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Quality analysis of European Commission impact assessments

Developments during the 2019-2024 term

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Quality analysis of European Commission impact assessments

Developments during the 2019-2024 term

This study provides an assessment of the quality of European Commission ex-ante impact assessments (IAs) published between December 2019 and November 2024, on the basis of their appraisal by the Ex-Ante Impact Assessment Unit (IMPA) of the European Parliamentary Research Service (EPRS). This study, which draws on a review of 143 initial appraisals of Commission IAs, analyses them according to quality criteria stemming from the Commission's Better Regulation Guidelines, relevant European Parliament resolutions and the Parliament's Impact Assessment Handbook. The review is based on the statistical data collected by IMPA and on a qualitative analysis of Commission IAs. The aim is for the findings of the review to feed into the broader discussion on better regulation in the European Union, and impact assessment in particular.

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Executive summary

The start of the European Parliament's 10th legislative term, with a new European Commission in office since December 2024, provides the momentum to enhance cooperation on ex-ante impact assessment (IA) between the European institutions, in line with the commitments they made in the **2016 Interinstitutional Agreement on Better Law-Making (IIA BLM)**. In particular, they agreed on **IAs' positive contribution to improving the quality of Union legislation**. In addition, they agreed on a common definition of an IA under the IIA BLM. The Parliament committed to take full account of the Commission's IAs when considering the latter's legislative proposals.

In its 2021 'Better regulation: Joining forces to make better laws' communication, the Commission proposed to improve the EU law-making process to further advance the better regulation agenda. The most prominent innovation of the **2021 reform** was the introduction of the concept of **regulatory offsetting ('one-in, one-out')**. This places an emphasis on quantifying regulatory costs and benefits, to offset new administrative burdens in IAs. Other new features include the integration of **strategic foresight** into IAs, to add a longer policymaking horizon; streamlined **stakeholder consultations**; a more systematic consideration of **impacts on SMEs** and the **EU's competitiveness**; and a commitment to support the **UN Sustainable Development Goals (SDGs)**.

At the beginning of the legislative process in the Parliament, the Ex-Ante Impact Assessment Unit (IMPA) of the European Parliamentary Research Service (EPRS) routinely **assesses the quality of the Commission's IAs** accompanying legislative proposals in the form of initial appraisals. These briefings offer parliamentary committees a **critical overview and assessment of the quality of Commission IAs**. IMPA evaluates IAs on essential dimensions which are closely linked to those any IA should cover according to the Commission's Better Regulation Guidelines and include aspects that are particularly important to Parliament's scrutiny role. For each dimension, IAs are rated on a **scale from 1 to 5, corresponding to the perceived quality of 'very poor', 'poor', 'satisfactory', 'good', and 'very good'**.

The analysis is the third review of its kind.[1] Findings of the 2019 review[2] (hereafter 'previous review term') conducted by EPRS and carried out at the end of the eight legislative term are referenced and compared in this study, where relevant. The study draws on a review of IMPA's initial appraisals (APINs) of 143 Commission ex-ante IAs accompanying legislative proposals that were adopted between December 2019 and November 2024.[3] It analyses the strengths and weaknesses of the IAs and points out good practice, where possible.

The review shows the trend in the overall average quality by year. Based on the review undertaken in this study, **the overall average quality of the 143 appraised IAs is 'satisfactory', with an average score of 3.5**. The analysed IAs scored 3.3 in 2020 and 2021 on average, saw a slight increase in 2022 (3.4), and a quite significant improvement in 2023 (3.8). The six IAs published in 2024 attained an average score of 3.5.

The results appear to be in line with a **generally positive trend in the quality of IAs** and the Commission's efforts in the framework of better regulation. However, **room for improvement on several dimensions** persist, as can be seen in the **following findings for each dimension**. An IA can

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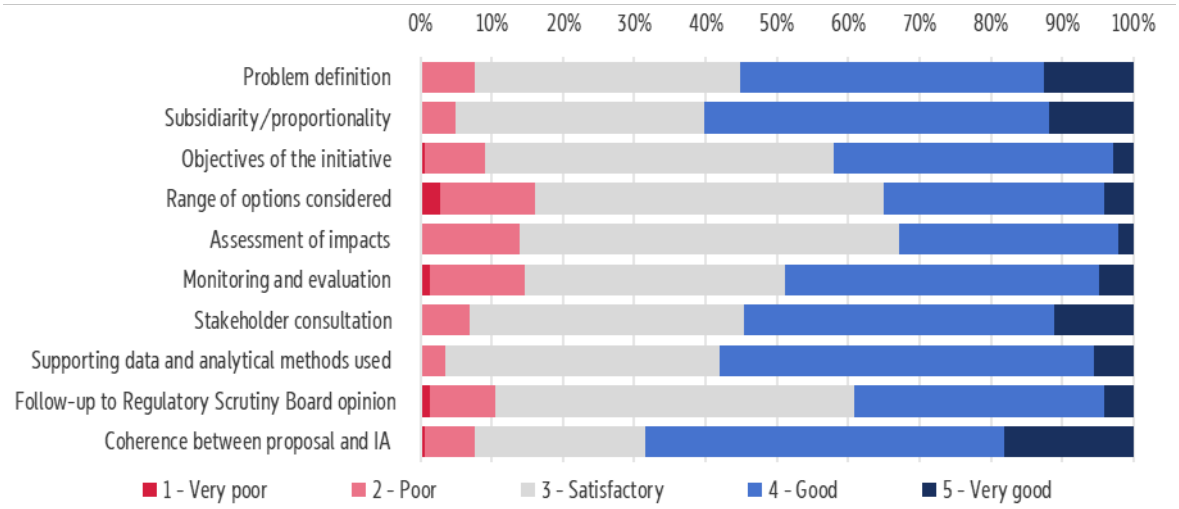
1 Ex-Ante Impact Assessment Unit, Appraising the quality of the European Commission's impact assessments: Trends and developments from 2015 to 2018, EPRS, European Parliament, December 2019; J. Dunne and W. Hiller, European Parliament work in the fields of Impact Assessment and European Added Value, Activity report for July 2014 – December 2015, Annex 1.

2 IMPA, Appraising the quality of the European Commission's impact assessments, 2019.

3 A total of 203 IAs were published in the reference term. Due to time and capacity restraints, IMPA cannot assess all IAs, generally giving preference to files adopted under the ordinary legislative procedure, the Commission work programme and the Joint Declaration on annual interinstitutional programming.

be strong in one area, but weak in another; the purpose of this review is therefore to analyse the trends in each dimension and to highlight the strengths and weaknesses of the appraised IAs, as well as to show any evolution by comparing the current findings with those of the study from the previous review term.

Figure 1 – Score distribution on the 10 essential dimensions of IAs appraised between December 2019 and November 2024



Source: IMPA, EPRS.

