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The debate on the EU Better Regulation Agenda: a literature review

A contribution to the Stocktaking of the Commission's Better Regulation approach

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Foreword

This study was carried out in support of the Stocktaking of the Commission's 'Better Regulation' Approach. It feeds into the relevant Staff Working Document and Communication:

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Executive summary

This report aims at providing an overview of the **literature debate addressing the Better Regulation Agenda** adopted by the European Commission in 2015 (henceforth, also indicated as BR 2015)¹.

The review, which focuses on peer-reviewed and grey literature published from 2015 onwards, has been structured according to the following major areas: i) evidence-based policy-making, including methodology and quantification; ii) integrated policy cycle (including Impact Assessments, IA, and evaluation²); iii) stakeholder consultation, participation and involvement; iv) level of regulation, including REFIT; v) regulatory scrutiny and quality assurance; vi) transparency in policy making; vii) inter-institutional relations; viii) subsidiarity and proportionality. For each of these areas, the main messages of the various authors on achievements, remaining issues and what can be further improved have been identified, analysed and brought together. More general issues referring to the BR 2015 have also been reported.

What emerges is a **complex picture**. The relevant academic fields are political science, public administration, and law. The debate addresses a wide range of aspects, from the technical to the political level. The presence of little consensus in some cases, together with the still scarce empirical evidence, makes a synthesis very challenging³.

In general, **the great majority** of the papers **welcomes one or more aspects of the BR 2015**. These are notably the commitment to evidence-based policy making, the attempt at closing the policy cycle by paying more attention to the evaluation phase, the increased responsiveness to stakeholders, a greater role of scrutiny, transparency, consideration for subsidiarity.

At the same time, all **authors** also **underline** various still existing **issues, make observations** on what can be further improved and stress that what can be achieved concretely will depend on actual implementation.

The text that follows summarizes the main elements of the literature debate.

Evidence-based policy-making, including methodology and quantification

- In general, authors welcome the European Commission's (EC) commitment to a sound use of evidence for all policy making activities. The attempt to provide practical coherent guidance via the BR guidelines and toolbox is also welcomed, as well as the consideration of both qualitative and quantitative approaches.
- However, some authors also note that such a rich toolbox still allows for a variety of practices and that a consolidated methodological framework is somehow missing. Difficulties in quantification, notably on the benefits of regulatory intervention, are also observed.
- The literature highlights that appropriate standards to select and weigh evidence should be further developed, and additional support and guidance on methodological aspects should be provided, by considering also the European Union's (EU) vision for the medium and

⁽¹⁾ European Commission (2015).

⁽²⁾ Consistently with the terminology used in the BR 2015, we here use the term 'Impact Assessment' (IA) to indicate ex-ante analysis and 'evaluation' for ex-post analysis.

⁽³⁾ In addition, in some cases, the technical meaning of the terminology used might also be different in the various contributions.

long term. Some authors also suggest promoting a strengthened in-house capacity of the EC, as well as external peer-review mechanisms.

Integrated policy cycle

- The BR 2015 is regarded by authors as a step forward for the EU in closing the policy cycle and becoming a leading example of good regulatory governance worldwide. The new BR Guidelines are found to be broader in scope and more user-friendly than the previous ones, providing guidance throughout the policy cycle (specific messages on evaluations and IAs are reported in Box 1 and Box 2, respectively).
- However, some authors also express concerns on how strong actually the link between IAs and evaluations is and how much the information they provide is fully embedded in the decision-making process. These authors mention in particular the limited use of IAs in evaluations and of evaluations in IAs; the better institutionalisation of the IA process with respect to evaluation; the influence of political timetables; lack of coverage of 'comitology' and insufficient account for the mainstreaming objectives⁴ defined in the EU treaties.
- The literature highlights the need for focusing on producing effective support to policy-making rather than on meeting procedural requirements: IA and evaluation documents should be kept accessible, understandable and useful for decision-makers. Some authors underline that coordination between evaluation and IA work should be ensured in a consistent cyclical approach, and that the 'evaluate first' principle should be more prominently enforced.

Box 1. Evaluation

Authors welcome the EC's commitment to a systematic, high-quality policy evaluation, which has been extended from financial to regulatory instruments, and to comprehensive 'fitness checks'. Its participatory dimension has also been strengthened. At the same time, some authors also express concerns on the scope and focus of policy evaluations, on data limitations and on the methodological quality. The timing dimension needs to be taken into account: if evaluations are too early, their results might not be conclusive, but if they are too late they could miss the possibility to influence the next programme round. This also renders difficult temporal alignment with IAs. Some papers claim poor use of evaluation and insufficient follow-up and stress that review and evaluation clauses should clearly define and ensure the accompanying data collection at Member State (MS) level. Methodological coherency and quality need to be ensured.

(⁴) A political objective is said to be 'mainstreamed' when it becomes horizontally applicable across all policy areas.

Box 2. Impact Assessment

The literature recognizes that the use of IAs has been extended and further consolidated, and that quality has improved. However, in the debate it is also argued that there is no clear definition of which initiatives should be subject to IA and what constitutes a substantial amendment prompting an additional IA. It is also unclear if and how IAs genuinely inform the development of the proposals. Some authors report quality weaknesses, such as the tendency to prepare a justification for a predetermined preferred option, as well as insufficient coverage of certain impacts regarding objectives included in the EU Treaties (such as consumer and environmental protection). For both IA and related supporting studies, these authors call for transparency on data, assumptions and methodology, and for a balanced implementation of methods that consistently assess and quantify monetary and non-monetary impacts.

Stakeholders consultation, participation and involvement

- The literature recognizes that the BR 2015 strengthens stakeholder involvement commitments and their implementation: consultation is extended to more types of EU legislation and to every stage of the policy cycle. This process provides the opportunity for new information to be gathered by the EC, contributing to better insights into stakeholders' positions.
- Some authors however also observe that current procedures generate a somehow high workload on stakeholders and the EC itself, but it is difficult to verify how this affects policy making activities. They also note that participation in consultations is often confined to the actors already having access to the political process, therefore providing limited added value. In the questionnaires, there is little room for free input. The analysis of results is also questioned (for example, either because it only relies on statistical analysis, or, on the other extreme, because it is purely qualitative) as well as the lack of clear commitment on their use in policy-making activities.
- The literature highlights that consultations should be designed as effectively as possible to ensure early and balanced stakeholder input. The need for additional guidance about methodologies for analysing the results is also observed by some authors.

Level of regulation, including REFIT

- The literature welcomes the prominent role given by the BR 2015 to improving EU legislation by a more streamlined legislative activity, promoting reinforced criteria and procedures to ensure the quality of regulation. The REFIT agenda can help identifying overlaps and inconsistencies, while the REFIT Platform is an explicit institutionalisation of participation.
- However, some authors also note that the rhetoric of the EC is focused much more on costs than benefits: the real issue is instead whether legislation ultimately brings benefits that outweigh the costs. Some authors found that the rationale of the REFIT programme is unclear, and its methodological foundations shaky, while the platform has a narrow focus on reducing regulatory burden. Some authors also see the risks of a possible 'deregulation' policy agenda. It is also noted that regulatory streamlining is not simply a technical matter, but involves making political choices. Some authors also claim that,

by formulating (and possibly without sufficient evidence) that 'EU over-regulation' is an issue, the BR 2015 indeed feeds the existence of the very problem it intends to solve.

- The literature observes that less costly alternatives can also be considered to reduce the level of EU regulation. Some authors also suggest engaging in positive public relations campaigns about the benefits of EU regulation.

Regulatory scrutiny and quality assurance

- Authors welcome the renewed composition and dedicated personnel of the Regulatory Scrutiny Board (RSB), which promise to enhance its independence. Its opinion adds transparency and flags up issues to be considered in the legislative procedure. The extension of scrutiny also to evaluations gives a more holistic approach to quality control mechanisms.
- However, in the literature it is also noted that the RSB retains the character of an 'in-house' body, and that, considering the amount of work done, it is not adequately supported by a dedicated secretariat and team of economists and social scientists. Moreover, some authors question that the mandate for the scrutiny of evaluations is less systematic than the one for IAs. On quality assurance, some authors note that there is no judicial scrutiny over the obligation to respect BR principles and also that, in the absence of agreed indicators, it is difficult to draw conclusions about BR performance.
- Some authors express the opinion that RSB should scrutinise IAs earlier in the process and not just the 'end products'. It is also noted that in IAs it should be stated clearly if a political decision is made to continue despite a negative opinion of the RSB.

Transparency in policy making

- The literature recognises that BR 2015 strives to open up EU policy-making for public participation, and therewith to make the EU more transparent and accountable. The Interinstitutional Agreement on Better Law-Making (IIA)⁵ increases the transparency of the pre-legislative process.
- However, in the literature it is also highlighted that further improvement is needed. For example, some authors claim that it is not easy to obtain a complete picture of all ongoing and completed EU evaluations (and of the respective link to the review clauses), and that the access to original studies is sometimes difficult. For IAs, it is claimed that the internal nature of the draft report makes it difficult to determine its actual influence on the proposal. Lack of transparency is also reported in input data, calculations and modelling, as well as in key data and findings' presentation.
- Some authors propose that EU institutions and MSs commit to providing information throughout the whole policy cycle, namely on the evidence in support to evaluations and IAs.

Interinstitutional relations

- The literature considers the IIA an essential part of the BR 2015, by confirming a procedural framework of interinstitutional cooperation to

⁽⁵⁾ European Parliament, Council of the European Union and European Commission (2016).

progress in the direction of more effective EU legislation. Some authors note that BR tools are now increasingly used by the European Parliament (EP) and the Council.

- Some authors also note that the EC wants to ensure that responsibilities for inefficiency of regulatory outcomes are separate (i.e., to make clear when higher compliance costs are generated by the EP, the Council or the MSs). Other authors observe that the Council and the EP still lack political ownership of the evaluative mechanisms. In this respect, they notice that the European Parliamentary Research Service (EPRS) is actively involved in analysing EC's IAs, but not yet in assessing amendments proposed by EP committees, and that, while the Council is increasingly using EC IAs, so far it has failed to develop its own capacity. Authors also note that the final version of the IIA was heavily watered down, as for example, IAs on amendments are not mandatory anymore.
- Some authors suggest advancing in the implementation of the IIA, to include a procedure to structure the oversight of legislation and, in parallel, to respect the place of the consultative bodies⁶ as part of the EU institutional design.

Subsidiarity and proportionality

- Authors see the BR 2015 as a possibility to broaden the application of subsidiarity and proportionality principles. In particular, IAs could be a useful guidance to conceptualize these principles in the judicial review of the EU legislation.
- However, some of them regret that evidence use and a systemic vision are still lacking. In IAs, they find that the respect for the principles of subsidiarity and proportionality is not underpinned by evidence-based instruments. Some authors also report lack of overarching vision of the role of co- and self-regulation and argue that National Parliaments (NPs) occupy a fairly peripheral place in the BR 2015.
- Some of the reviewed papers propose that the Court of Justice of the European Union (CJEU) should further recognize the BR 2015 as establishing the guidelines on how to conceptualise proportionality and subsidiarity. More specifically, they suggest that in IAs the subsidiarity and proportionality analysis should be improved by using sound evidence; that all soft law initiatives could be subject to IA to better serve both subsidiarity and democracy; that the role of NPs should be strengthened.

Concluding remarks

- The literature emphasizes that assessing the BR 2015 is a challenging task not only because of the difficulty of evaluating policies aiming at better regulatory quality, but also, notably, due to its complex nature and, not least, the relatively short implementation period.
- The OECD defines the EU as the most ambitious regional regulatory co-operation framework involving supra-national regulatory powers. Indeed, the great majority of the papers reviewed welcome the ambition of the reform and one or more specific aspects.

⁽⁶⁾ Committee of the Regions and European Economic and Social Committee.

- The debate appears to be extremely varied. Some authors observe that the term 'better' implies an evaluation element, but this does not automatically ensure high quality, or even that the notion of regulatory quality is accepted by every player. For example, regulation can be 'better' because it conforms to the political preferences of citizens or because it meets certain technical standards. Other authors underline that the complaints about the (too high or too low) level of EU regulation are often of a political nature, while EU institutions prefer a 'neutral' approach. Authors also note various inherent tensions and dilemmas in the BR 2015 approach. A few go even further and argue that the BR 2015 operates based on possibly unproven assumptions, generates administrative burden and may overlook certain negative impacts.
- Some authors underline the importance of more widely communicating actions taken within the BR framework, and of developing a renewed narrative which highlights the benefits of EU regulation. They also acknowledge that success of the BR depends, ultimately, on effective and constructive co-operation from all of the actors participating in and benefitting from policy-making.

Introduction

This literature review aims at providing an overview of how the Better Regulation Agenda adopted by the European Commission (EC) in May 2015 (henceforth, also indicated as BR 2015)⁷ has been perceived and discussed.

The review takes into account peer review and grey literature from 2015 onwards⁸ and is structured around the main highlights of the BR 2015 as follows:

1. Evidence-based policy-making, including methodology and quantification;
2. Integrated policy cycle;
3. Stakeholder consultation, participation and involvement ;
4. Level of regulation, including REFIT;
5. Regulatory Scrutiny and quality assurance;
6. Transparency in policy making in the context of BR;
7. Inter-institutional relations in the context of BR;
8. Subsidiarity and proportionality in the context of BR.

Based on this conceptual scheme, for each of the above mentioned topics the **main achievements**, remaining **issues** and **overarching remarks** are presented. While the 'issues' refer to concrete and specific aspects of the topic at stake, the 'overarching remarks' refer to more general, systemic questions which in fact refer more broadly to the overall BR 2015 approach. Finally, we also report the **observations**⁹ made by the authors on what could be further improved¹⁰. Concluding remarks on the BR 2015 package are reported in the final section.

The length of the sections referring to the various topics can be assumed, in a way, to be a reflection of the interest relative to these topics. The messages can of course refer to more than one topic; whenever possible, this has been clearly indicated.

The analysis aims at addressing explicitly the **changes introduced in the BR in 2015**, but more general and pre-existing issues, if relevant, have also been included¹¹.

⁽⁷⁾ European Commission (2015).

⁽⁸⁾ The list of references includes academic papers, reports from international organizations (OECD), scrutinising bodies (European Parliament, European Court of Auditors) and Think Tanks.

⁽⁹⁾ Observations are only those formulated explicitly by the authors (they have not been extrapolated from the issues and challenges they mention).

⁽¹⁰⁾ Citations are kept as close as possible to the original language of the papers, although no brackets are used to avoid overburdening of the text. In many cases, authors either cite or endorse claims made by other authors. Simple quoting is not reported further. In the case of endorsement, the claims are reported also under the name of the author making the endorsement.

⁽¹¹⁾ This is the case, for example, for comments related to IAs, for which the distinction between issues before and after the BR 2015 is somehow more blurred with respect to the stronger changes introduced for evaluations.

To focus on the changes introduced by the BR 2015, the literature search includes only publications issued **from 2015 onwards** (the last update was made in September 2018).

The details on the criteria for the literature search are reported in Annex 1.

Overall, 76 papers have been included in the review. Figure 1 and 2 show their distribution over the years and their subdivision according to topics.

Figure 1. Distribution over the years of the publications included in the review

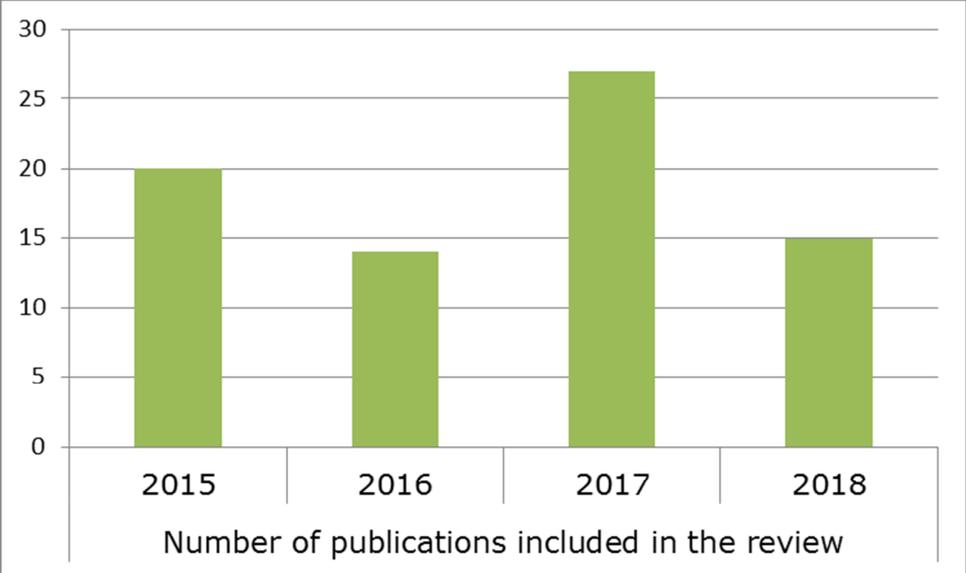
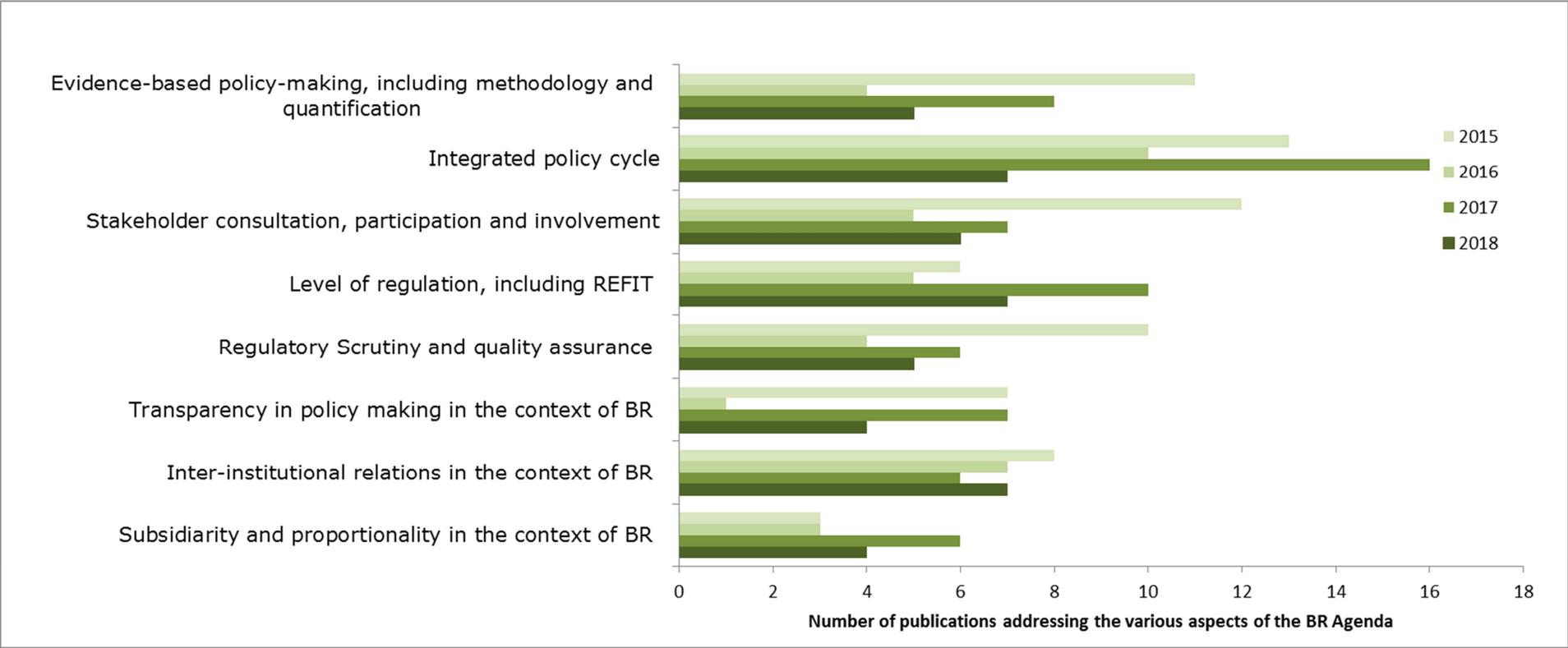


Figure 2. Number of publications included in the literature review addressing the various aspects of the BR Agenda (one paper can refer to more than one topic). Details in Annex 2



The papers revised cover a wide spectrum. Although it would be extremely difficult, if not impossible, to attempt at a clear cut classification, the following main categories can be identified:

1. **Assessment of the past system:** these papers present issues that may already have been addressed by the BR 2015. In these cases, we have retained only those elements which are found to be still relevant in the current debate.
2. **Theoretical assessment of the new system with expectations,** which may or may not manifest. In these cases, we tried to indicate transparently that those made are in fact claims and expectations rather than empirical assessments. Many relevant publications were in fact issued immediately following the communication on the BR 2015. They pointed at its positive and negative characteristics, taking the form of analytical discussions consisting of comments and claims.
3. **Assessment of the performance of the new system.** Unfortunately, overall, empirical studies¹² turn out to be limited in number. The short implementation period of the BR 2015 could be one of the reasons why empirical analysis is still scarce. In fact, in most cases, empirical analyses refer also to the years before 2015. If relevant, these papers have also been taken into account¹³, since they constitute an important benchmark for future studies on the BR 2015 both for their methodology and for their findings.

