commission), interim monitoring and ex-post evaluation enable Parliaments to control the effectiveness and efficacy of the measures proposed, assessed, and implemented by governments. Thus, they contribute to ensuring the accountability of governments towards elective bodies. It has indeed been affirmed that Parliament should play a key role in ex-post evaluation:

*Parliamentary committees and units should place themselves at the apex of the accountability structure and make efforts to be widely known as the prime location and focus of ex post legislative evaluation so that information, research and analysis is submitted to them as a matter of routine. In some countries, like Australia or Canada, one central motivation of ex post evaluation by the legislature is to make a judgment on the effectiveness of the RIA [regulatory impact assessment] and seek improvement from the executive when this is shown to be required.* \(^{53}\)

The effectiveness of ex-post evaluations is highly dependent on the quantity and quality of the available data:

*Increasing the amount of data associated with the outcome of a given policy allows for agile policy adjustments in the short term, but more importantly will generate better insights into the policy process in terms of accountability and learning in the mid- to long term. Those responsible*
for a given policy can establish whether their policies have had the desired effect or not and, if those data are published as OGD [open government data], so can other stakeholders. As a result, policy evaluation can turn into an open, inclusive and ongoing process rather than an internal, snapshot moment.54

The EU Parliament —through its Research Service’s Directorate for Impact Assessment and European Added Value as well as through the DG IPOL’s Policy Departments— is already playing a significant role in ex post evaluations, but our view is that this role should be expanded and facilitated.

Given the importance of regulatory assessments and evaluations for the EU Parliament, the JURI Committee should consider setting up a permanent Working Group on Better Regulation, to ensure a more active and persistent critical involvement by the Parliament. The Working Group should systematically contribute to identifying shortcomings and proposing improvements, with a special focus on data practices and corresponding technologies.

As noted above, the approaches to regulatory assessments and evaluations are today rapidly evolving, in connection to aspects such as accelerated dynamics of the regulated domains, the need for more comprehensive multi-criteria appraisals, the availability new digital technologies. In this context the involvement of academic and research institutions in reviewing current practices, identifying their strength and weaknesses, and proposing innovative methodologies, and technologies could be considered.

54 OECD (2019d, 94).
8. CONCLUSIONS AND POLICY SUGGESTIONS

This report has discussed the use of data in the public sector, focusing on ex-ante regulatory assessments and ex-post evaluations. The following indications emerge from the present inquiry:

1. The public sector should catch up with the private sectors in the capacity to collect and use data.

2. Better and larger datasets should support the policy cycle, for the purpose of forecasting, foresight, policy design, assessment, and evaluation.

3. The cost and benefits of data collection, curation, and use should be considered, and addressed by adopting cost-effective solutions, also involving the reuse and repurposing of data. The statistical processing meant to provide aggregate information should be distinguished from the processing of personal data meant to provide individualised outcomes.

4. The opportunities offered by AI for collecting and interpreting data, extracting aggregate information through analytics, and exploring scenarios and possible developments through simulation, should be exploited.

5. The need to support multicriteria evaluations with appropriate data, according to methods such as the UN Sustainable Development Goals, should be considered. Quantitative metrics should be used whenever possible, consistently with the nature of the data and the goals pursued.

6. Compliance with law and ethics should be ensured, as to uphold the rule of law, respect citizens’ rights, and foster trust.

7. Predictions should be matched against reality through monitoring and evaluation. An ex-post evaluation should accompany every ex-ante regulatory assessment, making it possible to adjust policies, in a process that contributes to democratic debate and makes for greater government accountability.

8. The JURI Committee should consider setting up a Working Group on Better Regulation, in order to expand and facilitate the role of the European Parliament in participating in the Better Regulation process and in contributing to its improvement and reform.

9. A platform involving academic and research institutions could be created, with the task to critically examine the Better Regulation process, identify strength and weaknesses of it, and propose methodologies, and technologies to make it more effective,
REFERENCES


OECD (2019a). Analytics for Integrity Data-Driven Approaches for Enhancing Corruption and Fraud Risk Assessments. OECD.


OECD (2019c). Digital Government Review of Argentina Accelerating the Digitalisation of the Public Sector. OECD.

OECD (2019d). The Path to Becoming a Data-Driven Public Sector. OECD.


This collection of studies, prepared by the Policy Department C at the request of European Parliament’s JURI Committee, indicates that better EU legislation and regulation can deliver gains to the European economy of over EUR 2,200 billion, while even selected sectorial legislation can deliver EUR 575 billion in case of free movement of goods and customs union, EUR 389 billion in case of free movement of services and EUR 177 billion in case of the Digital Single Market, annually.

At the same time delaying better legislation and regulation in the EU leads to an aggregate annual loss of EUR 319 billion just in the digital transformation area.

Experts indicate at an urgent need of new instruments for the EU better regulation agenda.