The IAs start **by defining the problem** and its underlying causes. In the current sample of appraised IAs, the **problem definition section scored 3.6 on average, with more than 50 % of IAs rated 'very good' or 'good'**. The IA identified the nature and scale of the problem well in 75 % of the cases, as well as who is affected by the problem and how the problem would evolve without further EU intervention. Two thirds (68 %) of the sampled initiatives concerned a revision of existing legislation. In line with the EU's 'evaluate-first' principle, most were informed by an earlier evaluation. However, it is worth noting that evaluations are, due to time constraints, increasingly undertaken in parallel with the IA ('back to back'), rather than in two consecutive processes. This practice has been criticised for its inherent risk that evaluation findings may not yet be available for the IA's design, and in particular for defining the problem.

The average overall quality of the **subsidiarity and proportionality** dimension reached the **satisfactory** level. The Commission took on board the Task Force on Subsidiarity, Proportionality and 'Doing Less More Efficiently' recommendation to use a model template ('**subsidiarity grid**') systematically to assess subsidiarity and proportionality in its IAs and explanatory memoranda on legislative proposals. However, the Better Regulation Guidelines (BRG) advise the use of the grid for politically sensitive and important initiatives accompanied by an IA. Of the IAs appraised, 46 % were accompanied by a subsidiarity grid. It **appears that the use of the grid facilitated and improved addressing subsidiarity and proportionality in a more structured way** in the appraised IAs. Almost all IAs appraised have addressed the necessity for EU action and expected EU added value. The 'cost of non-Europe', provided for in the IIA BLM and called for by Parliament, was generally not assessed in the IAs appraised.

The BRG and Toolbox requirements on setting **objectives** are rather complex. It is therefore key to set objectives in line with these requirements. Correctly defined objectives contribute positively to the overall quality of the proposed legislation and are especially important for monitoring and evaluation. There has been **improvement compared to the previous review term, whereas the average score for policy objectives reached 3.3, up from 3.1**. Furthermore, the share of IAs including operational objectives increased from 29 % to 36 %, as did full compliance with the

'S.M.A.R.T.'[4] criteria – from 30 % to 37 %. More effort is needed to ensure operational objectives are included in the IAs that clearly define the deliverables of policy actions, as they are missing in most cases so far.

A **considerable improvement can be observed in the quality of presentation of the policy options**, as in 64 % of cases the presentation was clear and balanced, compared to 37 % in the previous review term. On the other hand, while a high number of IAs continue to provide multiple policy options, this does not always appear to ensure a wide range of feasible alternatives. During the period under review, one third of the IAs did not entirely present realistic alternatives and in a number of cases, options were built around each other, which in fact limited the range of options. Even though **the share of the IAs providing realistic alternatives has increased from the previous legislative term** (from 49 % to 66 %), **this aspect requires further effort**, given its relevance to the objectivity and quality of the analysis.

The identification and **assessment of impacts** remains **one of the weakest among** the different dimensions covered under the present review, falling **slightly above the satisfactory** range. As in the previous review term, the current review reiterates the need to implement the BRG and Toolbox in the IA, during the preparation and design of new legislation or its revisions, as well as the need to duly justify which impacts are being analysed, to what extent and explicitly indicate whether one of the compulsory impacts (economic, social, environmental) is not relevant or why other potentially relevant impacts are not assessed. The analysis of the IAs appraised in this review shows **economic impacts of the policy options retained for the proposed legislative initiatives have been assessed more in a more systematic way than social and environmental impacts, and has been carried out to a higher standard**.

Other relevant direct and indirect impacts (such as territorial and gender equality related impacts), also need to be assessed when deemed relevant, depending on the initiative or policy area. Despite several calls from key actors, **territorial impacts** were found to have been addressed in only 15 % of 143 IAs appraised. Nevertheless, this represents a slight improvement compared to the previous review term. At the same time, **gender equality related impacts** were (partially) addressed in only 7 % of appraised IAs. Furthermore, following the Commission's 2021 Better Regulation communication and the 2021 revision of the BRG, there is a commitment to promote the '**digital by default**' principle in forthcoming EU legislation to support digital transformation, as well as the '**do no significant harm**' principle to help the EU achieve a successful and just transition towards a sustainable future. Given that the two principles were only introduced in the 2021 revision of the BRG, it not possible to compare the whole review period. However, 29 % of IAs appraised considered the 'digital by default' principle, while 23 % considered the principle as part of their analysis.

As in the previous review, the **assessment of impacts on small and medium-sized enterprises (SMEs)** and **competitiveness** were often underdeveloped. However, **an improvement in the quality of the SME analyses and increased use of the SME Test can be noted in the present review period**. Overall, a positive evolution is observed in the assessment of both competitiveness and SMEs from 2023 onwards. This appears to be linked to the Commission's **renewed focus on competitiveness and a growth-promoting regulatory framework**, including better regulation for SMEs and reduction of the administrative burden. Given the new requirement for a compulsory annex on a competitiveness check in the IAs, including impacts on SMEs, how this recent positive trend evolves in terms of the quality of the competitiveness and SME assessment remains to be seen.

[4] S.M.A.R.T. – specific, measurable, achievable, realistic, and time-bound.

The instruments for EU legislation **simplification and burden reduction** were complemented in the November 2021 revised BRG with a new tool to implement the **'One in, one out' (OIOO) approach**. The IAs need to systematically consider whether a new proposal would have significant cost implications for businesses and citizens and report on the expected additional administrative costs expected under the IA's preferred option(s). Following a transition period of gradual implementation, starting with 10 pilot IAs in 2021/2022, by the third quarter of 2022 nearly all IAs reviewed here complied with the OIOO application. However, IMPA noted a **varied application and a lack of methodological transparency**, notably in terms of the definition and distinction of cost categories and quantified aggregates. Given the limited time of full application, it is too early for a final assessment of OIOO implementation at EU level.

Reference to the **SDGs and impacts on developing countries** were among other new or revised elements of the 2021 version of the BRG and Toolbox. The IMPA analysts observed that roughly half of the 2022 IAs analysed considered SDGs, while all IAs considered this requirement consistently from 2023. **Impacts on developing countries, however, are seldom analysed substantially**. Roughly 43 % of all analysed IAs since the revision of the BRG and Toolbox considered impacts on third countries to some extent and only around 11 % explicitly mentioned developing countries; furthermore, the analysis often appears superficial. However, the Commission's political guidelines starting in December 2024 underline the **need for a more systematic approach to assessing the impact of EU laws on non-EU countries**. This may lead to growing relevance for ex-ante assessment of these impacts.