Finally, a **clarification on the terminology** is needed¹⁴. Throughout the text, in accordance with the BR 2015, we used the terms **Impact Assessment** (IA) to indicate ex-ante analysis and **evaluation** for ex-post analysis. In this respect, we note the considerable variation in the terms used in the literature. Even the choice made by the EC is addressed in the debate (see, for example, Smismans, 2015). To improve the readability of the report, we have decided to follow the BR 2015 terminology and, if needed and possible, we have substituted the terminology used in the various papers with the one used by the EC¹⁵.

⁽¹²⁾ Details on the empirical studies are reported in Annex 3.

⁽¹³⁾ For the sake of clarity, the reference period of the analysis is indicated the first time an empirical study is recalled in the text.

⁽¹⁴⁾ It should also be noted that, in general, the technical meaning of the terminology used might then be different in the various contributions, possibly also because they refer to different academic fields (see Annex 1). Where possible, this has been made explicit.

⁽¹⁵⁾ Concretely, this means, for example, that the term 'ex-post analysis' has been substituted by 'evaluation'; that 'ex-ante impact assessment' or 'integrated impact assessment' or 'ex-ante evaluation' have been substituted by 'IA'; and so on. The few exceptions to this rule have been highlighted in the text.

1 Evidence-based policy-making: methodology and quantification¹⁶

1.1 [Achievements] The Commission commits to a sound use of evidence for all policy making activities...

1. The BR 2015 represents a **step forward for regulatory reform** and signals that the European Union (EU) cares deeply about good governance and wants policy making to be effective and evidence-based, potentially taking a world leadership role (Broughel 2015).
2. This is a clear step towards the **completion of a fully evidence-backed policy cycle** (Renda 2015). The EC is prepared to be judged on the quality and usage of evidence-based instruments in all its activities (Radaelli 2018).
3. Discussions leading up to the **formal consultation** are **well informed by evidence**. IAs are being more systematically reviewed by the European Parliament (EP) and Council, and have also been used by the Court of Justice of the European Union (CJEU) as supporting evidence for certain judgements (Golberg 2018)¹⁷.
4. There is a **single set of methodological templates** (Radaelli 2018).
5. The **toolbox** provides **extensive and adequate guidance** on the quantification of costs and benefits (Renda 2017b)¹⁸.
6. There are attempts to include more **social validity**, more **behavioural insights** and **legal validity** into IAs (Purnhagen and Feindt 2015), as for example strategic foresight within the Joint Research Centre of the European Commission (JRC) (OECD 2018).
7. Compared to the US, the EU is **less focused on monetization exercises and more receptive to qualitative variables and the need for sound policy judgment** in the assessment process¹⁹ (Parker and Alemanno 2015).
8. There is a greater recognition of the role that good regulation can play in driving up **productivity, wages, and living standards**. Competitiveness impacts must now be considered at all times. The new requirements create the potential for a new landscape for risk management decision-making to emerge (Meads and Allio 2015).

⁽¹⁶⁾ It shall be noted that different authors might attach different meanings to 'evidence', which could, for example, include or not the results of stakeholders' consultations.

⁽¹⁷⁾ Golberg (2018) examines the performance of the EC BR approach by looking at available evidence on the quality and relevance/use of its outputs. She quotes various reports and other documents issued by the EU institutions, as well as studies carried out by external actors and authors.

⁽¹⁸⁾ Renda (2017b) explores the methodological and political feasibility of 14 possible options for the setting of net reduction targets on regulatory costs in Europe. See Annex 3 for details.

⁽¹⁹⁾ Parker and Alemanno (2015) mostly refer to before BR 2015 implementation.

9. The adoption of systematic IAs fostered a **cultural change** within the EC (De Feo 2017; Golberg 2018).
10. Organising evidence gathering within the bureaucracy facilitates **learning** (Smismans 2015).

1.2 [Issues] ...but methodological aspects need to be addressed

1. Existing BR guidelines and standards for scientific evidence lag global best practices (Meads and Allio 2015).
2. It remains uncertain **what type** and **amount** of **evidence** should be considered, **who** will provide the evidence, and **how** evidence will be taken into account (Ranchordas 2017).
3. There is a **residual lack of transparency in selecting evidence**, since the BR Guidelines do not force the authors to disclose the methodology used (Hines 2016). However, Meuwese (2017) notes that the BR Toolbox does contain a requirement for an annex to the IA to explain which evidence has been used.
4. **Difficulties in quantification** emerge in IA and evaluations due to lack of data and the need for appropriate methods that would allow for a proportionate assessment of costs and benefits (RSB SG and JRC Working Group 2018).
5. **Clear conclusions** cannot always be drawn from the evidence contained in evaluations and IAs (De Feo 2017).
6. The shift from project and programme assessment to **broader policy appraisal** requires **addressing methodological aspects**²⁰ (Smismans 2015), namely:
 - (a) There are important **uncertainties related to methodology used in IAs**, for example, when cost-benefit or multi-criteria analysis would be more appropriate (Renda 2015; Renda 2016; Renda 2017a)²¹. The very rich toolbox offered by the BR Guidelines allows for a variety of practices across the EC Directorates General (DGs), as well as for varying degrees of quantification and monetisation of impacts (Renda 2017a). The 'checklist' for assessing impacts is getting ever longer (Smismans 2015).
 - (b) Tools and methodology for **evaluation** are less readily available (Smismans 2015). Evaluation is a complex activity, in which most of the OECD countries have just raised awareness (OECD, 2014 cited in Radaelli 2018).

⁽²⁰⁾ For details on recurring quality issues in evaluations and IA see section 2.

⁽²¹⁾ Renda (2016) analyses 53 IAs conducted in the financial sector in the years 2003-2011. See Annex 3 for details.

- (c) Given the different types of approaches (cost-benefit analysis, multi-criteria analysis, etc.) that are applied, there is **insufficient consistency to facilitate meaningful aggregation** of either costs or benefits (Golberg 2018).
- i. The **BR does not require cost-benefit analysis**, differently from American executive agencies which show a somewhat better record in producing fully monetised assessments (Golberg 2018).
 - ii. However, the cost-benefit analysis command has long been criticized. The BR 2015 makes welcome attempts to include more social validity, more behavioural insights and legal validity. However, despite the EC's communicated intentions to develop 'a common approach' for IA, **a consolidated framework is lacking** (Purnhagen and Feindt 2015).
 - iii. **Counterfactual analysis** is not systematically done (Golberg 2018).
 - iv. Too little enthusiasm for quantitative targets, indicators of regulatory quality and strong commitment to a method or another **contrast with the OECD's Framework for Regulatory Evaluation** (Radaelli and Schrefler 2015).
 - v. There is an **implicit bias towards the techno-scientific knowledge**. This for example is implied by gathering as much quantitative evidence as possible (Hines 2016).
- (d) **Autonomous choices of Member States** on implementation and enforcement and **little comparable EU-wide data** make it difficult to quantify ex-ante costs and benefits (Golberg 2018).
7. Given the increased workload, **the availability of EC staff** with the right competences can be questioned (Renda 2015; Renda 2016).
 8. The new EC's interest in promoting BR has **not resulted in more concerted effort** by policy-makers in the EP and the EC to promote **risk-informed policy-making** (Lofstedt and Schlag 2017).

1.3 Overarching remarks

1. Despite a few additional mechanisms, **the essence** of the BR mechanisms of consultation, evidence-gathering and monitoring **has not changed** (Alemanno 2015). The question remains whether the BR can function as the legitimacy enhancing tool it aims to be (Eliantonio and Spendzharova 2017).
2. The BR 2015 is presented as a politically neutral initiative. Yet, concerns have been raised that **political preferences** will be wrapped in the language of 'evidence-based' policy-making (Eliantonio and Spendzharova 2017; Wegrich 2015). Banking sector reforms show that political discretion and interinstitutional bargaining are still important features of EU policy-making (Spendzharova 2016).

3. The **BR seems to operate on the basis of a faulty, unproven problem definition**. In fact, the problem (if any) with initiatives that have met with 'bad regulation' accusations instead seems to be that they were (presented as) too scientific and were not politically savvy. To the extent that some 'too scientific' initiatives have been withdrawn in light of the BR 2015, and that the latter might act as a deterrent to initiate new legislation whenever new problems emerge, the BR 2015 is applied to the contrary of its own objective to foster evidence-based decision-making (Garben 2018).

1.4 Main observations from the literature review

1. Develop new, '**horizontal**' **standards for scientific evidence** and for the provision of scientific advice (Hines 2016; Meads and Allio 2015). Changes could be included for scrutiny in the inception IA. All evidence accrued throughout the IA could be transparently graded through an online evidence portal (Hines 2016).
2. **Ensure external peer-review of the evidence** base in IA by reviewers selected on a case-by-case basis for their expertise on the subject (Hines 2016).
3. **Provide support on methodological issues**, as well as on consistency, quality and robustness of quantification and modelling. The JRC has expressed readiness to provide such support (RSB SG and JRC Working Group 2018).
4. Develop a **common methodology between the three institutions**. In particular, define a **methodological guide on sustainable development** (Van den Abeele 2015).
5. **Guidance on important methodological aspects**, though at least partially included in the new IA guidelines, would only be possible and effective if (Renda 2015):
 - (a) the Secretariat General (SG) and the other DGs would agree **on the approach to policy appraisal** (Renda 2015);
 - (b) the EC would adopt a **set of criteria and indicators that match Europe's vision for the medium and long term** (Renda 2015).
6. Make it possible for **citizens, organizations or businesses** to provide some form of **counter-evidence** about the factual information upon which proposed or adopted regulations are based, and to have it assessed by an independent body (Voermans 2016).
7. Develop a consolidated framework **to include social validity, behavioural insights and legal validity** into IA. The authors suggest the *Homo Oeconomicus Institutional* approach (Purnhagen and Feindt 2015).

8. Make the EC's **new mechanism for independent scientific advice work**, for example by ensuring appropriate funding and communication (Lofstedt and Schlag 2017) and use it to address related shortcomings in the BR process (Hines 2016).
9. **Strengthen the capacity of the EC** to further promote evidence-based and risk-informed policy-making (Lofstedt and Schlag 2017):
 - (a) hire more **in-house expertise** to be less dependent on outside consultants, to retain a long-term memory of decisions taken (Lofstedt and Schlag 2017);
 - (b) provide **detailed feedback if the EC decides to disregard scientific opinion** (Lofstedt and Schlag 2017);
 - (c) Move towards a **more evidence-based use of the precautionary principle** (Lofstedt and Schlag 2017).
10. **MSs** need to be **more receptive** to science-based policy-making (Lofstedt and Schlag 2017).
11. **Make the Regulatory Scrutiny Board (RSB) intervene to ensure scrutiny by social scientists** on public consultations as well as policy options in IAs (Hines 2016).
12. Make decisions only when benefits justify costs and encourage the selection of regulatory **options** that are **least restrictive**, make greatest use of market forces, and promote innovation (Meads and Allio 2015).
13. Highlight the need to ensure a high level of consumer protection, which specifically means that IAs should not focus on less protective options (van Schagen 2017).
14. The IAs and the subsidiarity principle tests should **always bear in mind the cost of non-EU**, as a consequence of non-existent EU legislative initiatives (Willermain and Cioriciu 2015).
15. The EC should take a lesson from the US and increase its standards of analysis (Parker and Alemanno 2015).

2 Integrated policy cycle²²

2.1 [Achievements] Closing the policy cycle as a fundamental step to produce more coherent legislation

2.1.1 Overall achievements (aspects common to both evaluation and IA)

1. The BR 2015 is a step forward towards **closing the policy cycle**, integrating all existing regulatory management standards in a **seamless, consistent, and coherent approach** (Broughel 2015; Eliantonio and Spendzharova 2017; Kubera 2017; Meads and Allio 2015; Radaelli 2018; Renda 2015; Smismans 2015; Stephenson 2017), also thanks to the fact that the RSB has a **formal task in judging the quality of evaluations in addition to IAs** (van Golen and van Voorst 2016)²³.
2. After receiving criticism from other EU institutions for a lack of accountability and transparency in its legislative process, the **EC launched a number of reforms in which evaluation played a key part** (van Golen and van Voorst 2016).
3. The new **Guidelines** are **broader** in scope than the previous ones, providing standardised guidance throughout the entire policy cycle (Chase and Schlosser 2015; EPRS 2015; Nowag and Groussot 2018); they encompass all the previous EC policies to improve the policy evaluation into a common toolbox (Raccah 2016) and are more user-friendly in presentation (EPRS 2015);
 - (a) The introduction of **extensive monitoring- and evaluation-specific guidance** is one of the principal developments, which emphasise more strongly evaluation should feed into IA (and vice versa) (EPRS 2015).
4. The **use of evaluation has improved**. The values of both evaluation and IA composite indicators²⁴ are higher than the averages of other OECD jurisdictions (OECD 2018).
5. Emphasis on the **timing of analysis** is crucial for being able to inform the legislative process (Broughel 2015).

⁽²²⁾ The section includes the debate on evaluations and IAs. Throughout the text, consistently with the 'evaluate first' principle, we decided to present first the messages related to evaluation and then those referring to IAs.

⁽²³⁾ The analysis of van Golen and van Voorst (2016) combines a dataset of 309 evaluations (2000-2014) and a dataset of 225 IAs of legislative updates (2003-2014). See Annex 3 for details.

⁽²⁴⁾ The OECD uses three composite indicators to assess regulatory requirements and practices: one for IA, one for stakeholder engagement and one for evaluation. Each composite indicator is composed of four equally weighted categories: systematic adoption; methodology; oversight and quality control; transparency.

6. This process has a **value in itself** since it has generated a greater awareness of the costs and of the benefits of regulatory actions (Golberg 2018).
7. The EC announced its intention to **mainstream the Sustainable Development Goals** (SDGs) in its policy process. BR elements in some respects already allow for this (for example, sustainable development is included in the BR toolbox as one of the impacts that should be considered in an IA) (Renda 2017a).
8. The **mechanisms set within the Interinstitutional Agreement on Better Law-Making** (IIA)²⁵ for evaluations and IAs **are important and cover most of the legislation** (De Feo 2017).

2.1.2 Achievements related to evaluation

1. The EC has, as a whole, a **well-designed system of evaluations and fitness checks**, which are well-managed and quality controlled (ECA 2018; Ruhl 2017)^{26,27}.
2. The EC committed itself to **systematic, high-quality evaluation** (Mastenbroek *et al.* 2016; Radaelli 2018).
3. The current agenda **extends policy evaluation** from financial to regulatory instruments (Eliantonio and Spendzharova 2017; Kubera 2017; Smismans 2015).
4. The evaluation system **combines systematic evaluations** of individual regulations with **comprehensive 'fitness checks'** of policy sectors (Dunlop and Radaelli 2017; Kubera 2017; OECD 2018).
5. Evaluation guidelines are **a more hierarchical document to be followed by all DGs** (Smismans 2015; Smismans 2017). The BR 2015 provides further guidance on certain practices, such as the use of 'back-to-back' evaluations and IA (EPRS 2017).
6. The BR 2015 strengthens the **participatory dimension of evaluation** as for IA, also *during* the evaluation process (Eliantonio and Spendzharova 2017; Kubera 2017; OECD 2018; Smismans 2017); this is supported by the EU initiative of publishing the forward planning of all evaluations ('evaluation calendar') (Kubera 2017).
7. Ex-post reviews are **publicly available and accessible** (ECA 2018). The majority of reports **contains useful recommendations** and has a concise executive summary (ECA 2018; Mastenbroek *et al.* 2016)²⁸.

⁽²⁵⁾ European Parliament, Council of the European Union and European Commission (2016).

⁽²⁶⁾ Note that the European Court of Auditors (ECA) audit covers 'ex-post reviews': these include evaluations and fitness checks, as well as a wider set of reports outside the scope of the BR. Weaknesses are identified notably for reviews other than evaluations (ECA 2018). For the sake of clarity, in this report we keep the original terminology used in the ECA report (most findings are referred to 'ex-post reviews' in general). Findings specifically related only to ex-post reviews other than evaluations are instead not reported. See also Annex 3.

⁽²⁷⁾ Ruhl (2017) considers selected aspects of evaluations carried out on the Regulations in the field of private international law. These refer mostly to the years before 2015.

8. There is a **considerable increase in evaluations** carried out in 2017, which also reflects complex exercises (EPRS 2017).
 - (a) Evaluation as thus far practiced in private international law is by and large on the right track (Ruhl 2017).
9. **Progress** is being made in **applying the 'evaluate first' principle** (RSB cited by ECA, 2018; Golberg, 2018).
10. It is to be expected that **review of legislation in its different forms** will benefit from an increasingly prominent role in the legislative cycle as such and also for the EP committees (Weber *et al.* 2017)²⁹.

2.1.3 Achievements related to IA

1. The EC has **improved the IA scope of application** by including also non-legislative initiatives, as well as delegated and implementing acts. Interesting is also the **introduction of a 'comply or explain'-principle**³⁰ (Stoffel 2015).
2. The new Guidelines appear to **increase the procedural coherence of the EC's IA process** (EPRS 2015; Hines 2016).
 - (a) The lack of a mandatory standard list in the Guidelines may help to **avoid a 'checklist mentality'** (van Schagen 2017).
 - (b) Certain **additional elements** must now always be included in the final IA Report, such as impacts on Small and Medium Enterprises (SMEs) and on competitiveness. Increased attention is given to consultation and stakeholders (EPRS 2015).
 - (c) **Behavioural economics and risk analysis** are strengthened (EPRS 2015).
 - (d) **Subsidiarity** is singled out more clearly as a self-standing issue; the **proportionality** principle is presented more clearly as a comparison criteria (EPRS 2015).
 - (e) They contain a strong call, when designing policy options, to **consider several alternatives** (EPRS 2015).
 - (f) **Operational objectives** are now to be presented more clearly (EPRS 2015).
 - (g) There are now also four **compulsory annexes** to any IA: procedural information; stakeholder consultation; who is affected by the initiative and how; analytical models used (EPRS 2015).

(²⁸) The dataset used by Mastebroek *et al.* (2016) refers to the years 2000-2012. See Annex 3 for details.

(²⁹) Weber *et al.* (2017) analyse review clauses and conducted reviews. The analysis draws on a desk-based review referring to the years 2004 to 2015. See Annex 3 for details.

(³⁰) In the BR Toolbox (European Commission, 2017, p.50), it is stated: '[w]henever it is concluded that no IA is needed, this must be flagged and explained to the public through the roadmap'.

- (h) The EC is amongst the few jurisdictions worldwide that formally provide guidance on how to consider the **international regulatory environment** as part of their IA guidelines (OECD 2018).
- (i) The new Guidance for assessing the impact of a proposed measure on **trade** is far more detailed and useful than previous guidance (Chase and Schlosser 2015).
3. The **quality of IAs** has improved over time (EP cited in Golberg, 2018).
 4. IA does not necessarily determine the nature of the decision of whether to regulate or not, but it (may) **improve on the quality of a decision** (Dunlop and Radaelli, 2017).
 5. Despite the omission in the Guidelines of reiterating compliance with the Charter³¹, there are **examples of IAs that have considered impacts on fundamental rights and consumer protection** (van Schagen 2017).
 6. The EC urges rightly that the **other European institutions should take more of an active role when producing IAs** (Lofstedt and Schlag 2017). IA can be conducted also at the initiative of the EP or the Council (Leszczyńska 2018).
 7. A growing number of **MS** are examining IAs also **as a basis for their own analysis of implementing EU law** (Golberg 2018).
 8. The use of **IA** as an efficient tool to promote a BR strategy at all levels of government has been **exploited by local and regional authorities** (Taulègne 2017).
 9. **IAs have the potential to bring more evidence/rationality to the core reasoning of the CJEU** (Nowag and Groussot 2018).
 10. The presence of **Inception IAs** allows a simplified analysis already at very early stages. A similar reform is sometimes called for in also the US (Broughel 2015; Parker and Alemanno 2015).

⁽³¹⁾ The Charter of Fundamental Rights of the European Union.

2.2 [Issues] ...but challenges to ensure a cyclical understanding of policy-making for all types of policy intervention still persist

2.2.1 Overall issues (aspects common to both evaluation and IA)

1. It remains unclear how much of the rhetoric about a '**regulatory cycle**' holds up in practice (van Golen and van Voorst 2016). Information from evaluation and IAs is still not embedded in the decision-making process (De Feo 2017; Voermans 2016).
2. There are **misfits between the key objectives of evaluation**, based on assessing outcome in relation to the objectives set at the origin of an initiative, **and IA**, which is set in relation to wider EU objectives (Smismans 2015).
3. **The IA process is better institutionally organized than for evaluation**. There are **also misfits in** the way IA and evaluation objectives have been institutionalised, for example on (Smismans 2015):
 - (a) the gap between the **type of evidence gathered**: IAs aim to assess future economic, social and environmental impacts, while for evaluation evidence may be gathered in function of (financial) programme or project assessment that is not necessarily linked to the IA system. Furthermore, evaluations with different scope, assessing different objectives or indicators of the same initiative may be adopted in parallel following different life cycles (Eliantonio and Spendzharova 2017; Smismans 2015; van Golen and van Voorst 2016);
 - (b) different **legal requirements** on when IA and evaluation need to be adopted (Smismans 2015);
 - (c) lack of **established time frames** and absence of a cyclical process in relation to regulatory intervention (Smismans 2015);
 - (d) different **focus** on accountability versus learning (Smismans 2015);
 - (e) different expectations about the **actors to be involved** (Smismans 2015);
 - (f) imbalance in **experience** and available evidence regarding IA and evaluation in different DGs (Smismans 2015).