Monitoring and evaluation remain core elements of policymaking aimed at assessing the performance and impact of EU policies. During the period under review**, 96 % of the IAs assessed included monitoring provisions and 85 % comprised evaluation provisions**. Moreover, the majority of the IAs were considered to have **good monitoring and evaluation systems**. To continue this trend is important to carry these provisions into the legislation. While operational objectives and timelines could have been clearer, both Commission and Parliament agree on the importance of a robust monitoring and evaluation framework.

An important component supporting evidence-based policymaking and underlying IA transparency, **stakeholder consultation scored better in the IAs reviewed**. While the average quality of this dimension was found to be **good**, **some scope for improvement** remains when it comes to transparent and detailed reporting on the use of stakeholder feedback in Commission IAs – a point already noted in the previous review term.

When assessing **supporting data and analytical methods used** in IAs, the average quality under review is satisfactory, representing a **steady improvement compared to the previous review term**. An 82 % share of the IAs were considered to provide an entirely clear explanation of the assumptions and limitations of the analysis, and found partially clear in 16 % of cases. As in the previous review term, IMPA identified issues regarding the lack of transparency of information, including the unavailability of supporting studies. This lack of transparency and access to the specific research supporting an IA prevents the co-legislators, other stakeholders and the public from verifying the IA's statements and conclusions. This was already noted in the previous review term. As regards the use of **analytical methods and models**, the variety between the IAs appraised is considerable and has not changed significantly. Also here, issues have been identified in the IAs regarding full transparency and availability of the analytical methods (cost/benefit analysis, cost-effectiveness analysis, sensitivity analysis, multi criteria analysis or other analytical methods) and models used. Evidence on **quantification of costs and benefits** shows a consistent year-over-year increase in the share of IAs that quantify costs. Overall, **costs are quantified in 42 % of the appraised IAs**. This assessment shows **an uptake in the share of IAs that quantify benefits between 2020 and 2023**. However, they remain **quantified in only 26 % of appraised IAs**.

The uptake of **Regulatory Scrutiny Board recommendations** to improve draft IAs was, on average, **one of the weaker dimensions** appraised by IMPA, scoring in the lower satisfactory area (3.3). A positive finding is that most of the IAs scrutinised by IMPA under this review explained transparently in their Annex 1 (to varying degrees of detail) how they addressed the RSB's comments. However, IMPA data shows that many final IAs addressed these comments only 'partially', even after 'positive with reservations' opinions, where often significant improvements to the draft IAs were considered necessary. It also suggests that **IAs fully integrating RSB comments obtained a higher overall average score (3.7) than those that did so partially (3.3 average quality score)**. It appears that in recent years internal 'upstream' RSB scrutiny after issuing its final opinion has intensified. This informal 'coaching' of the Commission services seems to have contributed to improving the quality of final IAs. Despite high numbers of (very) critical RSB opinions at first submission and still many critical 'positive with reservations' opinions even at second submission, the overall average IA quality is better under this review than in our December 2019 review. In addition, **internal consultation between the RSB and author Directorate-Generals was possibly better structured** than in the past. The relatively stable period between final RSB opinions and IA publication dates (between 96 and 127 days from 2020 to 2023, on average 154 days in 2024) suggests that the IA process as a whole followed a more streamlined and structured pattern. Notwithstanding this positive outcome, **full transparency** about the follow-up to the RSB's comments remains important for policymakers and stakeholders to understand the reasoning and evidence behind a Commission initiative, and to be able to use it correctly – including proper justification why certain RSB remarks might not have been taken on board.

Coherence between the Commission's legislative proposal and the IA, compared to the previous review term, remained the same (71 % of IAs analysed were deemed 'coherent' in both review terms. The rest (29 %) were either 'partially' coherent, meaning not all provisions were carried over to the legislative proposal or that some modifications were made.[5] The reasons for the partial lack of coherence, varied from case to case and most often concerned minor elements that did not question the preferred course of action. The quality of the 'coherence' element, however, **improved from a 3.3 to a 3.8 average score** in the current review term.

In conclusion, this quality analysis finds a **positive evolution**, not only in the overall average quality of the IAs, but also in several dimensions, which reflects the Commission's significant efforts to apply the better regulation rules and tools. At the same time, the study reveals **shortcomings in certain parts of IAs**, which will need a careful and systematic approach in future IAs to improve – particularly the assessment of impacts, the range of feasible options and elements such as the inclusion of operational objectives and the quantification of benefits. A full uptake of the RSB recommendations in the final IA, and intensified upstream RSB scrutiny appears to have benefitted the overall quality of IAs considered in this review and should therefore be maintained.

[5] IMPA, Appraising the quality of the European Commission's impact assessments, 2019, p. 24.

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List of abbreviations

APIN	Initial appraisal of a European Commission impact assessment
BRG	Better Regulation Guidelines
EPRS	European Parliamentary Research Service
IA	Impact Assessment
IIA BLM	Interinstitutional Agreement on Better Law-Making
IMPA	Ex-Ante Impact Assessment Unit
JRC	Joint Research Centre
MIDAS	Modelling Inventory and Knowledge Management System of the Commission
OIOO	One-in, one-out
PCD	Policy Coherence for Development
RSB	Regulatory Scrutiny Board
SDG	Sustainable Development Goal
SME	Small and medium-sized enterprise
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union

Introduction

The Ex-Ante Impact Assessment Unit of the European Parliamentary Research Service provides targeted, timely and specialised IA-related support to parliamentary committees in their legislative work, covering all policy areas. It offers committees a range of on-request services in accordance with Parliament's Impact Assessment Handbook,[6] in particular detailed appraisals of Commission IAs, complementary or substitute IA of the aspects inadequately or not dealt with in the Commission's original IA, and IA of substantial parliamentary amendments.

In addition to the above, IMPA routinely provides initial appraisals of Commission IAs accompanying legislative proposals, to provide a brief overview of each IA and a succinct analysis of its methodological strengths and weaknesses. These initial appraisals are sent to the lead parliamentary committee and to opinion giving committees to support the effective and informed consideration of Commission proposals in line with Parliament's commitment to take full account of the Commission's IAs when considering the latter's legislative proposals. In other words, IMPA initial appraisals analyse the methodological compliance of the Commission IAs with the existing better regulation rules, relevant Parliament resolutions and Parliament's Impact Assessment Handbook to support Parliament's scrutiny of the Commission's IA work.

This study assesses the quality of a sample of 143 ex-ante Commission IAs accompanying legislative proposals adopted between December 2019 and November 2024. It draws on a review of IMPA's initial appraisals (APINs) of these 143 IAs.[7] It analyses the strengths and weaknesses of the IAs and points out good practice, where possible. In addition, the study strives to identify developments and trends regarding the various IA dimensions over time, to contribute to advancing the discussion on better regulation in general and ex-ante IA in particular. This study presents the third review[8] of the quality assessment of Commission IAs and refers to the 2019 review, where relevant (hereafter 'previous review term').[9] It takes into account the Commission's stocktaking of its better regulation agenda in 2019[10] and its 2021 communication on better regulation.[11]

The study is divided into three parts. The first chapter discusses institutional developments in ex-ante IA in the Commission and in the Parliament during the first von der Leyen Commission, including the criteria and tools used to conduct Commission IAs, and their initial appraisal in the Parliament. The second chapter explains the methodology and presents key observations and the main findings of the quality check of the IAs assessed in this review. The third chapter provides conclusions, highlighting the points for further reflection.

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6 European Parliament, Conference of Committee Chairs, Impact assessment handbook, September 2017.

7 The total number of IAs published in the reference term was 203. Due to time and capacity restraints, IMPA cannot assess all IAs, generally giving preference to files adopted under the ordinary legislative procedure, the Commission work programme and the Joint Declaration on annual interinstitutional programming.

8 Ex-Ante Impact Assessment Unit, Appraising the quality of the European Commission's impact assessments: Trends and developments from 2015 to 2018, EPRS, European Parliament, December 2019; J. Dunne and W. Hiller, European Parliament work in the fields of Impact Assessment and European Added Value, Activity Report for July 2014 - December 2015, Annex 1.

9 IMPA, Appraising the quality of the European Commission's impact assessments, 2019.

10 European Commission, Better regulation – taking stock and sustaining our commitment, COM(2019) 178.

11 European Commission, Better regulation: Joining forces to make better laws, COM(2021) 219.

1. Impact assessment in the European Commission and its appraisal in the European Parliament

a) Institutional developments and practical aspects of ex-ante impact assessment at the European Commission

As a milestone in the EU institutions' IA work, the Commission, the Parliament and the Council concluded an **Interinstitutional Agreement on Better Law Making (IIA BLM)** in 2016 that aims to make the EU law-making process more efficient, transparent and accountable. Its title was changed from 'better regulation', as originally proposed by the Commission, to 'better law-making'[12] following the previous Interinstitutional Agreement, this new agreement paved the way to ex-post evaluation and stakeholder consultation.

The three institutions also agreed on a common definition of IAs and their purpose.[13] The Commission committed to carrying out IAs of its legislative and non-legislative initiatives 'which are expected to have significant economic, environmental or social impacts'. In addition, the **initiatives included in the Commission work programme or in the joint declaration on EU legislative priorities** will, 'as a general rule', be accompanied by an IA.[14] The development of the IIA BLM was initiated by the Juncker Commission. Better regulation became a priority and the better regulation agenda was adopted in 2015.[15]

In April 2019, the Commission published a **communication on 'Better Regulation** – taking stock and sustaining our commitment'. This focused on better regulation principles, on evidence-based policymaking and on the strengths and weaknesses identified. There was a demand for better regulation to continue as an integral part of the Commission's way of working, with a sustained commitment to achieving further improvement in the future.[16]

In April 2020, the Commission presented the work programme for 2020[17] and a **communication on 'Better regulation: Joining forces to make better laws'** a year after. Both documents showed the commitment to make regulation more effective, efficient and deliver better policies for citizens and businesses.

In April 2021, the Commission set out a policy-making framework that aimed to support post-crisis recovery and the digital and green transition with a view to advancing the better regulation agenda.[18] **The revised version of the BRG and the Better Regulation Toolbox**[19] included significant changes

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12 See J. Ferger and M. Aleixo, Interinstitutional Agreement on Better Law-making, European Parliament, 2016.

13 See 2016 Interinstitutional Agreement on Better Law-Making, OJ L 123/1, 12.5.2016, point 12.

14 ibid, point 13.

15 See C. Collovà, Ex-ante impact assessment in the European Commission's new Better Regulation Guidelines, EPRS, European Parliament, 2015.

16 European Commission, Better regulation – taking stock and sustaining our commitment, COM(2019) 178, p. 6

17 European Commission, Commission Work Programme 2020 'A Union that strives for more', COM(2020) 37.

18 European Commission, Better regulation: Joining forces to make better laws, COM(2021) 219. See also S. Vettorazzi and I. Anglmayer, New European Commission communication on Better Regulation: Joining forces to make better laws, EPRS, European Parliament, 2021.

19 Better Regulation Guidelines and Better Regulation Toolbox: https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation/better-regulation-guidelines-and-toolbox_en.

and new instruments, such as the 'one in, one out' (OIOO) approach and mainstreaming strategic foresight in policymaking.[20]

Main changes in the revised Better Regulation Guidelines and Toolbox

- The **OIOO** is a full category with calculations for specific cost categories.
- Reinforced **SME** test with the inclusion of SMEs impacts and an explicit reference to the result of the **SME test**.
- Impacts on **competitiveness** must be analysed and should, as far as possible, include quantitative estimates. New annex on a competitiveness check.
- Improved consideration of gender, territorial impacts, SDGs, 'do no significant harm', systematic consideration of fundamental rights.
- Integration of **strategic foresight** in policymaking (see text box below).

In addition, the latest communication on long term competitiveness strategy[21] introduced a **25 % burden reduction target**. The **competitiveness check annexed in the IAs** led to another revision of the Better Regulation Toolbox in July 2023.

As set out in the mission letter[22] from Commission President Ursula von der Leyen, Commissioner Valdis Dombrovskis confirmed during his hearing in the European Parliament in November 2024,[23] that he would lead the negotiations on **a renewed interinstitutional agreement on simplification and better law-making**. He also stressed that simplification and better law-making are a joint responsibility shared by all EU institutions.

An important aspect of the IA process in the Commission is the quality control by its own Regulatory Scrutiny Board (RSB). All IAs must be submitted to the Board, which checks their quality before the legislative proposal can be submitted to the College of Commissioners for adoption. The RSB issues an opinion (positive, positive with reservations, or negative) on the draft IA, including recommendations for improvement. In principle, IAs require a positive opinion from the Board to move forward. If the report receives a negative opinion, it is sent back to the service responsible for revision and must be resubmitted to the Board.

b) Appraisal of the European Commission's impact assessments in the European Parliament

Under the 2016 IIA BLM, Parliament committed to take full account of the Commission's IAs when considering the latter's legislative proposals.[24] At the beginning of the parliamentary legislative process, IMPA routinely assesses the quality of the Commission's IAs accompanying legislative proposals, in light of the criteria set out in the Commission's own BRG on the one hand and relevant Parliament resolutions[25] and Parliament's Impact Assessment Handbook, on the other (the handbook is based on the BRG and the IIA BLM).

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20 For an outline of the changes in the better regulation agenda, see S. Vettorazzi and I. Anglmayer, What is new in the Commission's 2021 Better Regulation Guidelines?, EPRS, European Parliament, 2022.