The challenges are so considerable that it may be that efforts **focus on one particular objective, namely reducing the regulatory burden** (Renda 2016; Smismans 2015).

4. There are **challenges for the BR 2015 to really embrace the SDGs** as announced by the EC. What is missing in the Guidelines is

notably an adequate methodological framework; a way to measure distance from SDG targets; and criteria to prioritise certain impacts over others in the case of trade-offs (Renda 2017a).

5. **Political timetables might have an effect on the quality** of the analytical or consultation exercise, which risks being rushed at the beginning and at the end of the five-year EC term (Golberg 2018).
6. There is an **ongoing tension between** special reports of the European Court of Auditors (ECA) (largely ex post), **EC IAs** and evaluations, and the **EP's** own IAs, when it comes to findings that influence the policy debate (Stephenson 2017).
7. The **world of comitology**³², which accounts for more than 80% of EU regulatory output, is not adequately incorporated in a cyclical approach (Voermans 2016).
8. For an **integrated regulatory management approach**, challenges arise with respect to (Radaelli and Schrefler 2015):
 - (a) **strategic and operational management** (Radaelli and Schrefler 2015);
 - (b) the **availability of additional capacity** to cope with an increased workload (Delogu 2016; Radaelli and Schrefler 2015). This might need redirecting resources from IA efforts to the REFIT programme (Radaelli and Schrefler 2015).

2.2.2 Issues related to evaluation

1. Scope and focus
 - (a) It is unclear what kind of study meets the threshold to **be defined an evaluation** (Radaelli 2018).
 - (b) Evaluation is challenging because of the **difficulty to identify the initial objectives** of initiatives; these might have a changing nature over time. The problems are exacerbated when evaluation is aimed towards performance rather than compliance, particularly when there is a shift from project and programme level to a broader political evaluation (Smismans 2015).
 - (c) **Deficiencies are found in the scope and focus** of the evaluations (Ruhl 2017).
2. The **different epistemic communities** engaging in evaluation may not share the same learning objectives and understanding of desirable policy goals and coherence (Elia Antonio and Spendzharova 2017).

⁽³²⁾ These are 'implementing rules drawn up by the European Commission - and assisted in this task by committees of experts from Member States' (Voermans 2016), p.21).

3. Data and methodology

- (a) Deficiencies are found as regards the **quality of available data** (Ruhl 2017).
- (b) Shortcomings exist in the recognition of **data limitations** (ECA 2018).
 - i. Incompleteness or lack of data, data quality and issues with stakeholders consultations can be due to a lack of monitoring or reviews being carried out at an inappropriate time. **Some ex-post reviews recognize those limitations and explain** how they were addressed (the 2017 update of the toolbox contains a recommendation to include an explicit assessment of the limits encountered in data collection and modelling) (ECA 2018).
 - ii. **Stakeholders' involvement is unsatisfactory** (Mastenbroek *et al.* 2016).
- (c) There is **no homogenous treatment of methodology** in the examined ex-post reviews (ECA 2018). The methodological quality is disappointing (Mastenbroek *et al.* 2016; Radaelli 2018).
 - i. The reason for **choosing** a particular methodology is not always provided and its **outline** is not always comprehensive (ECA 2018; Mastenbroek *et al.* 2016).
 - ii. The majority of studies **lack replicability** (Mastenbroek *et al.* 2016).
 - iii. The **tools for evaluation are far less established and clear-cut** than for IA so bound to raise more **political debate** (Smismans 2017);
 - iv. There is **lack of clarity** on a provision in the BR which refers to evaluation exercises aimed at verifying **too burdensome impacts on 'specific' sectors** (Renda 2015);
 - v. Evaluation is complicated and costly; measuring benefits is more difficult than measuring costs. Therefore, it may be that the **evaluation system will be used particularly in function of reducing the regulatory burden**, with a focus on measuring short-term costs (Smismans 2015).
- (d) A tendency towards a **more consistent presentation of conclusions** and next steps was found in the examined ex-post reviews, but this is not yet standard practice (ECA 2018).
- (e) The **quality of the external studies** underlying evaluations is extremely **uneven** (Ruhl 2017). In a few cases in the examined ex-post reviews a **clear reference** to the supporting study was **not available** (ECA 2018).
- (f) **Back-to-back evaluations/IAs entail risks** for the independence of the evaluation, as well as for the added value of the evaluation, when it is not completed in time (ECA 2018).

4. Monitoring

- (a) **Review and monitoring clauses** are widely present (ECA 2018) however they are often limited to a technocratic exercise (De Feo, 2017).
 - i. A **dedicated tool** was introduced only in the **BR 2015 revision** in 2017. There are **no common interinstitutional guidelines** (the IIA underlines their relevance but is not legally binding) (ECA 2018).
 - ii. It is not possible to draw a consistent **causal link between the type of ex-post review and its timing** (ECA 2018; Weber *et al.* 2017).
- (b) **Frameworks are missing or poor in many cases** (RSB cited in Golberg, 2018). This is often seen as the least important part of an IA/preparatory process (Golberg 2018).
- (c) **Monitoring is often hindered by a lack of data.** The requirement to collect data is often perceived as an **administrative burden by the MS** (Golberg 2018).
- (d) In **IAs** there is **no requirement** to include a separate section on **assessing data from previous evaluations**. For expenditure policy, data from evaluation do not always systematically feed back into the current type of ex-ante financial evaluation. For regulatory policy, there is no broad availability of ex-post data that could feed into new initiatives (Smismans 2015).

5. Timing

- (a) It is difficult to **align evaluation with IA** (Radaelli 2018; Van den Abeele 2015).
 - i. To conduct evaluation, the EC advises to wait until a reasonably **complete dataset for three years** is available. This may affect the planning of the evaluation and of ensuing legislative revisions (EPRS 2016).
 - ii. Given the length of the policy cycle, **evaluation cannot meaningfully start before a minimum of ten years from initial work on a proposal**. This period exceeds two EC terms. There is a tendency to consider evaluations of past performance as having a lower political profile. Even when linked to new proposals, the evaluation is often rushed to get the IA finalised (Golberg 2018).
 - iii. **Evaluations carried out too early** may not lead to conclusive results and need to be complemented at a later stage (EPRS 2017).
 - iv. Evaluation **could come too late** to inspire the next programme round (Smismans 2015).

- v. The EC **complies poorly with the evaluation deadlines** (Ruhl 2017).
 - (b) The **link between some planned studies and the subsequent evaluation** is not always clear (EPRS 2017).
 - (c) **Information and justification for delayed evaluations** is not regularly available (EPRS 2017).
6. **Outsourcing** of evaluation
- (a) Evaluation is **frequently outsourced** (Stephenson 2017), as the EC's staff is too small to perform these studies and external evaluations are believed to be more objective (van Golen and van Voorst 2016). **External parties lack the experience**, notably on consultations, the EC has built up in relation to IA (Smismans 2017). Note that OECD (2018) reports that the EC is amongst the best equipped institutions worldwide concerning full time analyst staff.
 - (b) **Independence** of evaluators is definitely required to ensure financial accountability, but may be **less appropriate if the aim is policy learning** (Smismans 2015).
 - (c) **Policy evaluation may be too heavily perceived as a European level game**, involving in particular the EC and an industry of consultancies which operate mainly as European or international businesses (Smismans 2015).
 - (d) **Not all policy issues lend themselves to the type of evaluation commonly conducted by external consultants** (Eliantonio and Spendzharova 2017).
 - (e) There is **no complete picture of the cost of reviews** that have so far been carried out by the EC (Weber *et al.* 2017).
7. **Transparency** and access to results are found to be limited (Mastenbroek *et al.* 2016; Ruhl 2017; Weber *et al.* 2017).
- (a) The EC **does not document** the results of all its evaluations of EU legislation **centrally** (Mastenbroek *et al.* 2016; Weber *et al.* 2017).
 - (b) Moreover, they are **not** published in a form which would **allow them to be easily linked** with specific review clauses in EU legislation (Weber *et al.* 2017).
 - (c) It **remains difficult to determine** when any given Regulation is **being evaluated** or what the status of an ongoing evaluation is. This is mainly attributable to the information on evaluations being found in a **large number of different, and sometimes quite lengthy, documents** (Ruhl 2017). There is also the possibility that some reviews have not been carried out at all (Weber *et al.* 2017).
8. Use

- (a) **Evaluations are not generating sufficiently convincing evidence** that results of EU intervention are being delivered in the most effective and efficient manner, notably for REFIT (Golberg 2018).
- (b) **Evaluation coverage is patchy.** Evaluation is primarily a matter of legislative obligation instead of own initiative. Process evaluation overall seems more important than product evaluation (Mastenbroek *et al.* 2016).
- (c) Analysis **shows that use of IAs by evaluations and of evaluations by IAs is limited** (van Golen and van Voorst 2016). This is not surprising, given what we know about the use of evaluations in other political systems like the USA (Dunlop and Radaelli, 2017).
 - i. Ex-post reviews are not always used by the EC when preparing IAs (ECA 2018).
 - ii. Analysis shows that **the proportion of IAs making use of an available evaluation is much larger than the proportion of evaluations making use of an available IA.** This could be explained by the fact that an IA of a legislative amendment is usually conducted right after an evaluation of the previous legislation; that IAs are often conducted internally, making it easier for the EC to stimulate the use of evaluation (van Golen and van Voorst 2016). It may be harder for evaluations to use IAs than the other way around, as IAs are often conducted before legislation is amended by the Council and the EP (van Golen and van Voorst 2016; Weber *et al.* 2017).
 - iii. **Timeliness is crucial.** An evaluation must be published at least a year before the IA, otherwise it is very unlikely to be used. For the use of IAs by evaluations, the analysis did not reveal any causes or combinations of conditions which are sufficient or necessary (van Golen and van Voorst 2016).
- (d) Most of the time evaluations remain **without follow-up** (De Feo 2017).
- (e) Analysis has shown that **evaluations may be used instrumentally**, even if their recommendations are opposed by important political actors in the legislative process. A lack of salience of the policy field in the eyes of the EC could, in combination with the institution's ambition to reduce its legislative output, be a sufficient condition for the non-use of that evaluation. The fact that evaluations often recommend changing legislation to improve it contradicts the EC's plans to propose little legislation outside of its priority fields. This contradiction

leads to **reduced possibilities for evaluation use** (Van Voorst and Zwaan 2018)³³.

(f) An analysis of to what extent and when Members of the EP use evaluations shows that the parliamentary questions hardly serve accountability aims. **Members of EP mostly use evaluation for agenda-setting purposes.** The main variable explaining differences in the usage of evaluations is the level of conflict between the EP and EC during the legislative process (Zwaan *et al.* 2016)³⁴³⁵.

9. The **RSB mandate for evaluations is not as systematic as for IAs** (for which RSB scrutiny is always required, with a few exceptions) (Smismans 2017).

10. The EC systematically forwards its reports on the ex-post reviews to the **EP and the Council**; the latter however **seldom react directly** (however this does not fully reflect the fact that the co-legislators can take into account and use EC reports at a later stage or within a different context) (ECA 2018).

11. The **impact of reviews of EU legislation on the work of the EP and the EC is limited.** There is, however, an increasing share of legislative reviews followed up by initiatives in the EC's annual working programmes (Weber *et al.* 2017).

2.2.3 Issues related to IA

1. **Decision** on whether to undertake an IA

(a) **For Inception IA, there is no explicit definition** of when it should be compiled; systematic **deviations** from procedures on timing are also found (Impact Assessment Institute 2017).

(b) There is no precise definition of **which initiatives are subject to IA** (Alemanno 2015; Golberg 2018; Renda 2015; Renda 2016; Stoffel 2015; Van den Abeele 2015). The decision is made by the responsible DG; this insufficient coordination is a very negative factor³⁶ and also affects the decision on whether to wait for the evaluation to be concluded (van Golen and van Voorst 2016). This

⁽³³⁾ Van Voorst and Zwaan (2018) analyse three evaluations in the years 2008-2012 See Annex 3 for details.

⁽³⁴⁾ Zwaan *et al.* (2016) use the same data set as Mastenbroek *et al.* (2016). See Annex 3 for details.

⁽³⁵⁾ An analysis of the EP questions for January 2017–March 2018 shows 39 questions that mention evaluations. Seven of these reflect on policies evaluated as underperforming. Five questions on on-going evaluations demand that the evaluation be geared towards dimensions of policy performance or ask the EC to be more explicit on the evaluation strategy. MEPs also question the method of evaluation (17 questions), ask for actions to be taken once the evaluation is done (10 questions) or point towards lack of evaluation (17 questions). Sometimes conclusions from an evaluation are the simply the introduction to the question (10 questions) (Radaelli 2018).

⁽³⁶⁾ *The Evaluation Partnership, Evaluation of the Commission's Impact Assessment System. Final Report, April 2007*, cited in Maśnicki 2016.

differs from, for example, the **American system** which uses **quantitative thresholds** (e.g. regulations having impacts greater than a given monetary amount) of the expected impacts (Golberg 2018).

- (c) There are cases where **IA is not carried** out or not done properly (Impact Assessment Institute 2017; Radaelli 2018).
- (d) **Justification when no IA** is carried out is **often lacking** (Impact Assessment Institute 2017; Van den Abeele 2015).
- (e) The need for **additional IA by the EP and the Council** lacks clarity concerning:
 - i. **what constitutes a 'substantial' amendment** prompting the duty to carry an additional IA (Alemanno 2015; Radaelli 2018); the principle that for substantive amendments the Council and EP should conduct their own IA appears **not to have been applied in practice** (the authors here refer to the application of the IIA in 2003, and comment the provisions in the draft of the new IIA which seems to acknowledge the existence of the problem) (van Golen and van Voorst 2016).
 - ii. the **exact timeline** to be followed (Alemanno 2015; Van den Abeele 2015);
 - iii. **a common methodology** to be shared by the three institutions (Van den Abeele 2015);
 - iv. **who within the EC might actually provide 'assistance'** (Alemanno 2015);
 - v. **what could happen if the very same amendment is assessed differently** by the co-legislators (EP and Council, with a role of MSs in the process) and the EC (Alemanno 2015; Van den Abeele 2015).
- (f) **National exhaustive IAs** are still **missing**. The amount of EU legislations that shall be enforced in 28 MSs renders any exhaustive study of potential impacts impossible (Racchah 2016).

2. Methodology

- (a) In the BR 2015 Guidelines, **there is no significant innovation** on procedural modalities and preferred methodologies (Alemanno 2015);
- (b) The EC doesn't explain whether the methodology that will be used for **delegated acts** is the same contained in the (new) guidelines: one would expect cost-benefit analysis to be applied more systematically (Renda 2015).

(c) **There are persistent weaknesses** (Golberg 2018).

- i. **Empirical evidence** is found to be presented in a **selective manner** (Leszczyńska 2018)³⁷ (She analyses one IA carried out in 2012. She notes that the improvements of the BR 2015 might help avoiding these shortcomings, but that it is still too early to conclude that it is the case).
- ii. There is a tendency to **prepare a justification for a predetermined preferred option** (Delogu, 2016; RSB cited in Golberg 2018)³⁸.
- iii. **Insufficient explanation** of the problem and the necessity for an EU-level solution (RSB cited in Golberg, 2018);
- iv. **Focus on actions** (what the EC wants to do) rather than on the results to be achieved (Golberg 2018);
- v. Despite an improvement on the quantification of both costs and benefits (RSB cited in Golberg, 2018), there are **concerns on:**
 1. **lack of specific data or evidence** (Council cited in Golberg, 2018);
 2. **outdated data** (Council cited in Golberg, 2018);
 3. performance indicators, methodologies, modelling, scenarios, criteria, and a **narrow scope of analysis** of the data (Council cited in Golberg, 2018);
 4. **inconsistent links** between calculations and policy choices (Council cited in Golberg, 2018);
 5. **insufficient coverage of certain impacts** (Council cited in Golberg 2018). The Guidelines have been criticised for their **lack of priority given to health, safety and environmental concerns** (van Schagen 2017):
 - a. The Guidelines do not reflect the need to prioritise **consumer protection** even though it is contrary to the Charter, the Treaty on the Functioning of the European Union (TFEU), and CJEU case law (van Schagen 2017).
 - b. The Toolbox refers to consumer protection but it does not consider **consumers' legal position** and assumes the beneficial effects of the free market. There is a tendency towards consumer confidence and empowerment rather than protection (van Schagen 2017).
 6. **better enforcement** is rarely considered separately (van Schagen 2017);

⁽³⁷⁾ Leszczyńska (2017) deals with the IA issued in 2012 by the EC with a Directive proposing a 40% obligatory female representation on the boards of directors in European public companies.

⁽³⁸⁾ Delogu (2016) reports the claims of business organizations.

7. **Insufficient understanding of national circumstances and impacts** (RSB, Council cited in Golberg, 2018);

- (d) Analysis shows that **all six mainstreamed objectives**³⁹ defined in the EU treaties have a place within the IA system, but their systematic consideration is not ensured (Smismans and Minto 2017)⁴⁰.

3. Use

- (a) IAs can be **difficult to rely on in practice**. This is due to their **complexity, cost and methodology**. The useful IA is difficult to realise (Nowag and Groussot, 2018).
- (b) It is unclear if and how IAs really **genuinely inform** the development of the proposals (Radaelli 2018; Van den Abeele 2015), also because they are published simultaneously (Radaelli 2018).
- (c) If we assume that politicians and bureaucrats are smart, we should also assume that **gaming of BR procedures is happening**. For IAs, this could mean that the evidence that supports the initially preferred option has received a more prominent treatment than the others (Wegrich 2015). IAs may become a source of abuse and inefficiency when used as a political control tool or in an inappropriate way (Delogu 2016).
- (d) The IA has only **post-decision effect**, since the decision on whether to initiate legislation is made already within the Inception IA (Dunlop and Radaelli 2015; Mańnicki 2016).
- (e) The fact that more IAs should be conducted at **different stages** raises a number of questions (Van den Abeele 2015):
- i. **targeted IAs might unbalance the entire proposal** (Van den Abeele 2015);
 - ii. the obligation for 'significant amendments' to be systematically justified by a neutral IA risks **compromising the fluidity of the process** (Van den Abeele 2015);
 - iii. an IA **conducted after the triilogue risks delegitimising the ordinary legislative procedure** (Van den Abeele 2015).
- (f) **IAs are not binding** on either the EP or the Council (Golberg 2018). The Council amendments to legislative proposals are not subject to any assessment (Renda 2016).

⁽³⁹⁾ A political objective is said to be 'mainstreamed' when it becomes horizontally applicable across all policy areas (in the analysis, these are: gender equality; the horizontal social clause; non-discrimination on the basis of gender, racial or ethnic origin, religion or belief, disability, age or sexual orientation; environmental policy integration for sustainable development; consumer protection; securing fundamental rights. Smismans and Minto, 2017).

⁽⁴⁰⁾ The analysis in Smismans and Minto (2017) considers 35 IAs adopted between 6 May 2011 and 20 February 2014. See Annex 3 for details.

- (g) The **BR is considered soft law**⁴¹ without clear legal effects. It is highly unlikely that a direct challenge of a particular IA would be successful (Leszczyńska 2018).
- (h) None of the **external IAs reviewers** (RSB, the European Ombudsman, the ECA and the CJEU) takes a comprehensive view (Meuwese 2017).
 - i. The review undertaken by **ECA** and **European Ombudsman** remains limited in scope. There is an incremental increase of activities by the **CJEU** (Meuwese 2017).
 - ii. The **move from Impact Assessment Board (IAB) to the RSB** implies that more attention for substantive review may be expected. Yet the 'procedural approach' remains an attractive option. The RSB only provides a non-specialist peer-review (Hines 2016).
 - iii. The RSB is attempting to contribute to an informational level-playing field. One risk related to this type of review is that its role becomes so **routinised** that the EC start relying on the RSB as an additional source of expertise, rather than trying to meet its standards as a reviewer (Meuwese 2017).

4. IA of implementing regulations (Voermans 2016):

- (a) Exemption to the need for an IA can readily be claimed since the basic regulation itself will most of the time have been subjected to an IA (Voermans 2016);
- (b) not technically possible from a cost and capacity perspective (Voermans 2016).

2.3 Overarching remarks

1. The **BR philosophy is today the dominant 'doctrine'** in the EC thinking about what IA and evaluation should be and for what purposes (Dunlop and Radaelli, 2017).
2. At the moment, the **actors as well as the problems and methods** of the different types of **IAs and evaluations** (including REFIT) **are not the same** (Dunlop and Radaelli, 2017).
3. The changes introduced by BR 2015 will bring about a **degree of politicisation**⁴² in evaluation (Smismans 2017), favored by:

⁽⁴¹⁾ Soft law instruments are acts with no legally binding force, but which may be characterized by normative content. Official EU soft law, as recognised by the TFEU, consists of recommendations and opinions. Other forms of soft law are, for example: annual reports, legislative agendas, white books, green books, guidelines, notices, and communications, codes of conduct, declarations, resolutions and inter-institutional agreements.

⁽⁴²⁾ The term politicisation is used here as a 'neutral' concept, referring to a process in which the topic becomes increasingly part of a debate and agenda that is set, influenced by and played out in the political realm and not simply by experts and administrators (Smismans 2017).

- (a) **evaluation becoming a political priority** (linked to the one of reducing the regulatory burden), **despite being presented as a neutral exercise**. Interest groups and citizens are encouraged to contribute, but are not supposed to put into question the objectives of the process itself. Evaluation also becomes a tool of centralization within the new EC (Smismans 2017);
 - (b) its more **systematic planning and scrutiny** (Smismans 2017);
 - (c) the focus on **linking evaluation and IA** (Smismans 2017);
 - (d) the application of evaluation to **regulatory intervention as well as to expenditure policy** (Smismans 2017);
 - (e) increased attention for the **interinstitutional dimension** (Smismans 2017; Stephenson 2017);
 - (f) increasing **participatory dimension** of evaluation (Smismans 2017).
4. The **mainstreamed objectives** are **overshadowed** in the IA system by concerns about economic impact and regulatory burden, although these have not been constitutionalized in the treaties as horizontal objectives (Smismans and Minto 2017).
 5. By increasingly **stressing the need to reduce 'regulatory burden'**, the EU risks strengthening a populist discourse that is **not evidence based**. At the same time, **evaluation is a key tool** of evidence-based policy-making to falsify the claims of populist discourse (Smismans 2017).
 6. So far, the CJEU has not subjected the IA to any further requirements, so that one might even argue that an **IA provides immunity to a measure** (Nowag and Groussot 2018) (see also section 4.3).
 7. **Overstating the potential of IA** to determine decisions creates excessive expectations and inevitable frustration. And the political decision-makers would be more willing to invest on consideration of technical assessments if it were clear that the role of experts in the decision-making process is to better inform, not to constrain the political process (Delogu 2016).
 8. **IA has a strategic role** (Dunlop and Radaelli 2017):
 - (a) for **MSs and pressure groups**, for possible control on the policy formulation activity of the EC (Dunlop and Radaelli 2017);
 - (b) for the **EC**, for strategic and operational management (Dunlop and Radaelli 2017).

2.4 Main observations from the literature review

2.4.1 General observations (aspects common to both evaluation and IA)

1. **Keep IA and evaluation documents accessible, understandable and useful for decision-makers** (Golberg 2018).
2. **Enforce the 'evaluate first' principle** (ECA 2018; van Golen and van Voorst 2016). The EC should not validate a proposal the IA of which is not based on previous evaluation; the RSB should pay due attention to its effective use (ECA 2018).
3. **Focus on supporting policy-making**, rather than on meeting procedural requirements (Golberg 2018).
4. The BR 2015 **should become an instrument for policy coherence with long-term goals and with global strategies**. This would also help to acquire more EP and Council's ownership of IA (Renda 2016; Taulègne 2017).
5. **Mainstream SDGs in the EU policy process**. This would require changes in definition of the problem and objectives in EU IA; to improve scientific input; to adjust the methodology to compare alternative policy options; to choose adequately monitoring and evaluation indicators; to involve other EU institutions; to plan regular reporting (Renda 2017a).
6. **All Institutions should acquire ownership** of the procedure. Structure the scrutiny exercise by including a procedure for the oversight of legislation based on performance (De Feo 2017) (the author makes a concrete suggestion in this respect).
7. **Formalise the EU pre-legislative procedure** (Racchah 2016).
8. To achieve the objective of an encompassing **cyclical approach** (Smismans 2015):
 - (a) **evaluation and IA units should not operate in isolation** and should reach those responsible for drafting policy (Smismans 2015);
 - (b) a **more participatory approach to evaluation would** provide valuable information but **also create a continuum in the broader set of actors involved**. However, this raises a wider question about who is expected to organise such broader participation (Smismans 2015);
 - (c) the more political nature of the type of cyclical policy level learning suggests envisaging **a more important role for the EP** (Smismans 2015);

- (d) **policy coherence** might be improved if **IA relied on more ex-post data** assessing policy outcomes in relation to broader EU policy (Smismans 2015).

2.4.2 Observations related to evaluations

1. Enhance the **coverage** of evaluations (Mastenbroek *et al.* 2016).
2. Conduct a gap analysis of data collection and management capabilities (ECA, 2018).
3. Establish a **systematic and ongoing obligation of the MSs to collect data** (Ruhl 2017).
4. Improve the **methodological quality** (ECA 2018; Mastenbroek *et al.* 2016). The EC should grant the RSB the right to scrutinize ex-post reviews other than evaluations (ECA 2018); stakeholders (Mastenbroek *et al.* 2016) and experts should be involved, the latter by creating a permanent expert panel (Ruhl 2017).
5. Require external evaluators to **state whether they used the corresponding IA in their analysis and why** (van Golen and van Voorst 2016).
6. More efforts appear to be necessary to make best use of the **review clauses** (Weber *et al.* 2017).
 - (a) Clearly define the **scope and the data** collection (EPRS 2017).
 - (b) **Costs and benefits** should be key elements of **monitoring and evaluation frameworks** (Golberg 2018).
 - (c) Ensure a **coherent** approach between the **EC and both co-legislators** (Weber *et al.* 2017). Develop a vademecum within the IIA. The EC should propose to enhance its binding nature (ECA 2018).
 - (d) Streamline the **terminology** used in legislative acts (Weber *et al.* 2017).
7. Increase transparency with a **centralised search engine** or 'evaluation monitor' (Mastenbroek *et al.* 2016; Ruhl 2017).
8. **Ensure adequate levels of staff expertise** (Eliantonio and Spendzharova 2017; Stephenson 2017). This would ensure adequate learning (Lofstedt and Schlag 2017).
9. **Spend more funds** on evaluations and on setting up an evaluation culture (Lofstedt and Schlag 2017).
10. For **significant changes or delays**, insert a message in the roadmap (EPRS 2017).
11. Move evaluation **from one-off complex exercises to ongoing assessment** (Golberg 2018).

12. Include a **societal dimension** linked to citizen perceptions of the impact, consequences and added value of European legislation (Taulègne 2017).
13. The BR itself could benefit from a **broad sectorial**, and above all, **independent evaluation of the implementing acts** (Voermans 2016).

2.4.3 Observations related to IA

1. **Conduct IA by default** for every proposal; if not possible, provide a clear justification (Impact Assessment Institute 2017).
2. Clarify the **benchmark criterion of 'significant impacts'** (Stoffel 2015)
3. Ensure the **starting point is a neutral one** (Impact Assessment Institute 2017).
4. **Analyse all relevant options and always include the one that is presented** in the corresponding legislative proposal (Impact Assessment Institute 2017).
5. The Guidelines should make clearer that in the drafting of proposed measures, their **impact on fundamental rights and principles, including consumer protection, must be assessed** (van Schagen 2017).
6. IAs should **actively explore policy options** that are likely to **maintain or raise the level of consumer protection** (van Schagen 2017) and should **consider complaints** of non-compliance with consumer rights (GfK Belgium quoted in van Schagen, 2017).
7. Systematise **national IAs of EU policy** in each legal system (Raccah 2016).
8. On the methodology:
 - (a) **be more transparent** about the assumptions and methodologies (RegWatchEurope⁴³ cited in Golberg, 2018; Impact Assessment Institute 2017);
 - (b) **more clearly differentiate between direct and indirect costs** (RegWatchEurope cited in Golberg, 2018);
 - (c) **separate recurring costs from one-off costs** (RegWatchEurope cited in Golberg, 2018);
 - (d) ensure that **assessment methods to identify the costs and benefits** of a regulation are **more objective** (e.g. the standard cost model developed in the Netherlands) and **jointly developed**

⁽⁴³⁾ RegWatchEurope is the banner under which Europe's seven independent national advisory boards coordinate to address and maximise the benefits of Europe's 'smart regulation' agenda and reduce regulatory burdens.

- with citizens, organizations or businesses (see the US) (Voermans 2016);
- (e) **further develop** and ensure a balanced implementation of **methods that correctly assess costs and both monetary and non-monetary benefits** (Delogu 2016);
 - (f) **structure the multi-criteria assessment and appraisal of risks**. The assessment of risk-related regulation must take into account results of the risk assessment made by EU specialized bodies (Delogu 2016);
 - (g) grant more attention to **competitiveness impacts** (RegWatchEurope cited in Golberg, 2018);
 - (h) improve quantification and **analysis of effects at MS level** (RegWatchEurope cited in Golberg, 2018);
 - (i) introduce the **analysis of legal risks**⁴⁴ in the IA (Racchah 2016);
 - (j) the guidance and the toolbox should be more explicit about data and methodology to be used for the impact on **trade** (Chase and Schlosser 2015).
9. IAs should **alert** officials to the need of particularly **justifying** the choices that **diverge from mandatory provisions** (van Schagen 2017).
10. **Use simpler**, more streamlined methods for **delegated and implementing acts** (Golberg 2018).
11. **Improve the mainstreaming potential of IAs**, for example by clarifying the IA guidelines and by adopting a more participatory approach (Smismans and Minto 2017).
12. There should be **clarity and honesty about the limitations** of IA (Delogu 2016).

⁽⁴⁴⁾ The definition of legal risk formulated by the author is the following: the prejudicial occurrence arising from an unclear, imprecise or uncertain normative provision imposing obligations to an individual, a company or an authority, which would be inequitable or financially unreliable (p.20).

3 Stakeholder consultation, participation and involvement

3.1 [Achievements] A positive pledge from the Commission to listen more closely to stakeholders...

1. The BR 2015 **strengthens public consultation and stakeholder involvement commitments** (Cărăușan 2016; Garben 2018; Golberg 2018; Lofstedt and Schlag 2017). This systematic open approach is welcome, **in view of more transparency** and thus **improved confidence** in legislation (Alemanno 2015; Impact Assessment Institute 2017; Renda 2015).
2. **Consultation⁴⁵ is extended to more types of EU legislation⁴⁶ and to every stage of the policy cycle** (Chase and Schlosser 2015; Delogu 2016; Eliantonio and Spendzharova 2017; Parker and Alemanno 2015; Radaelli 2018; Stoffel 2015). Consultations on Inception IA represent an opportunity also **for MSs** to receive more information (Sarpi 2015).
3. The decision to **open draft non-legislative acts⁴⁷ for consultation is a long-awaited major change**. It addresses not only a growing internal demand, but also expectations expressed by the US within the Transatlantic Trade and Investment Partnership (TTIP) negotiations (Alemanno 2015; Parker and Alemanno 2015).
4. **Participatory democracy** is therefore used to anchor both the **legitimacy** and the **effectiveness** of proposals (Dawson 2016; Meads and Allio 2015) – to identify obstacles to effective implementation in advance, and to avoid technocratic rule-making (Dawson 2016). The BR 2015 also uses participatory democracy to anchor its REFIT programme⁴⁸ (Dawson 2016; Radaelli 2018).
5. The consultation process provides the opportunity for **new information** to be gathered by the EC (Eliantonio and Spendzharova 2017; Impact Assessment Institute 2017; Radaelli 2018). Policy actors and analysts are provided with unprecedented systematic insight into the stakeholders positions (Eliantonio and Spendzharova 2017). There are no significant differences between insiders and outsiders when evaluating the regime (Bunea 2017).⁴⁹
6. Compared to the situation assessed in 2014, there is an **improvement** of stakeholder engagement. The value of the related

⁽⁴⁵⁾ Consultation here includes also the possibility to give feedback (as in the case of roadmaps, draft delegated and implementing acts, and adopted legislative or policy proposals).

⁽⁴⁶⁾ Including, notably, non-legislative acts (delegated and implementing acts) and other initiatives subject to IAs.

⁽⁴⁷⁾ i.e. delegated and implementing acts.

⁽⁴⁸⁾ REFIT is discussed in section 4 of the present document.

⁽⁴⁹⁾ Bunea (2017) examines stakeholders' preferences expressed in two consultations in 2012 and 2014. See Annex 3 for details.

composite indicator is the **highest among OECD countries** (and thus also among the single MSs of the EU) (OECD 2018).

7. **The timing for public and stakeholder consultation allows to take into account** the feedback and information received (Delogu 2016).

3.2 [Issues] ... but there are concrete challenges to translate consultation results into more streamlined and coherent policy proposals

1. **Participation** of stakeholders

(a) **Self-selection** bias (Impact Assessment Institute 2017).

(b) **Limited** participation.

i. Consultations seem to be targeting **individuals and groups with expertise** and technical knowledge (Alemanno 2015).

ii. Those participating are often **those already having access to the political process**, rather than those who are mostly affected by a certain policy initiative (Alemanno 2015; Dawson 2016; Eliantonio and Spendzharova 2017; Garben 2018; Pachi 2015; Sarpi 2015).

iii. Difficulty to adequately communicate and attract stakeholders (Ranchordas 2017).

iv. The **participation** of MSs, stakeholders, academics, citizens and other parties **in evaluation**, as is stressed in the BR guidelines, **is missing concrete mechanisms** (Smismans 2015); two online consultations do not automatically ensure that all relevant parties have an opportunity to express their opinion (Smismans 2017).

v. **Limited involvement of stakeholders in consultations on evaluations** is in line with what we know from other jurisdictions where the vast majority of notice and comments generate little public input, whilst few consultations attract a disproportionate attention because they are **politicised** by pressure groups' campaigns (Dunlop and Radaelli, 2017).

(c) **Unclear representation** of stakeholders' interests (organisations of differing size, representation and economic weight; 'stakeholders campaigns'; role for European Social Partners in the area of social policy) (Garben 2018; Impact Assessment Institute 2017; Van den Abeele 2015).

(d) Varying **level of expertise** of respondents (Impact Assessment Institute 2017; Van den Abeele 2015).

(e) **Ambiguous role of the 'high-level experts'** of the REFIT Platform (Van den Abeele 2015).

2. **Workload** and **consistency** of procedures

- (a) **Duplication** in the consultation procedures (roadmaps/Inception IAs and adopted proposals) (Impact Assessment Institute 2017).
- (b) The **period** allowed for replying to consultations has been **considered too short** for preparing positions on complex issues (Delogu 2016); this is true also for implementing measures and delegated acts, and certain agencies may be exempt from the requirement (Chase and Schlosser 2015).
- (c) **Too many consultations** running in parallel (Garben 2018).
- (d) Significant **workload** on stakeholders and on the EC itself (Impact Assessment Institute 2017; Radaelli and Schrefler 2015; Renda 2015; Renda 2016; Stoffel 2015).
- (e) **Non-Governmental Organisations (NGOs)** have **lamented** not to have sufficient **resources** to compete with business in a technical and scientific debate (Delogu 2016).
- (f) Significant work for **delegated and implementing acts**, and difficulties given their technical character (Renda 2015).
- (g) Lack of **corresponding proceduralisation**, as suggested by Article 11 of the Treaty of the European Union (TEU). This prevents a real engagement of public participation (Alemanno 2018).

3. Design of the **questionnaires**

- (a) Significant room to remove key aspects from the consultation, since participants are asked to comment on a **defined set of questions** which could preclude certain outcomes (Dawson 2016; Eliantonio and Spendzharova 2017; Garben 2018).
- (b) Heavy reliance on **closed questions** and limited room for free input. In certain cases, the questions are 'leading' (Impact Assessment Institute 2017).
- (c) **Limited added value of the responses**; the positions are usually along pre-determined political lines of which the EC is well aware (Garben 2018).
- (d) **Complex** and technical character (Ranchordas 2017).
- (e) **Lack of differentiation** between the consultation that would be run before, during or immediately after completion of the IA (Renda 2015).

4. Evaluation of **results**

- (a) Heavy reliance on **statistical** analysis, which might not offer an adequate representation of results (Impact Assessment Institute 2017).

- (b) **No or purely qualitative evaluation** of consultation outputs mentioned in the legislative proposal or IA (Impact Assessment Institute 2017).
- (c) Where conclusions are reached based on the statistical results of consultations (i.e., use of percentages of opinions), it is not always clearly stated that they are **based on the analysis of opinions, rather than evidence** (Impact Assessment Institute 2017).

5. Availability and use

- (a) **Insufficient access** to documentation related to consultations (Impact Assessment Institute 2017).
- (b) Lack of clear commitments on **how to use the results** of the consultations for policy-making (Chase and Schlosser 2015; Dawson 2016; Eliantonio and Spendzharova 2017; Garben 2018; Impact Assessment Institute 2017; Ranchordas 2017) notably in the case of adopted proposals (Alemanno, 2015), which carries the risk of reducing consultation to a ritual activity only (Dawson 2016; Maśnicki 2016).
- (c) Difficulty of verifying how the consultation process **has affected policy making**: it is not easy to find a direct reflection of the stakeholders' input in the further legislative proposals (Maśnicki 2016). Some cases show a lack of consideration of stakeholders' inputs (Bartlett 2018). On the other hand, excessive expertise and consultations might interfere with the political mission of the legislators (Willermain and Cioriciu 2015).
- (d) Unclear how **divergent information** and opposing views are contemplated in the regulatory process (Ranchordas 2017).
- (e) In its 2017 Report, the RSB noted improvements but also identified **quality issues** in the use of consultations (RSB cited in Golberg, 2018). The Ombudsman found maladministration in relation to shortening or not conducting public consultation (Ombudsman cited in Golberg, 2018).
- (f) **Contradiction** in some of the stakeholders' requests, between wanting to comment on a draft proposal (that is, before the decision is taken) and at the same time wanting to influence the policy choices at an early stage (Delogu 2016; Golberg 2018).

6. **Little is done to tackle other problematic features** of the current legislative process, such as the frequent use of dialogues, informal interinstitutional negotiations taking place behind closed doors (Garben 2018).

3.3 Overarching remarks

1. **Tensions** arise:
 - (a) between the ambition for **inclusive stakeholder participation** and its goal of processing stakeholders' feedback in a systematic, scientific manner **consistent with the exigencies of evidence-based** policy-making (Bunea 2017);
 - (b) between the idea of BR as a vehicle for more **participatory** decision-making and as a guarantee for **evidence-based** governance. What if the public consultation clearly shows a majority preference for a policy option that is not based on any sound facts? What guarantees legitimacy? (Garben 2018; Radaelli 2018).
 - (c) between an emphasized idea of **bottom-up** policy-making and political **and hierarchical control** over decision-making, which is reflected both in the internal re-enforced central authority within the EC and, externally, in the IIA in which a key objective is the policy agenda agreed by the principal institutions (Dawson 2016).
2. The consultation process brings up **considerations about preserving the institutional balance** at the EU level among the EC, EP, Council, national parliaments (NPs) and other advisory bodies (Alemanno 2015; Eliantonio and Spendzharova 2017; Van den Abeele 2015). Furthermore, the rather hostile BR stance on '**gold-plating**' in the form of national rules that 'go beyond' the standards set in EU rules goes against any idea that the BR would foster democracy by empowering the national legislator (Garben 2018).
3. The introduced additional consultation occasions raise **legal as well as practical challenges**, also related to institutional balance issues (Alemanno 2015).
4. The EC is in a way delegating its work to stakeholders who have many, varied and conflicting interests. Their influence can **open the door to hidden influences** (Van den Abeele 2015).
5. The techno-political approach to policy-making of the BR 2015 might paradoxically have **led to a compression of participatory democracy** and somehow chilled stakeholder engagement (Alemanno 2018).
6. Conflict over the BR is rooted in **what stakeholders prefer as a regulatory system of governance**. Evidence shows that stakeholders express different preferences: national authorities responsible for coordinating the BR and cross-sectoral business organizations support deregulatory and technocratic reforms. Business and public interest organizations are equally supportive of strengthening participatory policy-making. This complexity makes it difficult to evaluate the level of success in the implementation of BR reforms. Moreover, it raises questions about the methodology used by

policy-makers to systematically and accurately process and integrate stakeholders' policy input and feedback into policy-making (Bunea and Ibenskas 2017)⁵⁰.

3.4 Main observations from the literature review

1. Step up the efforts to ensure **balanced stakeholder input** (Pachl 2015).
2. Comments and feedback from stakeholders should be actively sought earlier in the process (Chase and Schlosser 2015; Delogu 2016).
3. Provide **additional guidance about methodologies** for evaluating the comments received (Chase and Schlosser 2015).
 - (a) **Design consultations as effectively as possible**, to generate evidence by summarizing the consultation results qualitatively and quantitatively (Impact Assessment Institute 2017).
 - (b) Favour **open-ended questions** and additional room for **comments** (Ranchordas 2017).
 - (c) Issues to be explored should be formulated in a way that takes into account all the relevant concerns (Delogu 2016).
 - (d) **State clearly when conclusions are based on the analysis of opinion**, rather than evidence (Impact Assessment Institute 2017).
4. Develop a method for **interactive public exchange** throughout the legislative process (Impact Assessment Institute 2017):
 - (a) online public expert forum (Impact Assessment Institute 2017);
 - (b) early publication of IAs in advance of their review by the RSB (Impact Assessment Institute 2017).
5. Adopt a set of requirements for a more **proceduralised approach** to consultation practices (Parker and Alemanno 2015).
6. Include **citizen narratives** as they can provide first-hand and diverse perspectives (Ranchordas 2017).
7. Clarify and uplift the **concretisation of the European Citizens' Initiative's** modus operandi (Willermain and Cioriciu 2015).
8. **Alternative types of action to strengthen legitimacy** should be explored, such as enforcing transparency for 'trialogues' (Garben 2018; Willermain and Cioriciu 2015).