21 European Commission, Long-term competitiveness of the EU: looking beyond 2030, COM(2023) 168.

22 U. von der Leyen, President of the European Commission, Mission letter to Valdis Dombrovskis, September 2024.

23 Confirmation hearing of Valdis Dombrovskis, 7 November 2024: https://elections.europa.eu/european-commission/en/dombrovskis

24 2016 Interinstitutional Agreement on Better Law-Making, point 14.

25 The European Parliament has adopted several resolutions asking for particular attention to be paid to impact assessment. A 2022 resolution underlines that the Commission's better regulation agenda should consider economic, environmental, gender and social impacts in an integrated and balanced way. The Parliament made a series of

The IMPA Unit's initial appraisals of the Commission's IAs support the informed and effective consideration of legislative proposals at committee stage by drawing the committees' attention to the IA's content and the methodological strengths and weaknesses. Their findings can incite committees to invite the Commission to explain any potential weaknesses or unclear elements of an IA or to request additional or complementary IA work. As set out in the Impact Assessment Handbook, IMPA can also provide additional on-request services complementing or substituting Commission IAs, in particular detailed appraisals, complementary or substitute IAs, or conducting IAs of Parliament's own substantial amendments.

Initial appraisals systematically scrutinise the main dimensions any IA should cover against the BRG. To this end, IMPA specifically checks whether the IA addresses the following **seven key questions** in a clear and transparent manner:

1. What is the **problem** and why is it a problem?
2. Why should the EU act (**subsidiarity and proportionality** principles)?
3. What should be achieved (**objectives** of the initiative)?
4. What are the **options** for achieving the objectives?
5. What are their **impacts** and who will be affected (including economic, social and environmental impacts, all other relevant impacts, notably on SMEs, competitiveness simplification and burden reduction)? [26]
6. How do the **options** compare (effectiveness, efficiency and coherence)?
7. How will **monitoring** and subsequent evaluation be organised?

In addition to these seven dimensions, initial appraisals check the following **aspects, which are particularly important to Parliament's scrutiny role:**

8. The quality of the **stakeholder consultations** and their use in the IA analysis and **the quality and transparency of the data and research** underpinning the IA.
9. The uptake in the final IA of the criticism and recommendations expressed in the **Regulatory Scrutiny Board opinions on the draft IA**. This is done under the caveat that draft IAs are not made public and are thus not available to Parliament.[27] This is why the RSB opinions provide the sole source to deduce, at least partly, the evolution of an IA, and to understand, for example, which provisions of the BRG were not adequately implemented despite the RSB recommending to do so.
10. **Coherence between the IA and the legislative proposal**, i.e. whether a justification or explanation is provided in case of discrepancy between the conclusions of the IA and the provisions of the final legislative proposal. While the Commission is free to decide the content of the final proposal, in line with the fact the IA is not a substitute for political decisions, assessing the coherence between the IA and the legislative

recommendations to strengthen the EU's strategy on better law-making, including on sustainable development, digitalisation, fundamental rights, protection of SMEs, improvement of consultation procedures and IAs, cooperation with national parliaments and between institutions, strategic foresight, transparency in decision-making and the independence of the Regulatory Scrutiny Board. See European Parliament resolution of 7 July 2022 on 'better regulation: Joining forces to make better laws'; European Parliament resolution of 23 November 2023 on 'European Union regulatory fitness and subsidiarity and proportionality – report on better law-making covering 2020, 2021 and 2022'.

[26] According to the Better Regulation Guidelines, the assessment of economic, social and environmental impacts is mandatory for all IAs. Other relevant impacts depend on the initiative and the policy area, and include for instance impacts on health, gender, national or EU budgets, as well as territorial impacts or impacts on third countries. See Better Regulation Guidelines, 2021, pp. 31-35.

[27] Parliament has called on the Commission 'to make ... draft impact assessments that are submitted to the board available to the co-legislators', European Parliament resolution of 7 July 2022 on 'better regulation: Joining forces to make better laws', paragraph 82.

proposal allows evaluation of whether and how the evidence gathered in the IA fed into the proposed legislation.

While addressing a broad variety of elements depending on the IA's subject matter and context, each initial appraisal is structured around the quality check of the above-mentioned main dimensions and issues. Therefore, they also form the core of this review.

2. Main observations and trends

The analysis in this study is based on 143 initial appraisals of IAs the Commission put forward between December 2019 and November 2024. Table 1 shows the number of appraised IAs (by the publication year of the legislative proposal they accompanied). The outbreak of the COVID-19 pandemic required an emergency response from legislators. The Commission issued its first proposals accompanied by an IA in July 2020, which IMPA subsequently appraised. The relatively low number of legislative proposals published by the Commission in 2024 can be explained by the approaching end of the 2019-2024 legislative term.

Table 1 – Appraised IAs covered in this review, December 2019-November 2024

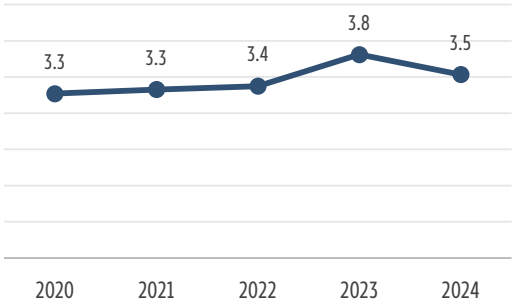
2020	2021	2022	2023	2024	Total
17	45	39	36	6	143

Source: IMPA, EPRS

As noted above, IMPA evaluates IAs on the following essential dimensions: problem definition; subsidiarity/proportionality; objectives of the initiative; range of options considered; assessment of impacts; monitoring and evaluation; stakeholder consultation; supporting data and analytical methods used; follow-up to the opinion of the Regulatory Scrutiny Board; and, finally, coherence between the Commission's legislative proposal and the preferred option of the IA. For each dimension, IAs are rated on a Likert scale from 1 to 5, corresponding to the quality of 'very poor', 'poor', 'satisfactory', 'good', and 'very good'.

The overall average quality of the appraised IAs is calculated as the sum of the scores on all dimensions divided by their total number.[28] Notably, an IA with a high overall score may still be weak in some areas, and a low-scoring IA may nevertheless be strong in certain dimensions. **The overall average quality of the 143 IAs appraised under this review is satisfactory, with an average score of 3.5**. This is an improvement compared to the overall average quality of IAs appraised during the previous review term (3.1). Figure 2 shows the trend in the overall average quality by year. The appraised IAs scored 3.3 on average in 2020 and 2021, saw a slight increase in 2022 (3.4), and a quite significant improvement in 2023 (3.8). The six IAs published in 2024 attained an average score of 3.5.

Figure 2 – Trend in overall average IA score during the review period



Note: 1 - Very poor, 2 - Poor, 3 - Satisfactory, 4 - Good, 5 - Very good.