⁽⁵⁰⁾ Bunea and Ibenskas (2017) analysis refers to the 'Stakeholders Consultation on Smart Regulation in the EU' organized by the European executive in 2012. See Annex 3 for details.

4 Level of regulation, including REFIT

4.1 [Achievements] An attempt to improve and streamline EU legislation...

1. The BR 2015 gives a **prominent role to improve** EU legislation. As a result, there is a **decrease in the number of legislative proposals and adopted acts**, and more streamlined Annual Work Programs of the EC (Alemanno 2018; Eliantonio and Spendzharova 2017; Golberg 2018).
2. The expected reduction of legislative activity presents an **opportunity to concentrate more deeply on what has already been achieved** and to develop its full potential (Pachl 2015). Institutions can devote more time to oversight of the legislation (De Feo 2017).
3. While introducing **reinforced criteria and procedures for the quality of regulation**, the EC has dispelled any concern on alleged 'de-regulatory' orientations (Delogu 2016).
 - (a) The **active reaction** to the first initiatives of the new EC by **civil society organisations** might have positively affected the definition of the BR Agenda (Renda 2015).
 - (b) **Deregulation is a 'myth'** of the BR Guidelines. The tools discussed are developed to give the answer to the question: 'how to legislate?', not to the question: 'to legislate, or not to legislate?' (Maśnicki 2016). Debates reducing the BR to the issue of deregulation are simplistic (Bunea and Ibenskas 2017).
 - (c) **The BR may very well lead to more regulation**, if this is warranted by the outcome of evaluation exercises and coincides with political priorities (Garben and Govaere 2018).
4. The package has the **potential to improve the multilevel governance of the EU**, by ensuring involvement of MS which is needed in order to oversee transposition measures, as well as to reach end-users and to gather information on the impacts of EU regulation on the ground (Golberg 2018; Renda 2015; Sarpi 2015).
5. The REFIT programme:
 - (a) allows to **extend the scope of evaluation to whole policy areas** (Delogu 2016);
 - (b) can **identify overlaps and inconsistencies** that have arisen over time, together with the negative effect of the practice of so-called 'gold-plating' (Taulègne 2017);
 - (c) deserves appreciation because of its **clear mission, realism, and comprehensiveness** (Voermans 2016);
 - (d) has a **permanent** character (Delogu 2016);

- (e) **is much more political** than the evaluation of projects within the structural funds (Dunlop and Radaelli 2017);
- (f) **business stakeholders become co-responsible** for the initiatives carried out by the program (Dunlop and Radaelli 2017);
- (g) although REFIT is a channel for de-regulatory demands, **it is not framed as anti-EU or anti-regulation** per se (Dunlop and Radaelli 2017).

6. The REFIT Platform:

- (a) is an explicit **institutionalization of participation** and an instrument of advocacy for stakeholders (Renda 2015; Smismans 2017);
- (b) in terms of good governance, refers to the **accountability and coherence principles** (Maśnicki 2016);
- (c) makes it possible for the **public to intervene** on technocratic aspects (Alemanno 2015; Maśnicki 2016);
- (d) has a **concrete role** to identify suggestions and proposals (Sarpi 2015);
- (e) allows a **continuous exchange** not only on administrative burdens but **also on the impact of EU laws** (Sarpi 2015);
- (f) **puts together national experts and stakeholders** (Sarpi 2015);
- (g) is a connection between the BR and the approach to **subsidiarity** (Radaelli 2018).

7. The portal '**Lighten the load – have your say**'⁵¹ shows how the BR has also become a major communication and signalling tool (Dunlop and Radaelli, 2017). Though it seems more addressed at companies wishing to signal burdensome pieces of legislation, there is **no restriction** on the possibility that **citizens voice their concerns** (Renda 2017b).

8. '**Innovation deal**'⁵² will address regulatory uncertainties which can hinder innovation (Renda 2017b).

4.2 [Issues] ... but criticalities remain

1. The **rhetoric** of the EC is **focused much more on burdens and regulatory costs than benefits** (Golberg 2018; Pachi 2015; Renda 2015; Van den Abeele 2015). The real issue is whether the legislation

⁽⁵¹⁾ The platform is available at https://ec.europa.eu/info/law/better-regulation/lighten-load_en

⁽⁵²⁾ 'Innovation deal' is a new instrument launched by EC in 2016 that aims at creating a fast-track channel for 'quick fixes' in EU and national legislation, through clarification and interpretation of legislation, rather than through changes in the text of the law. It will in principle address regulatory uncertainties identified by innovators, which can hinder innovation within the existing legal framework (Renda 2017b). https://ec.europa.eu/research/innovation-union/pdf/innovrefit_staff_working_document.pdf

in question ultimately brings benefits that outweigh the costs they generate, not only in economic but also in broader (e.g. social and environmental) terms (Pachl 2015; Van den Abeele 2015).

2. The focus on streamlining **assumes that rational policy design is feasible**. However, this is not the case when multiple actors are involved. Overlap and redundancy can however create more resilience if a particular solution fails (Eliantonio and Spendzharova 2017).
3. On the REFIT programme
 - (a) The **rationale is unclear**, as are the criteria by which initiatives have been labelled as REFIT (ECA 2018).
 - (b) It is **inward looking: procedural and interinstitutional**. It takes insufficient account of the different perspectives and contexts of complaints about regulations (Voermans 2016).
 - (c) Targets and regulatory budgeting **are not suited to EU-level governance** (Golberg 2018).
 - i. If the methodology is based on **numbers of laws** and not costs, insignificant regulations would have the same weight as significant ones (Golberg 2018).
 - ii. Any request to safeguard cost reductions are seen as **restricting the co-legislator's prerogatives** (Golberg 2018).
 - iii. Regulatory budgeting risks being a **paper exercise** (Golberg 2018).
 - (d) Methodological foundations are shaky (Radaelli 2018).
 - i. REFIT can be a political springboard for a variety of actions (Dunlop and Radaelli 2017; Radaelli 2018).
 - ii. The **choice of the Directives** which have been assessed **is far from neutral** and transparent (Laulom 2018)⁵³.
 - iii. There is a **conceptual ambiguity**: REFIT is not a proper evaluation tool since some REFIT exercises are just appraisals of some regulatory costs. Since 2013, 'cumulative cost assessment' has also been under REFIT. This is not an evaluation (Dunlop and Radaelli 2017; Radaelli 2018). 2016 EC REFIT initiatives only focus on some cost categories (Dunlop and Radaelli 2017).
 - iv. The methods can be questioned for **lack of a transparent methodology** for the use of stakeholders' opinions, and the **difficulty to isolate the effects** of the evaluated Directives in the **national context** (Laulom 2018).
 - (e) The **exclusion of flexibility or gold plating** risks negatively impacting consumers and citizens and is also counterproductive for improving the public perception of the EU (Laulom 2018; Pachl 2015).

⁽⁵³⁾ Laulom (2018) analyses the three areas in the social field within the first REFIT Programme (results were summarized in a Staff Working Document (SWD) adopted in 2013).

- (f) **Communication** to external stakeholders is **poor** (ECA 2018).
- (g) The **results** need to be assessed (Golberg 2018).
 - i. There has been a **limited withdrawal** of proposals or pieces of legislation⁵⁴.
 - ii. In the 2017 Eurobarometer survey, **few businesses thought that costs were decreasing** (Golberg 2018). The RSB reports that 71% of REFIT initiatives had quantified cost saving (RSB cited by Golberg 2018).
 - iii. Despite a reduction in legislative output, **the volume of delegated and implementing acts increased** significantly. Additional monitoring and surveillance parameters in IA have been introduced (Van den Abeele 2015).
 - iv. Analysis shows that the REFIT Programme has legitimised the EC's lack of action and has fulfilled its social agenda, but **has not yet led to deregulation**. On the contrary, some gaps have been identified which have led the EC to begin a legislative review process (Laulom 2018).
 - v. **The costs/benefits balance of the REFIT** has never been questioned (Laulom 2018).
- (h) REFIT might **affect the EC's right of initiative**, limiting the pursuit of Treaty-sanctioned goals, such as public health or environmental protection, by prioritising 'alternative approaches' when 'regulatory costs are disproportionate to the goals pursued'. What 'alternative approaches' could entail remains far from defined (Alemanno 2015).
- (i) The REFIT programme did **not necessarily lead to more evidence-based and risk-informed decisions** (Lofstedt and Schlag, 2017)⁵⁵.

4. On the REFIT Platform

- (a) There is a **narrow focus on reducing regulatory burden** (Alemanno 2015; Smismans 2017), which raises questions also on the appropriateness of its institutional design to bridge the gap between policy-makers and stakeholders (Alemanno 2015).
- (b) The current set-up has **significant shortcomings** (Voermans 2016):
 - i. it seems to work on an **ad hoc basis** and is not itself able to carry out systematic studies (Voermans 2016);
 - ii. the work of the REFIT Platform **is not anchored in the standard decision-making processes** (Voermans 2016).
- (c) The **composition of the group** reflects the prioritization of the regulatory burden as an objective of REFIT (Smismans 2017).

⁽⁵⁴⁾ Zbiral R. (2018). *The Better Regulation Agenda and the Deactivation of EU Competences: Limits and Opportunities*. In S. Garben and I. Govaere (Eds.), *The EU Better Regulation Agenda: A Critical Assessment*. Bloomsbury Publishing. cited in (Garben 2018).

⁽⁵⁵⁾ Note: the authors here refer to examples before 2015.

- (d) **The European Economic and Social Committee (EESC) was included in the group of stakeholders, causing outrage** in the EESC quarters who believe they belong to an institution rather than being yet another stakeholder (Dunlop and Radaelli, 2017).
 - (e) It is a **top-down** process, in which the EC leads the REFIT Platform which in turns drives the Lighten the load portal (Alemanno 2018).
 - (f) Whilst aimed at stakeholder involvement, it is **expected not to politicise the debate** (Smismans 2017). However, there is a high risk of ending up as a forum for political discussion reproducing already existing cleavages (Jarlbæk Pedersen 2017).
5. The **Lighten the load – Have your say** portal has a very low impact:
- (a) the **focus** seems very much only on whether the **existing regulatory framework is too burdensome** (Smismans 2017);
 - (b) it has well-known **self-selection biases** typical of online consultations⁵⁶ (Ranchordas 2017; Sarpi 2015).
6. In the BR there is little attention to some **other crucial issues** (Radaelli and Schrefler, 2015):
- (a) alternatives to traditional regulation (Radaelli and Schrefler, 2015);
 - (b) draw on cognitive and behavioral economics to design regulation (Radaelli and Schrefler, 2015).

4.3 Overarching remarks

1. There are concerns about **a deregulation policy agenda** (Dawson 2016; Delogu 2016; Eliantonio and Spendzharova 2017; Laulom 2018; Van den Abeele 2015).
 - (a) It is unclear whether 'reduce regulatory burden' implies **deregulation**. There is a **danger** that the decision-making process will be subjugated to technocratic and cost-focused criteria and procedures. Negative repercussions such as 'paralysis by analysis' or lower protection are to be expected (Pachl 2015).
 - (b) Certain elements of the BR 2015 risk a systematic bias against regulatory standards, particularly to pursue non-economic interests (Garben and Govaere 2018).

⁽⁵⁶⁾ For example, the most vulnerable stakeholders might not have the digital skills to offer their contribution (Ranchordas 2017).

- i. BR is **defined largely in terms of implementing costs**, a framing that may in itself be unfriendly to legislation aiming at non-market objectives (Dawson 2016).
 - ii. The preference for **quantification** is not neutral vis-à-vis different EU objectives. It may be far easier to quantify costs associated with market impacts (Dawson 2016). One of the main methodologies used in IAs and evaluations is **cost-benefit analysis**, which poses a number of problems in terms for the quantification of non-quantifiable benefits⁵⁷.
 - iii. There are doubts about **how objective BR assessments are from a methodological perspective** (subsidiarity is operationalised in IA in a default preference for 'non-regulatory alternatives'; the REFIT has the explicit aim to address burdensome regulation; Garben, 2018).
 - iv. The **administrative resources** and the **expected burdens** and difficulties of passing an IA may deter from developing new proposals from the outset, most likely in the **non-economic policy areas** (Garben and Govaere 2018)
- (c) Certain stakeholders and interests, such as SMEs, have a **privileged position** within the measuring of policy impacts (Dawson 2016). Exceptions for microenterprises and SMEs are not always acceptable. What constitutes a burden for some is a necessary protection or right for others (Pachl 2015).
- (d) The danger is that the **main targets** of REFIT will be proposals whose implementation **costs are high**, such as those which implement the EU's environmental and social acquis (Dawson 2016; Eliantonio and Spendzharova 2017; Laulom 2018; Renda 2015). The BR has been **regarded with suspicion** by most of the NGOs and other organisations focusing on health, safety, environmental, consumer and worker protection, which have seen it has a business/lobby-driven approach aimed at deregulation (Delogu 2016).
- (e) There is a strong emphasis on **conceptualising subsidiarity** in terms of a preference for the use of less harmonising and hierarchical regulatory instruments (Dawson 2016).
- (f) **An excessive focus on simpler, flexible and more lenient regulation may result in an opposite outcome**, with high cost to business, market disruption, loss of competitiveness and jobs loss (Delogu 2016).
- (g) The assessment of the **legitimacy of the BR as a tool of 'deregulation'** depends on the EC's proper **constitutional**

⁽⁵⁷⁾ Renda A. (2018). Cost-Benefit Analysis and EU Policy: Limits and Opportunities. In S. Garben and I. Govaere (Eds.), *The EU Better Regulation Agenda: A Critical Assessment*. Bloomsbury Publishing cited in (Garben and Govaere 2018)

- role.** What, under the 'regulatory paradigm', may be improper – the prioritising, for example, of competitiveness over social Treaty objectives – is legitimate if we accept a politicised role of the EC (Dawson 2016).
- (h) The BR does nothing to address **the EU-induced deregulation on the national level** that triggers the need for EU reregulation (Garben 2018).
 - (i) Politically, there is **tension between the deregulatory vision of some Council formations and some MSs, and the approach of the EC** (Radaelli 2018), as shown by controversy on the feasibility of an EU-wide business impact target (Renda 2017b).
2. On the relationship between **regulatory and political** aspects.
 - (a) **Regulatory streamlining is not simply a technical matter**, but it involves making political choices (Elia Antonio and Spendzharova 2017).
 - (b) Proposals with the **higher risk of politicisation** dominate even among the regulatory proposals (Jarlbæk Pedersen 2017).
 - (c) The BR has been used **foremost** as an **instrument of control** of which proposals to adopt and which to withdraw (Alemanno 2018).
 3. **Withdrawal** of proposals may be **worrying for the EU's legitimacy, as well as for the EC authority** and competence (Willermain and Cioriciu 2015).
 4. **The implicit assumption that there is indeed a problem of over-regulation in the EU system is not so evident** (Garben 2018).
 - (a) There are **significant methodological biases in the calculation of the 'regulatory burden'**. There is no evidence for a cause-and-effect relationship established between the volume of EU regulations, on the one hand, and the EU's prosperity, on the other hand (Van den Abeele 2015).
 - (b) **This aim is based on evidence on perceptions of a problem and on political choices.** Indeed, the narrative of an over-regulating EU stands in stark contrast to competing accounts of the EU's regulatory asymmetry, said to lead to an overall deregulatory bias in European integration (Garben 2018).
 - (c) **The BR is a counterproductive policy:** by formulating 'EU over-regulation' as a part of the problem definition, feeds the existence of the very problem that it intends to solve (Garben 2018). The message is that the EU produces legislation that is not fit for purpose. This even reinforces mistrust of the EU (Van den Abeele 2015).

- (d) **The BR is criticised** both by Euro-sceptics, arguing that the regulatory process creates red tape, and by those supporting regional integration, expressing concerns that the efforts fall short of the true ambitions of the European project (Willems 2016).
5. A crucial aspect is the **relationship between EU regulation and the rule of law** (Dawson 2016).
- (a) On the one hand, the package provides mechanisms to **rationalise EU policy-making**, and to make judicial review easier (Dawson 2016).
- (b) On the other, it promotes the channeling of regulation through mechanisms in which normal processes of **interinstitutional consultation and judicial review are limited**. The principle danger is that the CJEU increasingly confines its review to formal assessment of *whether* an IA has been conducted⁵⁸. Furthermore, the **current BR package is far more accommodating of alternative methods of regulation** that may either escape normal legislative procedures, or be difficult to review judicially at national or EU levels (Dawson 2016).
6. The **legitimacy of the BR 2015** is also debated (Garben and Govaere 2018).
- (a) The BR 2015 shows growing **independence from political authority** through its institutionalisation (for example, by autonomous institutions like the RSB). This raises questions about its democratic legitimacy (Garben and Govaere 2018).
- i. Certain of the Agenda's objectives are **conducive to legitimacy**, such as commitments to participatory government through public consultation and to transparency (Garben and Govaere 2018).
- ii. Others are instead about curbing political discretion in pursuit of the 'regulatory paradigm' of evidence-based policy. In some cases, legitimacy could be found in the EU Treaties (examples: explicit subsidiarity component in IAs), but there are **some constitutional arguments against certain aspects of the BR 2015** (for example, the BR 2015 at times hostile stance towards higher national regulatory standards) (Garben and Govaere 2018).
- (b) The BR 2015 **fails as a substantive reform agenda and as a public relations exercise** designed to combat criticisms that

⁽⁵⁸⁾ As long as preparing an IA is optional, as confirmed by the latest BR package, the lack of an IA could not be itself the reason for annulment. However, as follows from the CJEU judiciary review, the evaluation of the assessment studies usually does not result in the annulment of the contested EU measure (Mańnicki 2016).

the EU suffers from onerous regulations that strangle businesses⁵⁹.

4.4 Main observations from the literature review

1. By formulating 'EU over-regulation' as a part of the problem definition that it is aimed at addressing, the BR 2015 feeds the existence of the very problem that it intends to solve. It would be more effective **to engage in a positive public relations exercise on the benefits of EU regulation instead**⁶⁰.
2. If the political aim is to freeze regulatory activity and to deregulate, **there are less costly ways to achieve the same result**, such as **legislative moratoria**. If there are unnecessary costs, irritation or other burden, zero in on that legislation or areas of legislation so that **tailored cost reduction** measures can be developed (Golberg 2018).
3. **Adopt a sequential approach to cost reduction** by setting reduction targets in selected policy areas, and gradually build capacity on the quantification of regulatory costs for all the relevant EU's *acquis* (Renda 2017b).
4. The EC should **clarify the REFIT concept** and mainstream its presentation and its use to avoid the perception that REFIT is separate from the standard BR cycle (ECA 2018).
5. In REFIT, the EC needs to function as an effective gatekeeper to ensure depoliticisation (Jarlbæk Pedersen 2017).
6. Equip the EU with **smart rules** forcing the paradigm of 'all for competitiveness' to be replaced with a 'smart revolution for sustainable development' (Van den Abeele 2015).

⁽⁵⁹⁾ Kelemen R.D. (2018). Eurolegalism and the Better Regulation Agenda. In S. Garben and I. Govaere (Eds.), *The EU Better Regulation Agenda: A Critical Assessment*. Bloomsbury Publishing. cited in (Garben 2018).

⁽⁶⁰⁾ Kelemen R.D. (2018). Eurolegalism and the Better Regulation Agenda. In S. Garben and I. Govaere (Eds.), *The EU Better Regulation Agenda: A Critical Assessment*. Bloomsbury Publishing. cited in (Garben 2018).

5 Regulatory Scrutiny and quality assurance

5.1 [Achievements] A redefined scrutiny body as an important achievement ...

1. The RSB has a **renewed composition and dedicated personnel** (Chase and Schlosser 2015), which promise to **enhance its independence** (Alemanno 2015; ECA 2018; Leszczyńska 2018; Radaelli 2018; Stoffel 2015), as illustrated by the number of negative opinions it has issued (ECA 2018).
2. The RSB can handle **different types of scrutiny including evaluation and fitness checks** (Alemanno 2015; Delogu 2016; ECA 2018; Radaelli 2018; Stoffel 2015).
 - (a) This will strengthen the overall capacity and inject a **more holistic approach** to its quality control mechanism (Alemanno 2015).
 - (b) The new Guidelines also appear to **increase the procedural coherence** of the EC's IA process (EPRS 2015).
 - i. This involves **strengthening the role of the SG and of the RSB** (EPRS 2015).
 - ii. All members of the RSB are **now attached to the SG** of the EC, whereas before they retained a stronger link with their DG of origin (EPRS 2015).
 - iii. It is now more clear that **the positive opinion of the RSB is necessary** for any initiative to go ahead (Delogu 2016; EPRS 2015; Stoffel 2015).
 - (c) The **EU approach is at the policy frontier**, ahead of the corresponding oversight body in the US (Office of Information and Regulatory Affairs, OIRA), which is yet not involved in retrospective analysis on a regular basis (Broughel 2015).
3. The opinion of the RSB **adds transparency** (Lofstedt and Schlag 2017; Radaelli 2018) and **flags up issues** to be considered in the legislative procedure. The latter are valuable even when, for political reasons, the EC would still carry on with proposals despite negative RSB opinions (Radaelli 2018).
4. In the terms of the good governance requirements the tasks conducted by the RSB fit in the **accountability** (Maśnicki 2016).
5. The emergence of oversight bodies in both the US and the EU confirms the **desirability of regulatory oversight** (Wiener and Alemanno 2017).
6. The shift of **consumer protection and fundamental rights and principles** from the Guidelines to the Toolbox has not stopped the

RSB from considering these principles and the Charter (van Schagen 2017).

5.2 [Issues] ...but RSB resources and mechanisms to enforce its decisions could be improved

1. RSB composition

- (a) The **RSB retains the character of an 'in-house' body** (Meuwese 2015; Meuwese 2017). **The transformation of the IA Board is a partial one only.** A tripartite Board for all three institutions seems to be the end game, but the institutions are not ready yet for such a radical institutional design (Meuwese, 2015).
- (b) Considering the amount of work done, **RSB members are not adequately supported** by a team **of economists and social scientists** (Radaelli, 2018a).
- (c) The **lack of a dedicated secretariat** separate from the SG of the EC poses a risk to its independence (ECA 2018).
- (d) The RSB has been granted **little new power or authority** and remains insulated from stakeholder input (Chase and Schlosser 2015).
- (e) It took **2 years for the RSB to be fully staffed**; slow process could be interpreted as lack of commitment (Impact Assessment Institute 2017).
- (f) The head of the RSB chairs the REFIT platforms, deputising the first Vice-President on this exercise. However, there is **no conceptual connection** between the RSB scrutiny activity and the REFIT platforms (Radaelli 2018). This could jeopardise the perception of the independence of the RSB (ECA 2018).
- (g) It is not easy to ensure the **independence and impartiality of external experts** (Sarpi 2015; Willermain and Cioriciu 2015). Since external members are temporary agents, the 'revolving door' phenomenon should be avoided (Meuwese 2015).
- (h) The **relationship between the external and internal members** might **affect** overall independence. The voting rules may split the insiders over the outsiders (Alemanno 2015).
- (i) The underlying idea of the EC seems to be that **ultimate responsibility on quality** should be **outsourced to be credible** (Sarpi 2015). The addition of three 'independent' members reflects interest in external expert input (Wiener and Alemanno 2017).

- i. It is not clear if this solution ultimately **hinders or enhances confidence** in the neutrality of these assessments (Sarpi 2015).
- ii. True **independence is most likely unattainable and perhaps also undesirable**, given the need to retain the IA relevance to the policy process. The question is then which model for quality control of IA approximates 'independence' most fittingly (A. Meuwese, 2015).

2. RSB role and procedure

- (a) Once the RSB has approved an IA, it does not seem to have a clear way to ensure that **all its recommendations are there reflected** (van Schagen 2017).
- (b) There is an issue of **legitimation of the RSB role in the institutional structure**, since its appointment is not discussed in the EP. This could be interpreted as a partial privatisation of the EC's decision-making process (Van den Abeele 2015).
- (c) The competences of the RSB will need to be examined with **respect to the REFIT Platform**, especially when they come to different conclusions (Mańnicki 2016).
- (d) **Ex-post reviews other than evaluations are not within the scope** of competence of the RSB (ECA 2018).
- (e) There is **a risk that the RSB will become the censor of legislative activity** (Van den Abeele 2015).
- (f) **No formal appeal proceeding is foreseen against an RSB opinion**, differently from the US (Wiener and Alemanno 2017).
- (g) The **role of the RSB is more fragmented** compared to the corresponding body in the US (OIRA) (Wiener and Alemanno 2017):
 - i. The RSB's (and, previously, the IAB's) review of proposals for legislation occurs **much earlier in the policy cycle**, before further amendments and the details of implementation are worked out (Wiener and Alemanno 2017).
 - ii. The RSB (and, previously, IAB's) oversight role is **nested in other bodies**, including the CJEU, the ECA, and the European Ombudsman (Wiener and Alemanno 2017).
 - iii. The **positioning of the RSB may mean it is less political**, but **also potentially weaker** than in OIRA, which functions as part of the Executive Office of the President (Broughel 2015).

- (h) The **Toolbox and the Charter do not serve as a basis for evaluation by the RSB** (van Schagen 2017):
 - i. the guidance on how to analyse measures' impact on consumer protection is provided **only by the Toolbox** and not by the Guidelines (van Schagen 2017);
 - ii. non-compliance with fundamental principles **does not necessarily lead to a negative opinion** (van Schagen 2017).

5.3 Overarching remarks⁶¹

1. In general, there is a **fundamental question about who is and should be in control of the life cycle of a policy**. Behind the emergence of the RSB lies a tension between those MSs in favour of a totally independent oversight body, and the EC, for which this should remain a component of the internal process of monitoring and learning (Radaelli, 2018a).
2. In most of the recent legislation, **performance objectives and indicators** together with evaluation and reporting arrangements made the scrutiny activity more relevant. Review clauses should raise scrutiny from a technocratic exercise to a **more political dimension** (De Feo 2017).
3. The **BR** programmes themselves have **never** as such been **subjected to such evaluation** (Voermans 2016).
4. New procedures and institutions to improve the quality of EU legislation have been put into place. **But the mere existence of medicine can never in itself provide the proof that the disease has been cured** (Voermans 2016).
5. While the **BR seemingly addresses poor legislative quality**, since EU's diversity is the root cause of the problem and cannot realistically be resolved, the **BR is fighting an unwinnable battle** (Garben 2018).
6. In the **absence of agreed indicators**, it is **difficult to draw definitive conclusions on the performance** of the BR (Golberg 2018).
 - (a) The **RSB requests resubmission in relatively more cases than the UK's scrutiny body**.
 - (b) The RSB estimates that **only around 4% of IAs failed to take comments of the Board into account**.

⁶¹) Authors also report general considerations on the quality assessment of the BR 2015 itself. Since these remarks are related to the quality assurance of the process, they are reported both in this section and in the Concluding remarks.

- (c) The **ECA** recently released a special report (ECA 2018) on the ex-post review of EU legislation (see related text in the present document).
 - (d) The **EC internal audit department** concluded in 2016 that there was a continuous improvement of the process and of the development of comprehensive guidelines and that the BR tools are embedded in policy preparation processes and generally accepted. Critical elements are the lack of a monitoring framework and low participation in stakeholder consultation. They also pointed to the need to continue to foster a 'BR culture' and to communicate more clearly on the internal workflows for policy development.
 - (e) The **EP and the Council** review mechanisms **have usually supported the opinions of the RSB** in their documents.
7. **There is no judicial scrutiny over the obligation to respect fundamental BR principles** throughout the process (as e.g. in the US) (Renda 2016).
 8. The **RSB oversight activity** on evaluation is a novelty and **capacity** will have to be built (Dunlop and Radaelli, 2017).

5.4 Main observations from the literature review

5.4.1 Observations related to BR quality assessment

1. Adopt a **broad view** (notably on goals) when evaluating the success of EU Better law-making and regulation policies (Voermans 2016).
2. Any evaluation will have to be **problem-oriented: addressing complaints** and concerns about EU legislation is the **yardstick for success** (Voermans 2016).

5.4.2 Observations related to BR

1. In IAs, **state clearly if a political decision is made to continue despite a negative opinion of the RSB**, and explain in full the reasoning for continuing with the proposal (Impact Assessment Institute 2017).
2. Based on **other existing models** like the Council of State model and the Offices of Goodness in the US, **consider adding to the toolkit of the RSB** (Meuwese 2015):
 - (a) **a type of complaint investigation** (Meuwese 2015);
 - (b) **the possibility to scrutinise IAs as they are being prepared** instead of just the 'end products' (Meuwese 2015).
3. Seek **external members capable of measuring whether regulations benefit society as a whole**, including non-economic

impacts of regulations such as health, safety, citizens' well-being and the environment (Pachl 2015).

4. **Improve citizens capacity to understand, and engage with** inevitably imperfect legal texts (Garben 2018).

6 Transparency in policy making in the context of BR

6.1 [Achievements] Enhanced openness, in particular concerning information on evaluations...

1. Compared to other organisations and national entities, the EU is **one of the most transparent structures in the world** (Willermain and Cioriciu 2015).
2. The BR strives to further **open up EU policymaking for public participation** (through extended consultations) **and therewith make the EU more transparent and accountable** (Jancic 2015; Willermain and Cioriciu 2015).
3. The **open web portal where legislative initiatives could be tracked** is one very welcome component of the reform since it is a crucial tool for transparency and was supposed to be in full swing a long time ago (Willermain and Cioriciu 2015).
4. There is an **improved accessibility** to the information on **evaluation**.
 - (a) The idea that the evaluation should feed back into the political decision-making process underpins the EC's attention to **ensuring better communication and transparency**, so as to increase the number of actors that can be involved in the 'policy-learning' process (Smismans 2015).
 - (b) Implementation of the **2015 BR Guidelines** has clarified the status **of ongoing and planned EC evaluations** considerably, by making fully centralised and easily accessible the relevant information. **Roadmaps** are in many respects **the most informative source** of information on planned and ongoing evaluations and fitness checks (EPRS 2017).
 - (c) The **Interinstitutional Database of EU Studies**⁶² has the potential to become the internal 'one-stop-shop' on **planned, ongoing, and completed evaluation** work in the EU institutions (EPRS 2017).
 - (d) The publication of the Overview of Commission's **Completed Evaluations and Studies**⁶³ in 2016 is a welcome addition to the existing sources (EPRS 2017)⁶⁴.
5. Compared to 2016, the **RSB now tracks systematically quantification efforts** in IAs and evaluations in its 2017 Report⁶⁵. It

⁽⁶²⁾ The Interinstitutional Database of EU Studies allows those working in the EU institutions to follow which external studies are currently being conducted for the Commission or have been published (EPRS 2017).

⁽⁶³⁾ Available at https://ec.europa.eu/info/sites/info/files/finalised_studies_and_evaluations_2016.pdf

⁽⁶⁴⁾ The creation of a central **database of evaluation files** on the EC's evaluation website is an important improvement, but it is not updated anymore (EPRS 2017; Smismans 2015).

also started to annex to its opinions, which are publicly available, the standardised tables suggested by the BR Toolbox for the preferred options (RSB SG and JRC Working Group 2018).

6. The **IIA** is a significant step forward in the application of openness (Maśnicki 2016); in particular, it **increases** the quality and **transparency of the pre-legislative process** (Alemanno 2018).
 - (a) The **access for EP** experts to documents and meetings concerning the **preparation of delegated acts** has improved (EPRS 2018).
 - (b) On 12 December 2017, the **joint register of delegated acts**⁶⁶ became operational (EPRS 2018).
 - (c) The **IIA** sets out a common understanding of the **timing** and **processes** to make the **legislative cycle more transparent** (De Feo 2017).
7. The European Parliamentary Research Service (**EPRS**) is arguably contributing to more informed and transparent law making, in line with the goals of the BR 2015 (Stephenson 2017).
8. Compared to the US, the EU pre-legislative process, **even before 2015, was more transparent**, rigorous and inclusive of stakeholders, largely due to the almost systematic use of IA (Parker and Alemanno 2015).

6.2 [Issues] ...but there are still deficiencies in information completeness, accessibility, consistency and timeliness

1. Issues concerning transparency of evaluations.
 - (a) It is complicated to obtain a **complete picture of finalised evaluations**, even more so for the wider public (EPRS 2017).
 - i. The central **database of evaluation files** is **not exhaustive** (Smismans 2015).
 - ii. There is **diversity in the amount of information available on DG websites** (EPRS 2017; Smismans 2015).
 - iii. The **Overview of Commission's Completed Evaluations and Studies** published in 2016 **has no date**; it is **unclear whether** and how often it **will be updated** and if it will become the main reference source on completed EC evaluations (EPRS 2017).

⁽⁶⁵⁾ Regulatory Scrutiny Board (2018).

⁽⁶⁶⁾ Available at <https://webgate.ec.europa.eu/regdel/#/home>.

- iv. It is difficult to access **original studies**, for example because of outdated links. Sometimes only an executive summary is provided (EPRS 2017).
2. Issues concerning transparency of IAs.
 - (a) The internal nature of the draft IA report combined with the delayed disclosure of its final version make it:
 - i. **difficult to determine whether the IA actually influenced the proposal** (Van den Abeele 2015; Wiener and Alemanno 2017)⁶⁷; there is also lack of transparency behind the decisions to submit or not certain legislative proposals where the IAs were ignored or not conducted at all (Van den Abeele 2015);
 - ii. **difficult** for the public **to comment** on the draft proposal (Wiener and Alemanno 2017).
 - (b) Background data and analysis of impacts (Impact Assessment Institute 2017):
 - i. **lack a synopsis** of key data and findings;
 - ii. **lack transparency** regarding calculations and modelling (input data, algorithms, raw output data).
 - (c) Many documents, in particular long ones such as complex IAs, **are split into a number of separate files**. This requires more effort to access and store, whilst reducing transparency (Impact Assessment Institute 2017).
 3. **The location of RSB (and previously, IAB) reviews in the regulatory process limits its transparency.** RSB opinions are released only when the EC has adopted the corresponding legislative proposal. Thus the public does not have an opportunity to see and comment on the draft proposals and draft IAs before they are final (Wiener and Alemanno 2017).
 4. There are **implementation issues on the IIA**: negotiations on information-sharing when negotiating and concluding international agreements have still to be concluded (EPRS 2018).

6.3 Overarching remarks

1. The **lack of homogeneity of the various components of the BR Package** (language, targets, nature and underlying philosophies) **limits the understanding** of the procedures governing the preparation, adoption and implementation of acts and thus the inclusiveness (Alemanno 2015).

⁽⁶⁷⁾ The author gives examples behind this statement that are prior to the launch of the BR in 2015.

2. **Transparency has also been used to avoid blame** for the state of EU's regulation: in fact, the REFIT scoreboards are built in such a way as to differentiate the regulatory costs created by EU regulation from the responsibility of the MSs (Dunlop and Radaelli 2017).

6.4 Main observations from the literature review

1. To close the policy cycle all the EU institutions and the MSs should **provide information about** (Radaelli and Schrefler 2015):
 - (a) **who** does what;
 - (b) **how** the different actors will be **accountable** for the results;
 - (c) **how** these results will be **measured**;
 - (d) in what **type of institutional forum** the results will be discussed.
2. There is a need of a fast-paced transparency spillover into the **areas where transparency is currently the exception** and not the norm (Willermain and Cioriciu 2015):
 - (a) the EU should have a more automatic and swift system of response when dealing with **access to documents**;
 - (b) **sporadic litigations** should not define EU transparency;
 - (c) the **citizens** should be able to clearly grasp the legislative flow and be familiar with the contributors who make decisions affecting their lives;
 - (d) EU leadership should prioritise the **Transparency Register** making it mandatory, and implement it in all EU institutions.
3. Move away **from fish-bowl transparency to science-based transparency**, where some specific data are shared but at the same time explained (Lofstedt and Schlag 2017).
4. Adopt **editorial measures** that could facilitate the communication of IA and evaluations (RSB SG and JRC Working Group 2018).
5. For evaluations, it would be helpful:
 - (a) to set up a **publicly available repository**, underlying external studies (if present) and other related information (EPRS 2017);
 - (b) to **signal any significant delays or changes of scope** to the evaluation/fitness check in the original **roadmap** (EPRS 2017).
6. For **IAs**:
 - (a) **publish all evidence used for IA**: include the original studies as an annex to the Commission SWDs and, where possible, the underlying data (EPRS 2017), models and algorithms, also those related to Inception IAs. The analytical model should be

published by default at as early a stage as possible (Impact Assessment Institute 2017);

- (b) **explain all evidence** used for IA (Impact Assessment Institute 2017);
- (c) make IAs on subordinate legislation **available at the stage of consultations** on its draft, with the opportunity to comment on the analysis (OECD 2018).

7. For the implementation of the **IIA**, there should be:

- (a) a **better flow of information from the Council**;
- (b) greater efforts to set up a **joint database** on the state of play of legislative acts;
- (c) more transparency from MSs **about 'gold-plating'** when transposing EU legislation (EPRS 2018).

7 Interinstitutional relations in the context of the BR⁶⁸

7.1 [Achievements] The IIA is a step towards a greater coordination amongst the EU bodies, essential to improve legislation...

- 1) The IIA is the **most important part** and the **major novelty** in the BR 2015 (Alemanno 2015; Mańnicki 2016). It confirms a procedural framework of interinstitutional cooperation which is essential to progress in the direction of more effective EU legislation (De Feo 2017).
8. A small step is made towards **voluntary** cooperation between the three institutions (Van den Abeele 2015).
9. **The reference to law-making instead of regulation** goes beyond the BR to capture in principle all law-making activities where the three main institutions of the EU need to co-operate on evidence-based policy (Radaelli 2018)⁶⁹.
10. The **IIA** is a further step towards defining some **common principles** shared by the Council, the EC and the EP. It sets out a common understanding of the timing and processes. This has led to a better coordination upstream of the policy process (De Feo 2017).
 - (a) The IIA recognises the **whole policy cycle** (Stephenson 2017).
 - (b) The three institutions define **annual lists of the EU's legislative priorities** (Alemanno 2018; De Feo 2017; EPRS 2018; Mańnicki 2016; Sarpi 2015).
 - (c) The **EC** commits to **give serious consideration to the requests** made by the EP or the Council (Sarpi 2015).
 - (d) **The access for EP experts to documents** and meetings concerning the **preparation of delegated acts has improved**. The joint register of delegated acts became operational in December 2017 (EPRS 2018).
11. **BR tools, and namely IAs, are increasingly used** in a systematic way **by the EP and the Council** in the working groups of the legislature (Golberg 2018).
 - (a) The **EP** has considerably **stepped up its efforts on IAs and evaluations** (Dunlop and Radaelli 2017; EPRS 2016), as well as

⁽⁶⁸⁾ Note that reports prepared by the EPRS are also included in this section for consistency with what has been done in the remainder of the text. These reports also include statements assessing the activities of the EP itself.

⁽⁶⁹⁾ Note as well the interpretation of (Cărăușan 2016): 'The Better regulation system is about the whole policy cycle, from planning, implementation and evaluation to monitoring and revision. It is a more comprehensive concept than 'better law-making', which refers only to the process of law-making (meaning the preparation, drafting and enactment of legal acts)'.

invested in capacity building to exercise oversight of the EC's IAs and evaluations (Radaelli 2018; Renda 2017a).

- i. **The work of the EPRS complements what the RSB does** (Radaelli 2018) and can be regarded as the result of the weak pre-existing evaluation capacity within the EU institutions (Stephenson 2017). In the last five years, the EPRS is beginning to play an important role in learning (Stephenson 2017).
 - ii. There is an **emerging role of the EPRS in monitoring the outputs of the ECA and other bodies engaged in audit and evaluation**. While all scrutiny by MEPs is inherently political, it is less likely that reports drafted by the EPRS will have a political agenda (Stephenson 2017).
- (b) The **Council's engagement is recent, and rather in IA than evaluation** (EPRS 2016). Its secretariat has elaborated a procedure so that the different formations should start their discussion with an examination of the underlying IA. They have responded with different degrees of commitment. The secretariat of the Council, which is endemically under-staffed to produce IAs, launched a tender in autumn 2017 for a framework contract to support this analytical work (Radaelli 2018). Moreover, the Council has stressed the importance of cooperation between the EC and the MSs to ensure that data required for monitoring and evaluation purposes are adequately collected (EPRS 2016).
- (c) **EC's assistance with the IAs can boost the use of IA** among the three institutions (Sarpi 2015).
- (d) The preparatory work done in IAs strengthens the EC in negotiations and contributes to **more rapid agreement on proposals** and to the **downward trend of infringements of EU law** by the MSs (Golberg 2018).

7.2 [Issues] ...but the effect on the institutional balance is unclear

7.2.1 Issues related to the institutional framework

1. The attempt of the EC to bind the EP, the Council and the MSs in relation to openness, participation and evidence-based policy-making, raises serious **doubts about the compatibility with the principles of** (Alemanno 2015):
 - (a) **the separation of powers** (Alemanno 2015);
 - (b) **the institutional balance** laid down by the Treaties (Alemanno 2015; Dawson 2016).