Source: IMPA, EPRS.

The **appraised IAs score highest on the 'coherence between the Commission's legislative proposal and the IA'** dimension, with an average score of 3.8 (see Figure 1) – an improvement from 3.3 in the previous review term. As was the case in the previous review term, **the lowest scoring dimensions are 'range of options considered' and 'assessment of impacts'**, with an average score of 3.2 each. Still, with both dimensions scoring 2.9 in the previous review term, this represents an improvement. The lowest overall average score in the sample is 2.4 (poor), for four

[28] Note that IMPA's method of evaluating an IA is different from the RSB's annual reviews, in which the Board rates 13 'quality components' as 'Unsatisfactory', 'Weak', 'Acceptable', 'Good', and 'Very good' (more on this in Annex 2 of the RSB Annual report 2022).

IAs.[29] The highest scoring IA is the IA accompanying the proposal for a regulation on toy safety,[30] with 4.7 (good).

To pinpoint strengths and weaknesses of the appraised IAs and identify evolutions and trends regarding the dimensions over time, IMPA refers, wherever relevant, to the findings of the previous review term.[31]

Problem definition

The Commission's BRG require an IA to start by identifying the existence of a problem and its underlying causes. **The IA should reflect on who is affected by the problem, estimate its scale and analyse its root causes and consequences**. Furthermore, it should assess 'how likely it is to persist in the absence of (further) EU policy intervention'.[32] It should develop a dynamic baseline scenario, i.e. the current situation, taking into account existing and pending legislation and also possible long-term developments, trends and challenges, thereby 'using foresight elements and scientific advice, where appropriate'.[33] Strategic foresight was added as a new element in IAs through the 2021 Better Regulation reform (see textbox on strategic foresight below).

The evidence-based and coherent definition of the problem to tackle is of particular importance for the quality of any IA, as it presents a building block and reference framework for the whole analysis. The RSB has emphasised this in several instances, including, most recently, in its 2023 annual report, which states that 'getting the problem definition right is essential as it lays the groundwork for other essential quality components and presenting a clear and consistent intervention logic'.[34]

If an initiative concerns a revision of existing legislation – this was the case for 96 IAs (68 %) of the sample under review – the findings of a preceding evaluation or fitness check should form the starting point of the problem definition, in line with the EU's evaluate-first principle. Parliament stressed the importance of this principle 'for ensuring that lessons learnt from the past can influence future policy cycle action'.[35] In a majority of cases (88 %), the evaluate-first principle was respected.[36] Only 12 of the 96 revisions in question do not seem to have been based on a previous evaluation. While IMPA's appraisal work does not generally assess how the evaluation findings informed an IA and how coherent they are with the problem definition in the IA on the basis of the preceding evaluation, the RSB has repeatedly commented on the Commission's use of evaluations. For instance, in its 2022 report, the RSB found that the 'first submission of draft impact assessments with a low-quality score often did not perform well in integrating evaluation findings, and often showed a lack of a clear problem identification and credible evidence demonstrating the existence and scale of a problem'.[37]

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29 These were the IAs accompanying the proposals on a computerised system for communication in cross-border civil and criminal proceedings (SWD(2020) 541); Combating violence against women and domestic violence (SWD(2022) 62); Establishing a framework for setting ecodesign requirements for sustainable products (SWD(2022) 82); and urban wastewater treatment (SWD(2022) 541).

30 The IA accompanying the proposal for a regulation on the safety of toys.

31 IMPA, Appraising the quality of the European Commission's impact assessments, 2019.

32 Better Regulation Guidelines 2021, pp. 31-32.

33 ibid.

34 Regulatory Scrutiny Board, Annual report 2023, p. 20.

35 European Parliament resolution of 7 July 2022 on Better regulation: Joining forces to make better laws, paragraph 52.

36 This figure broadly concurs with the findings of the Regulatory Scrutiny Board over the years, which indicates in successive annual reports an average compliance rate of 80 % for 2020-2023. The RSB found compliance to be the highest in 2022 (90 %). (The discrepancy between the RSB's 80 % and IMPA's 88 % can be explained by the different review scope: the RSB scrutinises all IAs, whereas IMPA examined a selection.)

37 RSB, Annual report 2022, p. 18.

In a few cases, IMPA's initial appraisals of IAs flagged issues with regard to relevance and transparency of evaluations. These include cases where the preceding evaluation was truly outdated.[38] It is questionable whether these evaluations are still sufficiently relevant and thus comply with the 'evaluate first' principle. In some cases, the preceding Commission evaluation or the underpinning studies were not published, which clearly goes against the spirit of better regulation, considering that transparency is a component of the better regulation agenda. This was, for instance, the case with the Commission's fitness check on violence against women,[39] which appears to never have been published, obscuring how its findings fed into the ensuing IA.[40] Similarly, the evaluation of the EU's general pharmaceutical legislation is not retrievable in EurLex or in the Commission's public register of documents (differing from the usual transparency standards, it remains hidden on a webpage of the lead Commission DG).[41] Recent examples of unpublished studies supporting an evaluation include, for instance, the revision of the Package Travel Directive.[42]

As full compliance with the evaluate-first principle may be a time-consuming process, often spanning several years, the Commission increasingly conducts evaluations and IAs in parallel ('back to back'), rather than consecutively, as is the rule. Back to back was introduced in 2017, as part of the first reform of the BRG.[43] According to the Better Regulation Toolbox, this abridged process may be chosen when 'political urgencies or timing constraints'[44] do not allow a standard process. Even if back-to-back initiatives are subject to the same quality standards as stand-alone evaluations and IAs,[45] they nonetheless bear the risk that evaluation findings are not yet available for the design of the IA. To mitigate this risk, the Better Regulation Toolbox sets out that 'the problem definition in the impact assessment cannot be finalised until at least tentative evaluation conclusions are available'.[46]

Several actors have raised concerns regarding the surge in back-to-back initiatives in recent years, including the European Parliament.[47] The European Court of Auditors also pointed to 'two inherent risks', the first pertaining to the independence of the two processes, and the second relating to the effective consideration of the evaluation conclusions for the IA when the evaluation is not yet completed.[48] In comparison, the RSB's view on the increased use of back-to-back initiatives appears more nuanced. The Board concedes that it 'allows analytical synergies and still allows the Commission to comply with the "evaluate first" principle and to respect political delivery

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38 See e.g. the IA on a proposed framework for ecodesign requirements for sustainable products (SWD(2022) 82), where the evaluations dated from 2012 and 2015, and the proposed regulation for combating late payment (SWD(2023) 314), where the evaluation was concluded in 2015.

39 See roadmap on the Have your say portal, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12472-Violence-against-women-and-domestic-violence-fitness-check-of-EU-legislation_en.