- i. The EC's role in the legislative procedure after the adoption of its proposal **cannot** amount to **transform the EC into a co-legislator** (Alemanno 2015).
- ii. A high level of **control by a non-democratically elected institution** could be seen at odds with the concept of representative democracy enshrined in the TEU (Willems 2016)⁷⁰.
- iii. **The EC** seems to be attempting to **increase its power ('power-grab')** (Alemanno 2015; Pachtl 2015). Some examples are:
 - 1. an **entirely new consultation period** following directly the adoption of an EC proposal (Pachtl 2015):
 - a. the EC occupies a new position as an intermediary and knowledge pool for citizens' concerns;
 - b. it would increase the EC's control over imminent changes that might be tabled in the legislative procedure;
 - c. it would provide advance warning about what IA could be required from EP or Council;
 - 2. **political validation from the lead Commissioner, Vice-President and First Vice President for 'major new initiatives**, before any policy appraisal work can start, may limit the discretion attributed to the EC services in adopting new initiatives (Renda 2015);
 - 3. **'technical assistance'** by the EC in the IA work of the co-legislators, which is set to inevitably **interfere with their exercise of political discretion** (Alemanno 2015).
- iv. The inclusion of the criteria that call **to carry out IAs** in the IIA has **a more strict character** than in the last 2003 IIA (Maśnicki, 2016). However, there seems to be **little legal basis** for the idea that EU institutions are obliged to conduct IAs, or even to follow those of the EC (Dawson 2016).
- v. While IAs had some appeal for the EP as a tool to hold the EC accountable, they also carry the **risk of making EC's proposals 'bullet-proof'** and making later changes to legislative proposals more difficult (Wegrich 2015).
- vi. The **appointment of members of the RSB** extends the power game between the institutions into another round (Wegrich 2015).

2. The IIA shows **weakness** as an instrument.

- (a) The restatement of the joint responsibility **hides the lack of a real attribution of responsibility to the EP and most importantly to the Council**, the most reluctant of all EU institutions when it comes to evidence-based decision-making (Renda 2015; Renda 2016). It indicates some continued resistance by the EU's legislative institutions to regulatory

⁽⁷⁰⁾ See the results of the substantive analysis conducted by Willems (2016).

models which constrain their freedom of *political* action (Dawson 2016).

- (b) **The final version was heavily watered down.** IAs on amendments are not mandatory anymore (Willems 2016), and there is no more mention of a tripartite 'Joint Panel' that would be tasked with assessing the quality of such IAs (Meuwese, 2017); also the EC proposals on 'gold-plating' were diluted (Dawson 2016).
 - (c) There is **no full agreement** among the institutions **about the level of control of the EC over the legislative agenda and process.** The EC's inability to come to a truly coordinated approach on IAs has severe adverse effects on both the duration and transparency of the legislative process (Willems 2016).
 - (d) The IIA is one of the most important negotiations as it defines how the three main institutions will work together, however **it seems no longer the number one priority, but instead a simple tool of the BR Package** (Willermain and Cioriciu 2015).
3. There is a **continuing recalibration** of the EU's institutional architecture (Wegrich, 2015).
- (a) The fact that experts and stakeholders can make their voices heard at a very early stage, but that the EP and the Council should carry out IAs on any substantial amendment that they propose, completely reverses the democratic system, which puts the co-legislators on the defensive and the **EC at the centre of the political game** (Van den Abeele 2015).
 - (b) The traditional 'Community method' of policy-making – with the EC in the driver's seat as the sole initiator of legislation – is increasingly sidelined by **a range of intergovernmental forms of decision making** around Euro crisis management and economic policy-making more widely (Wegrich, 2015).
4. The BR 2015 seems to **ignore the existence of the two institutionally recognised** (i.e. treaty-based) **advisory bodies:** the EESC and the Committee of the Regions (CoR) (there is no reference in the IIA, despite the obligation for the EC, the EP and the Council to consult with them) (Willems 2016).
5. The EC does not accept to take the blame for something that it has not done (**blame shifting**), by:
- (a) subjecting the **legislators amendments to IA**, in particular, on the regulatory costs (Radaelli and Schrefler 2015);
 - (b) greater **monitoring of transposition** into national legislation, by requesting detailed information on additional regulatory costs (Dunlop and Radaelli 2017; Radaelli and Schrefler 2015; Sarpi 2015).

6. There are issues with the **extension** of the **BR requirements to the MSs** when it comes to the **implementation of EU law** (Alemanno 2015).
 - (a) **It is an inappropriate instrument:** an IIA by definition binds only its own parties.
 - (b) There is a risk that any EU effort at **countering gold plating** might negatively affect the exercise of the MS's regulatory autonomy.
 - (c) **The EC** might be '**gold plating**' the exercise of **its own prerogatives** by requiring MSs to perform an IA on their 'additional' obligations.

7.2.2 Issues related to implementation

1. Better coordination upstream of the policy process and increased quality and transparency of the pre-legislative process have **not translated into an acceleration** in the rate of **adoption** of the EC's proposals **by the co-legislators** (Alemanno 2018).
2. There are **different levels of commitment to the BR**, both in the **pre-legislative** phase – among the EC's DGs – and in the **legislative** phase, by the co-legislators (Alemanno 2015).
 - (a) The **EPRS** is currently more actively involved in providing early assessments of the EC's IAs than in evaluating the impacts of major amendments proposed by EP committees. More generally, the work of the EPRS often seems to be ignored by the Members of the EP, also due to the wide distance between the logic of cost-benefit analysis and that of political decision-making⁷¹.
 - (b) The **Council** is making more use of the EC's IA, but has so far failed to develop its own capacity for IA and evaluation (Renda 2017a).
 - (c) The **Council** is **reluctant** to accept the use of **delegated acts**, despite the concessions made regarding the consultation of national experts in the preparation of such acts (EPRS 2018).
 - (d) **IAs** explain the rationale of the original proposal filed by the EC, but not of the final text approved at the end of the ordinary legislative procedure (Renda 2017a).
3. The **EC** in some cases **decides by itself** to use delegated acts. This is at odds with the IIA, which states that 'it is the competence of the legislator to decide whether and to what extent to use delegated or implementing acts' (Bartlett 2018).

⁽⁷¹⁾ Renda, A. (2016), 'European Union', in Claire A. Dunlop and Claudio M. Radaelli (eds), *Handbook of Regulatory Impact Assessment*, Cheltenham, UK: Edward Elgar, cited in (Renda 2017a).

4. On IAs of amendments.
 - (a) The concept of '**substantial amendments**' **deserves a clear definition** by the EC (Willermain and Cioriciu 2015).
 - (b) There are **implementation questions** linked to the preparation of the IAs of amendments and the **trialogues**, concerning time frame (Alemanno 2015) and process (Alemanno 2015; Radaelli and Schrefler 2015).
 - (c) **The Council and the EP lack political ownership of the evaluation mechanisms** used by the EC (De Feo 2017). IAs for each significant amendment suggested by legislators risk significantly slowing down and complicating the decision-making process, as well as generating increased administrative burdens (Pachl 2015; Van den Abeele 2015; Willermain and Cioriciu 2015). They should not overload or even substitute for the political character of the EU legislative mechanism (Willermain and Cioriciu 2015).
 - (d) The use of IAs by the Council could be used by some MSs as a tool for blocking or '**indefinitely**' **postponing** a proposal (Willermain and Cioriciu 2015).
 - (e) **Quality control** of IAs remains under the **responsibility of each institution** (Van den Abeele 2015).
5. **Negotiations** have still **to be concluded** on (EPRS 2018):
 - (a) **information-sharing** when negotiating and concluding international agreements;
 - (b) the non-binding criteria for **delineation of delegated and implementing acts**.

7.3 Overarching remarks

There are political issues in the interinstitutional relationships.

1. The EC wants to ensure that **responsibilities for inefficiency and poor quality of regulatory outcomes are separate**. It should be clear to the public if and when the EP, the Council or the MSs generate higher compliance costs (Radaelli 2018; Radaelli and Schrefler 2015).
 - (a) For both the EP and the Council, **evidence-based activities stand in the way of more political discussions** (Radaelli 2018).
 - (b) The **Council is notoriously hostile to raising awareness on the regulatory responsibility of MSs** in implementing and delivering EU legislation ('gold-plating') (Radaelli 2018).

- (c) The Council and the EC have competed over the definition of what the BR should be about. On specific details, the **Council wants** to see **more emphasis on the reduction of administrative burdens** (Radaelli 2018).
2. The following features warrant the **necessary vigilance** in approaching the BR 2015 (Willems 2016).
 - (a) The challenge of diverging interest is amplified. **The self-interest of the institutions** involved accounts for an **additional layer of complexity**.
 - (b) The BR is a **horizontal policy** that affects all the institutions. Therefore, it requires the institutions to engage in **active and structural coordination**, rather than respecting each institution's distinct mandate.
 - (c) IIAs are used to the extent they **even alter the institutional design** of the EU.
 3. The IIA has a strong **political meaning**.
 - (a) The revamp of the BR initiative has more to do with **honouring the political mandate of the EC** than with a genuine desire to restructure the administrative governance of EU policy-making (Alemanno 2015).
 - (b) The meaning of the joint declaration on the interinstitutional programming will be more of political than legal importance. The **EP and the Council** gain room for **political influence on the EC's exclusive right** to set up legislative proposals (Maśnicki 2016; Willems 2016).
 - (c) On the contrary, others also argue that the BR agenda seems to place **confines and limits** on the ability of national and EU legislatures to amend policy according to **purely political considerations** (Dawson 2016).
 4. On the role of IAs:
 - (a) BR 2015, and in particular an increased use of IAs and reinforced annual and multi-annual planning are among the instruments to **improve the EC's political leadership capacity** in the dialogue with Council and EP, according to officials from the EC, the Council and the EP (Bürgin 2018)⁷².
 - (b) The principle of **institutional balance constitutes a clear limit to** the establishment of **binding IAs** between EU institutions. A binding EC's IA would alter the democratic nature of the co-decision procedure (Nowag and Groussot 2018).

⁽⁷²⁾ The analysis of Bürgin (2018) refers to the years 2015-2017. See Annex 3 for details.

- (c) It is difficult to imagine that the IIA could succeed in practice without a **consensual clarification of the role of the BR, notably of its IA system** (Delogu 2016).
5. In the end, **for the SG**, evaluation is a **solution to the problem of creating policy leadership**. The SG is today the ultimate custodian of guidance on both IA and evaluation. This, in fact, is also where the MSs, the SG, the EC's DGs and the EP test and constantly redefine the question of who has control over EU policy (Dunlop and Radaelli 2017).

7.4 Main observations from the literature review

1. **Advance the implementation** of the IIA, namely regarding (EPRS 2018):
 - (a) **information-sharing** when negotiating and concluding **international agreements**;
 - (b) the non-binding **criteria for delineation of delegated and implementing acts**;
 - (c) the **Council's reluctance to accept the use of delegated acts**;
 - (d) the need of a better flow of information from the Council;
 - (e) the need of greater efforts to set up a joint database on the state of play of **legislative acts**;
 - (f) MSs' **transparency about 'gold-plating'**;
 - (g) the promotion of a **greater use of IAs by the EP committees** whenever needed.
2. Include in the IIA a **procedure to structure the oversight of legislation**. This would also improve the democratic accountability of implementation by reinforcing the role of the EP (De Feo 2017).
3. The EC should give a proper reason and **pre-alert** the other institutions about its intentions to **withdraw** a legislative proposal during the submission and the discussion of its Work Programme (Lupo 2017).
4. It is up to **MSs to decide whether to become simple suppliers of pieces of information** and data **or more active players** of the EU's regulatory policy cycle through a more effective use of tools like IA and evaluation that can integrate the usual negotiations (Sarpi 2015).

5. Indicate that the BR 2015 does **not intend to disrespect the place of the consultative bodies** (EESC and CoR) as part of the EU institutional design⁷³ (Willems 2016).
6. Promoting the BR as an instrument of **coherence with long-term goals** (especially SDGs) would improve the salience of IA and evaluations in the eyes of the EP and the Council⁷⁴.

⁽⁷³⁾ In particular, since the CoR has been granted legal standing before the CJEU to protect its prerogatives, depending on the institutional practise in consulting the EESC and the CoR, the latter could bring a case to the CJEU (Willems 2016).

⁽⁷⁴⁾ Ashford, N. and A. Renda (2016), 'Aligning Policies for Low-Carbon Systemic Innovation in Europe', CEPS-i24c report, cited in (Renda 2017a).

8 Subsidiarity and proportionality in the context of the BR

8.1 [Achievements] A possibility to broaden the application of subsidiarity and proportionality principles...

1. The BR 2015 seems to provide a **possibility to broaden the pre-legislative cooperation between EU institutions and NPs** (Jancic 2015).
2. The IIA **seems to honour the role of NPs** in scrutinising the EC's legislative planning (the earlier IIAs did not even mention them) (Jancic 2015).
3. Instruments provided by the BR 2015 (namely IAs) could be a **useful guidance on how to conceptualise** the very broad concept of the **proportionality principle in the judicial review** of the EU legislation (i.e. help to give a legal meaning) (Maśnicki 2016). This is because the Guidelines provide a structured approach for the IA process. In fact, the CJEU's case law shows that the Court uses the IAs in order to help and bolster its assessment of the proportionality/subsidiarity of the EU's legislative measure. This increased review by the CJEU might in turn lead to pressure for more meaningful IAs (Nowag and Grousot 2018).
4. The BR 2015 and the IIA are among the milestones that have led to the CoR's commitment to impose a **territorial dimension on the IA** framework (Taulègne 2017).
5. The BR 2015 **addresses** a number of the **shortcomings** of the old program concerning the conceptualisation and practice of **private regulation**⁷⁵ in the EU (Verbruggen 2017)⁷⁶.

(⁷⁵) In the Better Regulation Toolbox (2017, p.109), **co-regulation** is defined as 'a mechanism whereby the Union legislator entrusts the attainment of specific policy objectives set out in legislation or other policy documents to parties which are recognised in the field (such as economic operators, social partners, non-governmental organizations, or associations)'. **Self-regulation** is where business or industry sectors formulate codes of conduct or operating constraints on their own initiative for which they are responsible for enforcing. However, pure self-regulation is uncommon and at the EU level it generally involves the Commission in instigating or facilitating the drawing up of the voluntary agreement.'

(⁷⁶) The BR 2015 Guidelines provide a reference to the principles for better self- and co-regulation drafted by a forum of stakeholders. The principles concern a number of conditions for the adoption, governance and implementation of self- and co-regulation, including matters of participation, transparency, (legal) compliance, IA and funding. These conditions may be taken as parameters for answering the policy question of when and under what conditions private regulation may be deployed as a policy alternative (Verbruggen 2017).

8.2 [Issues] ...but the evidence use and a systemic vision behind these principles are still lacking

1. The implicit problem assumption **is unfounded** (Garben 2018).
 - (a) The factual basis for the **assumption that the EU lacks respect for the subsidiarity principle is unclear**. However, since it remains possible for the EU to act in virtually any policy area, this problem assumption can be accepted.
 - (b) There is **little evidence of a fundamental tendency to disrespect proportionality** in the legislative process. Furthermore, the Court has been willing to strike down EU legislation that does breach proportionality, and the Early Warning System adds political control of this principle to the MS toolbox.

Therefore, given that there is no evidence-based need to solve the proportionality problem in the EU, the **BR seems a rather disproportionate and unnecessary exercise**.

2. However, other authors state that in some cases the **EC does not act in compliance with the principles of subsidiarity and proportionality**, by assuming powers that lie outside the scope of those provided by TFEU (Bartlett 2018)⁷⁷.
3. **In IAs**, the argument of the respect for the principles of **subsidiarity and proportionality is not underpinned by the usage of evidence-based instruments** (Impact Assessment Institute 2017; Radaelli 2018). In the past, there is evidence that the IAB used to prefer a **procedural interpretation** of the principles of subsidiarity and proportionality to legal and economic interpretations (Meuwese, A., Gomtsian 2015)⁷⁸.
4. The IA can be said to have **two functions** in the context of the proportionality requirement (Nowag and Groussot 2018):
 - (a) as a **procedural element** (Nowag and Groussot 2018);
 - (b) for **substantive assessment of proportionality**, since it provides additional material and arguments for examining and justifying why the measure is proportional (Nowag and Groussot 2018).
 - i. In the current state of affairs, it seems to rather provide a 'shield against judicial review' with the danger of becoming a **box-ticking exercise** (Dawson 2016; Nowag and Groussot 2018).

⁽⁷⁷⁾ The author refers to Article 290 TFEU on delegated acts which can be adopted by the EC only within the strict parameters set by the delegating EU legislation.

⁽⁷⁸⁾ Meuwese and Gomtsian (2015) present an analysis of opinions from the IAB from 2010 and 2011. See Annex 3 for details.

- ii. Extending the adjudicative scope of subsidiarity and proportionality to a more substantive review is extremely difficult without **undermining the margin of discretion granted to the EU institutions** in adopting legislation (Nowag and Grousot 2018).
- 5. There is a **risk** that the EU falls into two **traps** (Van den Abeele 2015):
 - (a) invoking subsidiarity to justify the EU's legislative abstinence and renationalising, or even re-regionalising, **could lead to the disintegration of the EU** by weakening the *acquis communautaire*;
 - (b) replacing the co-legislators and social partners with experts, private consultants and other stakeholders attacks the 'Community method' by **delegitimising the EP and the Council**.
- 6. **In the name of subsidiarity**, the BR 2015 actually **promotes and encourages less democratic forms of EU integration, especially soft law**: indirectly, policy-makers in the EC, to avoid having to engage in arduous IA and being examined by the RSB, could tend to opt for a soft law initiative. It is open for debate whether soft law is more in line with the subsidiarity principle than legislation is (Garben 2018).
- 7. There is a **sidelining of private regulation** in the BR 2015 (Renda 2016; Verbruggen 2017).
 - (a) There is a **lack of overarching vision for the role of co- and self-regulation** on the part of the EU institutions. Private actors such as trade associations, NGOs and other public interest groups might be put off to engage with the EU legislature or MSs to construe clear, integrated and 'mixed' approaches to regulation (Verbruggen 2017).
 - (b) While the BR Toolbox does currently mention the possibility to combine the full range of policy options, the new IA Guidelines **fall short of providing guidance on how to combine alternative policy instruments** or combine EU legislative measures and such alternatives. Co- and self-regulation are regarded as 'alternatives to' EU legislative action, thereby neglecting the possibility to design a mix of regulatory instruments in which private regulation complements EU legislation (Verbruggen 2017).
- 8. While co- and self-regulation undoubtedly have several advantages, they also present clear shortcomings. From this perspective, the BR 2015 **seems to encourage forms of regulation that escape traditional legal and political accountability mechanisms**. In the case of the European standardisation process, the participatory

possibilities do not ensure sufficient ex-ante control and the current system of judicial protection does not fully work (Eliantonio 2017).

9. **NPs occupy a fairly peripheral place in the BR 2015** (Jancic 2015). The BR 2015 itself has not promoted any form of engagement for NPs in the evaluation of the added value of EU legislation that is already in force (Griglio 2017). Unlike that of stakeholders, their involvement therein has not been formalised (Auel 2017; Jancic 2015). Compared to these expectations, the BR 2015 has been considered to be a sort of 'missed opportunity' for introducing new forms of involvement by NPs (Auel 2017). Some examples:
- (a) the BR Guidelines specifically state **that stakeholders consultations do not apply to opinions of NPs**. Conversely, the BR Toolbox does envisage contributions from public authorities, among which NPs, without providing any further information about it (Auel 2017; Jancic 2015);
 - (b) the **formal institutional position of NPs remains restricted to ex-ante subsidiarity control** of draft EU legislative acts (Early Warning System), whose effectiveness is questionable. It excludes non-legislative acts that might only be scrutinized by NPs through the Political Dialogue, yet without being able to create any legal consequences (Auel 2017; Jancic 2015);
 - (c) the **REFIT Platform does not include NPs** (Auel 2017; Jancic 2015);
 - (d) in light of the strong pressure that a large number of NPs are putting on the EC for the latter, to accept an 'enhanced political dialogue' in the form of **a 'green card' for initiating or repealing EU legislation**, the BR 2015 appears as **a missed opportunity to address these requests** (Auel 2017; Jancic 2015);
 - (e) the **IIA** seems to **sideline NPs** because their reactions are only **officially solicited once the IA process has been completed** (Auel 2017; Jancic 2015);
 - (f) in spite of increasing progress in the institutionalisation of **IA** and in the call for greater interinstitutional participation, the **contribution of NPs** to the implementation of the procedure **is still uncertain**, partly due to persisting disagreements on the role and status of IA in the European legislative process (Griglio 2017);
 - (g) **involvement of NPs – and regional parliaments** for matters within their competence – in the comprehensive **evaluation**, several years after the legislation has been implemented, **risks complicating the process** of the political decision and action (Van den Abeele 2015).

8.3 Main observations from the literature review

1. The CJEU should further recognise the BR 2015 as establishing the guidelines on how the proportionality should be conceptualised (Maśnicki 2016).
2. **Improve the coherence of subsidiarity and proportionality analysis by using sound evidence** and arguments. In particular, the assessed impacts, for example in terms of costs and benefits, are a direct indicator of proportionality (Impact Assessment Institute 2017).
3. A rather weak review of subsidiarity, both in political as well as legal assessment, in terms of substantive and procedural assessment, could be improved by taking the requirements for IA (as expressed in the BR Guidelines and Toolbox) more seriously (Nowag and Groussot 2018).
 - (a) The CJEU **would need to ensure that the BR Guidelines as well as the actual IA are compliant with the requirements of the EU Treaties.**
 - (b) A **feedback loop** could be created: the CJEU improved use of IA would lead to improved and more frequent use of IA.
4. **Subject all soft-law initiatives to compulsory IA** (an alternative that would better serve both subsidiarity and democracy) (Garben 2018).
5. Achieving a **more systematic use of territorial IAs** in EU policy making needs a more systematic partnership approach by the EC and the EP (Taulègne 2017).
6. In the interest of a powerful subsidiarity principle, the **RSB should go deeper** into the substance of impacts and the details of methodology (Meuwese, A., Gomtsian 2015).
7. **The role of MSs in the process should be strengthened** (e.g. guidance on implementation, a constant interaction between the NPs and the EU authorities, and IAs of pending dossiers on national interests) (Renda 2016).
8. Strengthen the **role of the NPs.**
 - (a) Reinforce the **involvement of NPs** in the early stages of EU decision-making (Griglio 2017).
 - (b) **Institutionalize 'green cards'** to provide NPs with an active and more constructive involvement in EU law-making and to encourage NPs to assess existing EU legislation (Auel 2017).
 - (c) The **EU institutions**, and the EC in particular, need to be willing to take NPs' input into account (Auel 2017).