40 See Commission IA accompanying the proposal for a directive on combating violence against women and domestic violence, SWD(2022) 62. This IA includes no mention of the fitness check.

41 Revision of the EU pharmaceutical legislation, EPRS, European Parliament, 2023. Evaluation retrievable under https://health.ec.europa.eu/system/files/2023-05/mp_ia_revision-pharma-legislation_annex_5_en.pdf

42 Revision of the Package Travel Directive, EPRS, European Parliament, 2024.

43 European Commission, Completing the better regulation agenda: Better solutions for better results, COM(2017) 651. For a discussion of the 'back-to-back' practice, see F. Simonelli and N. Iacob, 'Can we better the European Union Better Regulation agenda?' *European Journal of Risk Regulation*, Vol. 12(4), 2021, pp. 849-860; I. Anglmayer, Evaluation in the European Commission: Rolling check-list and state of play, 5th edition, EPRS, European Parliament, 2023, pp. 34-36.

44 Better Regulation Toolbox, 2023, Tool #51, p. 450.

45 Better Regulation Toolbox, 2023, Tool #50, pp. 439-441.

46 Better Regulation Toolbox, 2023, Tool #50, p. 440.

47 European Parliament resolution of 7 July 2022 on Better regulation: Joining forces to make better laws, paragraph 52.

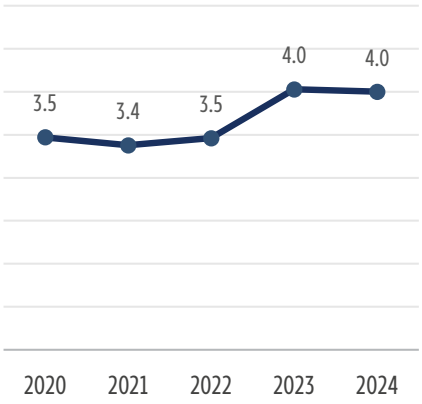
48 European Court of Auditors, Ex-post review of EU legislation: a well-established system, but incomplete, Special Report No 16, 2018, pp. 31 and 37.

commitments', but it also cautions that 'this can come also with several shortcomings'.[49] However, if well done, the findings of an evaluation can feed into the problem definition section of the associated IA. This was the case, for instance, with the IA on alternative dispute resolution for consumers.[50] In 'back-to-back' cases, transparency is generally an issue, as the Commission evaluation is typically not published as a self-standing staff working document, but as an annex to the IA.[51]

In the examined sample, 29 of the 143 examined IAs were carried out back to back, representing 20 % (or 30 %, if only the initiatives for revision are considered). This figure broadly concurs with the findings from a 2023 EPRS study that established that 22 % of Commission evaluations published between 1 July 2020 and 10 October 2023 were conducted back to back with an IA.[52]

In the sample of 143 IAs, the problem definition section was rated as 'very good' or 'good' in over 50 % of IAs, scoring 3.6 on average (see Figure 3). Thus, **this dimension is one that scored among the highest among the dimensions covered in this analysis**. In 75 % of cases, the IA identified the nature and scale of the problem well, as well as who is affected by the problem and how the problem would evolve without further EU intervention. In only a few IAs, the description of the scale of the problem was found to be more limited,[53] or the problem description did not entirely match the intervention logic scheme.[54] This **concurs with the previous review term**, where the problem definition was also one of the best-scoring dimensions, with 52 % of IAs being rated either 'very good' or 'good'.[55]

Figure 3 – Trend in average quality of the problem definition dimension



Note: 1 - Very poor, 2 - Poor, 3 - Satisfactory, 4 - Good, 5 – Very good.

Source: IMPA, EPRS.

[49] RSB, Annual report 2022, p. 26.

[50] Alternative dispute resolution for consumers, EPRS, European Parliament, 2023.

[51] Better Regulation Toolbox 2023, Tool #50, p. 440.

[52] I. Anglmayer, Evaluation in the European Commission: Rolling check-list and state of play, 5th edition, EPRS, European Parliament 2023, p. 35.

[53] Interoperable digital public services in the EU, EPRS, European Parliament, 2023; Certification of carbon removals, EPRS, European Parliament, 2023.

[54] Combating violence against women and domestic violence, EPRS, European Parliament, 2022.

[55] IMPA, Appraising the quality of the European Commission's impact assessments, 2019, pp. 7 and 28.

Strategic foresight in European Commission impact assessments

As part of the 2021 reform, the Commission integrated strategic foresight into the EU's better regulation agenda to render EU policies and legislation more future-proof and resilient. The European Parliament welcomed this move in its 2022 resolution on better regulation.

Since 2022, IAs should systematically take long-term developments, trends and challenges into account. This applies in particular to 'major policy initiatives' and 'policy areas subject to rapid structural change'. According to the Better Regulation Toolbox (Tool #20), foresight methods to be considered in IAs include the analysis of **megatrends** and **long-term scenarios**. Megatrends are defined as 'long-term global driving forces' that have 'the potential to lead to large- and broad-scale transformations' in the long term. According to the toolbox, future long-term scenarios may complement the megatrends analysis, if appropriate and proportionate, as scenario-building is 'resource- and time-consuming'. The toolbox also encourages the use of dedicated **foresight studies**.

In practice, as an EPRS briefing highlighted, foresight is most frequently addressed in the problem definition section in Commission IAs (Anghel, 2024, p. 10), in particular the baseline scenario. Foresight analysis may also be relevant for other sections of an IA, such as policy objectives and options. Moreover, where relevant to an initiative, foresight-related questions should also be part of stakeholder consultations.

In recent years, a growing number of Commission IAs included references to foresight and megatrends. However, cases where foresight elements are considered in greater depth or in a systematic manner (e.g. linking foresight reflections from the problem definition with the policy options), remain rare, although good practices are emerging. Some IAs, e.g. those on driving licences and accounting of greenhouse gas emissions of transport services dedicate an entire sub-chapter to foresight in the problem definition section.

When **megatrends** are deemed relevant in Commission IAs, their analysis is typically based on (one or more of) the 14 megatrends identified in the Joint Research Centre's (JRC) megatrends hub. This is the case, for example, in the IA supporting the revision of the pharmaceutical legislation, the IA on alternative dispute resolution for consumers and the IA on maximum authorised weights and dimensions for certain road vehicles.

Several IAs draw on dedicated **foresight studies**, most of which are carried out by the JRC. Examples include the IA supporting the EU's critical raw materials act, and the IA underpinning the revision of EU customs legislation. In the former, a foresight study examines the supply chains of certain strategic sectors, while in the latter, findings from the foresight study, 'The Future of Customs in the EU 2040', substantiates the dynamic baseline scenario. In practice, IAs rarely explore foresight-based **scenarios**, and if they do, the scenarios are developed in supporting studies, as is the case with the IA underpinning the proposal on the sustainable use of plant protection products.