- (d) NPs could **make more active use of the opportunities** for pre- and ex-post legislative scrutiny available to them (Auel 2017).
 - (e) **Strengthen NPs' oversight of the national government** represent an indirect means of strengthening their involvement in EU policy-making (Griglio 2017).
9. **Enrich interparliamentary** (between national and regional assemblies) **and interinstitutional dialogue on IA** (share national positions and views on the impact of EU legislation both in the pre-legislative and legislative stages, and in the monitoring of EU law implementation and transposition) (Griglio 2017).
10. Set up **follow-up requirements** (either binding or relying on informal interinstitutional practices) to which executives (the EC and national governments) are bound. A key part of the process lies in governmental accountability to parliament on IA work conducted by parliamentary scrutiny bodies (Griglio 2017).

9 Concluding remarks

Assessing the BR 2015 is not an easy exercise⁷⁹. Firstly, the BR is not a question of quick fixes or miracle cures (Voermans 2016). Since the legislative cycles of the EU take substantial **time**, it will take several years before the outcome of the agenda can be evaluated fully (Impact Assessment Institute 2017). Secondly, systematic evaluation of the regulatory quality policies is a **difficult exercise** (Voermans 2016). Compliance with formal procedural rules is (maybe) a necessary condition for the BR to work, but not a sufficient one (Wegrich 2015). Decisions on legislation are political, so it is difficult to assess if the BR 2015 helped producing better policy results or contributed to decision-making (Golberg 2018). Evaluation is made difficult also by the **complex, multi-faceted nature** of the BR 2015 (with many incarnations over time, different features and objectives), and by its impact also on the other institutional actors (Garben and Govaere 2018). At the same time, the BR is influenced by **external pressure**, such as international negotiations (Alemanno 2015; Dawson 2016). Finally, the **causal link** between the BR and the quality of EU rules is a **fascinating yet elusive object of study** since there is no counterfactual of how EU legislation would look if the BR did not exist (Radaelli 2018). In the **absence of agreed indicators**, it is **difficult to draw** definitive **conclusions on performance** of the BR (Golberg 2018).

The debates on the BR appear to be somewhat 'disparate and impoverished', yet are likely to have an influence on public attitudes towards EU integration, such as in the case of the recent Brexit vote (Garben and Govaere 2018). The complaints about the (too high or too low) level of EU regulation are often of a **political nature** (Delogu 2016; Garben and Govaere 2018; Golberg 2018; Mańnicki 2016; Wegrich 2015). In contrast with this polarised discussion, the EU institutions seem instead to prefer a depoliticised approach, presenting the BR as **neutral evidence-based policy-making** and a balanced approach (Delogu 2016; Garben and Govaere 2018). However, not all commentators perceive this approach positively since it seems to **limit the inherently political dimension of the EU decision-making process** (Willermain and Cioriciu 2015). Nevertheless, some authors observe enduring politicisation despite the commitment to evidence-based policy-making, **with tools and procedures having the potential to be used according to political logics** (Eliantonio and Spendzharova 2017).

The **academic and expert debate addresses a wide range of aspects**, at both technical and political level. The presence of little consensus in some cases, together with the lack of empirical evidence, makes the attempt of a synthesis extremely challenging.

The great majority of the publications welcome the ambition of the reform and at least one or more specific aspects of the **BR 2015, which are seen as further strengthening** the EU regulation system. These are notably the reliance on evidence-based policy-making, the attempt at closing the policy cycle by paying more attention to the evaluation phase, the increased

⁽⁷⁹⁾ See section 5.3.

responsiveness to stakeholders, a greater role of scrutiny, transparency, consideration for subsidiarity. Many authors recognize that the BR 2015 tries to address the most relevant criticisms and the difficulties encountered in the past.

OECD (2018) defines the **EU as the most ambitious regional regulatory co-operation framework** involving supranational regulatory powers.

However, while the **actual implementation is a key issue** (as shown by the remarks reported in the previous sections), **many critical elements** emerge at a more general level, as well. While the term '**better**' implies an **evaluation element**, this doesn't necessarily mean that it delivers high-quality regulation, or that the very notion of regulatory quality is accepted by every player. Objectively, the BR 2015 is one possible incarnation of some ideas about regulatory reform and the governance of EU legislation (Radaelli 2018). One of the main questions is how to reconcile the increasing tension in the EU between **different paradigms of regulation**. Regulation can be 'better' because it conforms to the political preferences of citizens or because it meets technical standards, able to improve its 'objective' quality. The EU has two avenues to respond, which are both observed in the debate: to double down on the regulatory model or to replace it with a more transparent political way of defining the BR (Dawson 2016). In this choice, the EC may be constrained by external pressure (Alemanno 2015; Dawson 2016). Some authors argue instead that the tools and procedures of the BR 2015 will be **used and gamed according to political logics**, and that the justification of political choices with BR tools will contribute to the further 'technocratisation' of EU policy-making (Wegrich 2015). It is noted that the BR Agenda further **proceduralises** EU policy-making, but still lacks homogeneity in its components (Alemanno 2015). Another critique is that the BR operates on the basis of **several unproven assumptions**, generates an enormous administrative burden, has serious cost implications and may overlook certain negative constitutional, social and environmental impacts by leaving gaps and **circumventing possibly controversial topics** (Garben and Govaere 2018; van Schagen 2017). It seems unlikely that the expected benefits can outweigh the costs (Garben and Govaere 2018). Others note that the EU Better Regulation Agenda is still coping with a **number of existential dilemmas** (for example, is it a cost-cutting agenda or a policy-coherence agenda?); existing imperfections in the policy cycle; and governance problems (Renda 2017a). Authors also point to some contradictory elements of the BR 2015, such as the one between the aims to streamline policy-making and the ambition to ensure meaningful consultation (Eliantonio and Spendzharova 2017).

On this basis, the following recommendations are made:

1. Make a **full and timely independent evaluation** of the BR 2015 (Impact Assessment Institute 2017).
 - (a) **Improve monitoring and reporting** on the BR, both for the EC, the EP and the Council (Impact Assessment Institute 2017), as well as in cooperation with the MSs (Golberg 2018).

- (b) **Clarify the evidence base** for the postulated problems the BR 2015 tries to address and be able to prove its own 'added value' (Garben 2018).
 - (c) **Abandon the Commission-centric approach.** To measure progress, the focus has to be on the MSs and stakeholders (Impact Assessment Institute 2017).
2. **Actions on the BR need to be more widely communicated** by the EC, the other European institutions, the MSs and the many organisations that are active in the process (Golberg 2018)
 3. Develop a renewed narrative.
 - (a) The EU does not regulate to impose costs, but to **bring benefits** (Golberg 2018; Radaelli 2018).
 - (b) **Address citizens' pressures and perceptions of deficiencies** in EU rule-making (Garben and Govaere 2018). The success of the BR depends also on the regain of confidence of all sides of the civil society, achieved through a balanced implementation approach (Delogu 2016).
 4. Ensure strong **political commitment** by the EU and the MSs, **and administrative discipline** in applying the BR (Cărbăușan 2016; Delogu 2016; Golberg 2018). Prompt and constructive co-operation is required from **all of the actors** participating and benefitting from policy-making, including stakeholders and Think Tanks (Meads and Allio 2015).
 5. Adapt the BR strategy to the changing nature of EU law-making which is increasingly focusing on **implementation by direct EU-level institutions instead** of secondary legislation implemented by MSs (Meads and Allio 2015).
 6. For **the next EC, primary issues** are the relation between **subsidiarity** and the BR; the relation between regulation and **innovation**; the evolution of the **RSB**; the added value of the **IIA**; the delivery of a set of **robust evaluations** (Radaelli 2018).

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List of abbreviations and definitions

BR 2015	Better Regulation Agenda adopted by the European Commission in 2015 (European Commission 2015)
CoR	Committee of the Regions
DG	Directorate-General of the European Commission
EC	European Commission
ECA	European Court of Auditors
CJEU	Court of Justice of the European Union
EESC	European Economic and Social Committee
EP	European Parliament
EPRS	European Parliamentary Research Service
EU	European Union
JRC	Joint Research Centre of the European Commission
IA	Impact Assessment
IAB	Impact Assessment Board
IIA	Interinstitutional Agreement on Better Law-Making
MS	Member State
NP	National Parliament
RSB	Regulatory Scrutiny Board
SDG	Sustainable Development Goals
SG	Secretariat General of the European Commission
SME	Small and Medium Enterprise
SWD	Commission Staff Working Document
TFEU	Treaty on the Functioning of the European Union
TEU	Treaty of the European Union

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Annexes

Annex 1. Criteria for the literature search

To focus on the changes introduced by the BR 2015, the literature search includes only publications issued from 2015 onwards. The last update was made in September 2018⁸⁰.

The search, which has been kept as comprehensive as possible but nonetheless cannot be meant to be exhaustive, was launched in Scopus and Google Scholar in English by using the search terms 'better regulation' and 'european commission'; 'impact assessment' and 'evaluation' and 'better regulation'; 'better regulation' and 'transparency'; 'better regulation' and 'eu'; 'regulatory scrutiny board'.

In addition, we considered academic journals which deal regularly with the BR; papers from academics and universities specializing on various BR topics; Think-Tanks' websites and other sources such as the EPRS and the ECA.

The list of references includes notably:

1. peer reviewed articles in academic journals;
2. book chapters;
3. studies and notes of the EPRS;
4. reports of the ECA;
5. OECD reports;
6. working papers;
7. workshop proceedings.

Publications by interest groups were not considered. Publications by the EC were also not taken into account, since the EC is part of the system this literature aims to assess (an exception is constituted by reports by the RSB and the JRC, which have been referenced when relevant). It is however possible that some of the authors of the papers retained might have had previous experience in the EU institutions.

The full list of reviewed literature includes **104 contributions**, which were all screened and shortlisted. The papers which directly address and discuss in an analytical way one or more elements of the changes introduced with the BR 2015 were retained, while, on the contrary, papers not making any reference to the BR 2015 or having a purely descriptive character were not considered. If relevant to the current debate, also papers addressing aspects related to the BR system before 2015 were taken into account. **Overall, 76 papers were included in the review** (the full list is presented in Annex 2, together with the relevant topics they address), while 28 were not retained further.

⁸⁰ The only exception is constituted by (OECD 2018), which was published online on 10 October 2018.

The academic fields of reference of the collected literature turned out to be mainly related to political science, public administration, and law. It is interesting to notice that other research areas, which can nonetheless also be deeply involved in BR related activities (such as economics, as far as IA and evaluation activities are concerned) are represented in this debate in a rather limited way.

Annex 2. List of publications included in the review and topics covered

	Evidence-based policy-making, including methodology and quantification	Integrated policy cycle	Stakeholders consultation, participation and involvement	Level of regulation, including REFIT	Regulatory Scrutiny and quality assurance	Transparency in policy-making in the context of the BR	Interinstitutional relations in the context of the BR	Subsidiarity and proportionality in the context of the BR
Alemanno 2015	X	X	X	X	X	X	X	
Alemanno 2018			X	X		X	X	
Auel 2017								X
Bartlett 2018			X				X	X
Broughel 2015	X	X			X			
Bunea 2017			X					
Bunea and Ibenskas 2017			X	X				
Bürgin 2018							X	
Căraușan 2016			X				X	
Chase and Schlosser 2015		X	X		X			
Dawson 2016			X	X			X	X
De Feo 2017	X	X		X	X	X	X	

	Evidence-based policy-making, including methodology and quantification	Integrated policy cycle	Stakeholders consultation, participation and involvement	Level of regulation, including REFIT	Regulatory Scrutiny and quality assurance	Transparency in policy-making in the context of the BR	Interinstitutional relations in the context of the BR	Subsidiarity and proportionality in the context of the BR
Delogu 2016		X	X	X	X		X	
Dunlop and Radaelli 2015		X						
Dunlop and Radaelli 2017		X		X		X	X	
Elia Antonio 2017								X
Elia Antonio and Spendzharova 2017	X	X	X	X				
European Court of Auditors 2018		X		X	X			
European Parliament Research Service (EPRS) 2015		X			X			
European Parliament Research Service (EPRS) 2016		X					X	
European Parliament Research Service (EPRS) 2017		X				X		

	Evidence-based policy-making, including methodology and quantification	Integrated policy cycle	Stakeholders consultation, participation and involvement	Level of regulation, including REFIT	Regulatory Scrutiny and quality assurance	Transparency in policy-making in the context of the BR	Interinstitutional relations in the context of the BR	Subsidiarity and proportionality in the context of the BR
European Parliament Research Service (EPRS) 2018						X	X	
Garben 2018	X		X	X	X			X
Garben and Govaere 2018				X				
Golberg 2018	X	X	X	X	X		X	
Griglio 2017								X
Hines 2016	X	X						
Impact Assessment Institute 2017		X	X		X	X		X
Jancic 2015						X		X
Jarlbaek Pedersen 2017				X				
Kubera 2017		X						
Laulom 2018				X				
Leszczyńska 2018		X			X			

	Evidence-based policy-making, including methodology and quantification	Integrated policy cycle	Stakeholders consultation, participation and involvement	Level of regulation, including REFIT	Regulatory Scrutiny and quality assurance	Transparency in policy-making in the context of the BR	Interinstitutional relations in the context of the BR	Subsidiarity and proportionality in the context of the BR
Lofstedt and Schlag 2017	X	X	X	X	X	X		
Lupo 2017							X	
Mańnicki 2016		X	X	X	X	X	X	X
Mastenbroek, van Voorst and Anne Meuwese 2016		X						
Meads and Allio 2015	X	X	X					
Meuwese 2015					X			
Meuwese 2017	X	X			X		X	
Meuwese and Gomtsian 2015								X
Nowag and Groussot 2018		X					X	X
OECD 2018	X	X	X			X		
Pachl 2015			X	X	X		X	
Parker and Alemanno	X	X	X			X		

	Evidence-based policy-making, including methodology and quantification	Integrated policy cycle	Stakeholders consultation, participation and involvement	Level of regulation, including REFIT	Regulatory Scrutiny and quality assurance	Transparency in policy-making in the context of the BR	Interinstitutional relations in the context of the BR	Subsidiarity and proportionality in the context of the BR
2015								
Purnhagen and Feindt 2015	X							
Racah 2016		X						
Radaelli 2018	X	X	X	X	X		X	X
Radaelli and Schrefler 2015	X	X	X			X	X	
Ranchordás 2017	X		X	X				
Renda 2015	X	X	X	X			X	
Renda 2016	X	X	X		X		X	X
Renda 2017a	X	X					X	
Renda 2017b	X			X				
RSB/SG/JRC 2018	X					X		
Ruhl 2017		X						
Sarpi 2015			X	X	X		X	

	Evidence-based policy-making, including methodology and quantification	Integrated policy cycle	Stakeholders consultation, participation and involvement	Level of regulation, including REFIT	Regulatory Scrutiny and quality assurance	Transparency in policy-making in the context of the BR	Interinstitutional relations in the context of the BR	Subsidiarity and proportionality in the context of the BR
Smismans 2015	X	X	X			X		
Smismans 2017		X	X	X				
Smismans and Minto 2017		X						
Spendzharova 2016	X							
Stephenson 2017		X				X	X	
Stoffel 2015		X	X		X			
Taulègne 2017		X		X				X
Van den Abeele 2015	X	X	X	X	X	X	X	X
van Golen and van Voorst 2016		X						
van Schagen 2017	X	X			X			
van Voorst and Zwaan 2018		X						
Verbruggen 2017								X

	Evidence-based policy-making, including methodology and quantification	Integrated policy cycle	Stakeholders consultation, participation and involvement	Level of regulation, including REFIT	Regulatory Scrutiny and quality assurance	Transparency in policy-making in the context of the BR	Interinstitutional relations in the context of the BR	Subsidiarity and proportionality in the context of the BR
Voermans 2016	X	X		X	X			
Weber, Edwards and Huber 2017		X						
Wegrich 2015	X	X					X	
Wiener and Alemanno 2017					X	X		
Willems 2016				X			X	
Willermain and Cioriciu 2015	X		X	X	X	X	X	
Zwaan, van Voorst and Mastenbroek 2016		X						

Annex 3. Empirical studies⁸¹

Author	Methodological approach	Year(s) of reference of empirical data	Aim / short description
Bunea (2017)	Mixed methods	2012, 2014	The author examines stakeholders' evaluation of the consultation regime expressed in two EC public consultations in 2012 and 2014. The aim is to understand if this reinforced bias in interest representation by benefiting policy insiders, or conversely created conditions that alleviated bias in supranational policy-making.
Bunea and Ibenskas (2017)	Mixed methods	2012	This research deals with stakeholders' expectations expressed in the open EC consultation on the BR. The authors mapped the preferences of different actors – namely national authorities, cross-sectoral business organisations, sectoral businesses, public interest organisations and professional associations – on what type of regulatory reform BR measures should achieve. The analysis refers to the 'Stakeholders Consultation on Smart Regulation in the EU' organised by the European executive in 2012.
Bürgin (2018)	Qualitative	2015-2017	The author aims to analyse the effectiveness of Juncker's organisational changes in contributing to both the centralisation of leadership inside the EC, as well as providing an assessment of the EC's leadership in the interinstitutional relations with the two co-legislators. To this end, interviews were conducted with 37 experienced officials from the EC, the Council and the EP.

⁽⁸¹⁾ An empirical study is here considered as a study that uses scientific research methodology to analyse systematically observed or measured phenomena.

Author	Methodological approach	Year(s) of reference of empirical data	Aim / short description
ECA (2018)	Mixed methods	2013-2016	The ECA assesses whether the EU system of ex-post review of legislation has been properly planned, implemented, managed and quality-controlled. The audit covers 133 ex-post reviews carried out between 2013 and 2016 by four DGs of the EC, as well as all legislation and IAs adopted between 2014 and 2016.
Mastenbroek et al. (2016)	Quantitative	2000-2012	The authors conduct a meta evaluation of the coverage and quality of ex-post legislative evaluations by the EC using two novel datasets containing, respectively, 216 evaluations commissioned or conducted by the EC from 2000 to 2012 and 156 major EU directives and regulations adopted from 2000 through 2002.
(Meuwese, A., Gomtsian 2015)	Mixed methods	2010-2011	The authors present an analysis of opinions by the IAB from 2010 (70) and 2011 (149) as an alternative jurisprudential source regarding subsidiarity and proportionality. The authors look in particular at the way in which the Board conducts scrutiny for compatibility with these principles.
Renda (2016)	Mixed methods	2003-2011	The author identifies 53 IAs conducted in the financial sector in the years 2003-2011 and scrutinises 36 of them by conducting a scorecard analysis in order to assess the methodology used for assessing impacts.
Renda (2017)	Qualitative	-	The author explores the methodological and political feasibility of 14 possible options for the setting of net reduction targets on regulatory costs in Europe. The study, commissioned by RegWatchEurope, is based on both desk research and interviews carried out with MSs' representatives as well as EC officials.

Author	Methodological approach	Year(s) of reference of empirical data	Aim / short description
Smismans and Minto (2017)	Mixed methods	2011-2014	The authors assess whether the EU's IA system contributes to the realisation of six mainstreamed objectives defined in the EU treaties. They analyse 35 IAs to assess the extent to which mainstreamed objectives are taken into account in practice.
Van Voorst and Zwaan (2018)	Qualitative	2008-2012	The authors address the variation in the instrumental use of evaluation by the EC. Three high-quality evaluations are studied in-depth to assess the influence of political factors on their use.
van Golen and van Voorst (2016)	Mixed methods	2000-2014	The authors combine a dataset of 309 ex-post legislative evaluations (2000-2014) and a dataset of 225 IAs of legislative updates (2003-2014) to show how many evaluations of the EC use IAs and vice versa . They also investigate the hypotheses that the timeliness, quality and focus of the IAs and evaluations are key explanations for their use.
Weber, Edwards, and Huber (2017)	Mixed methods	2004-2015	The authors analyse in review clauses and conducted reviews , the terminology used, timing, content, implementation, costs and impact on existing legislation on the EC's annual work programme. The analysis draws on a desk-based review. The analysis covers 501 pieces of legislation, which together mandate 681 reviewing obligations. 60 of these 501 pieces of legislation have led to 72 review documents which are publicly accessible.
Zwaan et al. (2016)	Quantitative	2000-2012	The authors address the question of to what extent and when Members of the EP use evaluations . They present an analysis of 220 evaluations, studying how many were referred to in parliamentary questions. They use the same data set as in (Mastenbroek et al. 2016).

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