In line with its mandate, the RSB pays close attention to foresight elements in IAs, as is evident from various comments in RSB opinions. In its 2022 annual report the Board commented that it 'noticed in a significant number of cases the integration of foresight analysis when presenting the expected evolution of the problem and future-proofing options' (p. 19).

Subsidiarity and proportionality

Subsidiarity[56] and proportionality[57] are of key importance in every IA. IAs should answer the question of whether only Member States could address the problem(s) deriving from the problem definition on their own, or whether the EU should act to address the problem(s), and how. The Commission is required to address subsidiarity and proportionality in its IAs in a dedicated section and in a separate

[56] See Article 5(1) TEU.

[57] See Article 5(4) TEU.

grid, if relevant. According to the BRG, if EU action is proposed in areas where the EU does not have exclusive competence, the IA should verify whether this action is compatible with the principle of subsidiarity. Policymakers should get the 'information they need to decide whether an *EU-level* policy response is required'.[58] The IA should also consider the added value of EU action compared to what could be achieved by Member States. This analysis should be complemented, whenever possible, by a consideration of the costs of not acting at EU-level ('cost of non-Europe') – an element agreed in the 2016 IIA BLM, in line with Parliament's request.[59]

An IA is also required to address the proportionality of the proposed EU action, i.e. whether the proposed measures go beyond what is necessary to address the problem. The BRG state 'the assessment of proportionality is clearly linked to the assessment of subsidiarity and the need to match the nature and intensity of a given measure to the identified problem'.[60]

The Commission took on board the 2018 Task Force on Subsidiarity, Proportionality and 'Doing Less More Efficiently'[61] recommendation to systematically use a model template ('subsidiarity grid') to assess subsidiarity and proportionality throughout the whole policy cycle in its IAs and explanatory memoranda on legislative proposals.[62] According to the recommendation, the assessment method should capture the criteria contained in the Protocol on subsidiarity and proportionality[63] and relevant European Court of Justice jurisprudence. The subsidiarity grid should be 'presented as a linked staff working document with each politically sensitive and important initiative accompanied by an impact assessment'.[64] [65] The Better Regulation Toolbox provides guidance on how to integrate this in the IA report. It presents a set of questions in the 'subsidiarity grid', which help to 'assess the

[58] Better Regulation Guidelines, 2021, p. 32.

[59] IIA BLM, paragraph 12; European Parliament resolution of 30 May 2018 on the interpretation and implementation of the Interinstitutional Agreement on Better Law-Making, paragraphs 23 and 24; European Parliament resolution of 24 June 2021 on European Union regulatory fitness and subsidiarity and proportionality – report on Better Law Making covering the years 2017, 2018 and 2019, paragraph 28.

[60] Better Regulation Guidelines, 2021, p. 34.

[61] Task Force on Subsidiarity, Proportionality and 'Doing Less More Efficiently', report 'Active subsidiarity - A new way of working', 2018, pp. 10-11.

[62] European Commission, Better regulation – taking stock and sustaining our commitment, COM(2019) 178, pp. 7-8. See also European Commission, The principles of subsidiarity and proportionality: Strengthening their role in the EU's policymaking, COM(2018) 703, pp. 6-8 and Annex II.

[63] Protocol (No 2) on the application of the principles of subsidiarity and proportionality, OJ C 115, 9.5.2008, pp. 206-209.

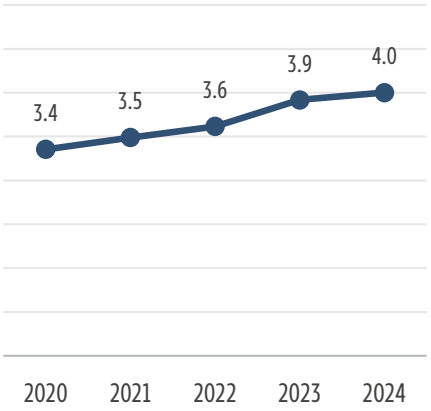
[64] Better Regulation Guidelines, 2021, p. 34.

[65] See European Commission, The principles of subsidiarity and proportionality: Strengthening their role in the EU's policy making, pp. 6-7.

issues of subsidiarity, proportionality, and EU value added that need to be analysed and reported in the impact assessment'.[66]

Over the review term, the average overall quality of this dimension reached the **satisfactory level – a steady improvement** compared to the previous review term. Of the IAs appraised, 46 % were accompanied by a subsidiarity grid. It appears that the use of the grid facilitated and improved a more structured approach to subsidiarity and proportionality in the appraised IAs. The average quality of this dimension increased steadily throughout the review term (see Figure 4), moving increasingly away from the general comments and circular reasoning observed in the previous review term. Almost all IAs appraised addressed the necessity of EU action (95 % of all cases, compared to 98 % in the previous review term) and expected EU added value (89 % of all cases, compared to 64 % in the previous review term). As in the previous review term, the 'cost of non-Europe', provided for in the IIA BLM and requested by Parliament, was generally not analysed in the IAs appraised.

Figure 4 – Trend in average quality of the subsidiarity and proportionality dimension



Note: 1 – Very poor, 2 – Poor, 3 – Satisfactory, 4 – Good, 5 – Very good.

Proportionality was addressed comprehensively in a majority of IAs appraised (62 %) and less so in 24 % of the cases. In 14 %, proportionality was not addressed.[67] While proportionality was included in the BRG as a fourth criterion against which options should be compared (alongside efficiency, effectiveness and coherence), policy options were not compared against proportionality in 25 % of the cases (compared to 32 % in the previous review term; see also 'assessment of impacts' dimension).

The overall evolution of the average quality of subsidiarity and proportionality throughout the review term is shown in Figure 4.

Objectives of the initiative

According to the BRG, an **IA should 'clearly identify the objectives of policy action, including the level of policy ambition'.[68] The objectives should correspond to the problem and the problem drivers and be linked with the policy options**. They should 'take account of the key long-term challenges and corresponding EU policy ambitions'.[69] The Better Regulation Toolbox further clarifies that the initiative's objectives must be in line with the strategic objectives of the Commission.[70] For

[66] Better Regulation Toolbox, 2023, Tool #11, p. 69.

[67] See an example, where proportionality has not been addressed: Adequate minimum wages, EPRS, European Parliament, 2021.

[68] Better Regulation Guidelines, 2021, p. 32.

[69] ibid.

[70] The IIA BLM links the three EU institutions' responsibility to deliver high-quality legislation with the achievement of the common policy objectives of the Union and sets how the principal policy objectives and priorities of the three institutions are integrated in the Commission work programme and the Joint Declaration on annual interinstitutional programming.

major policy initiatives, the objectives should also consider the challenges and opportunities identified through strategic foresight.

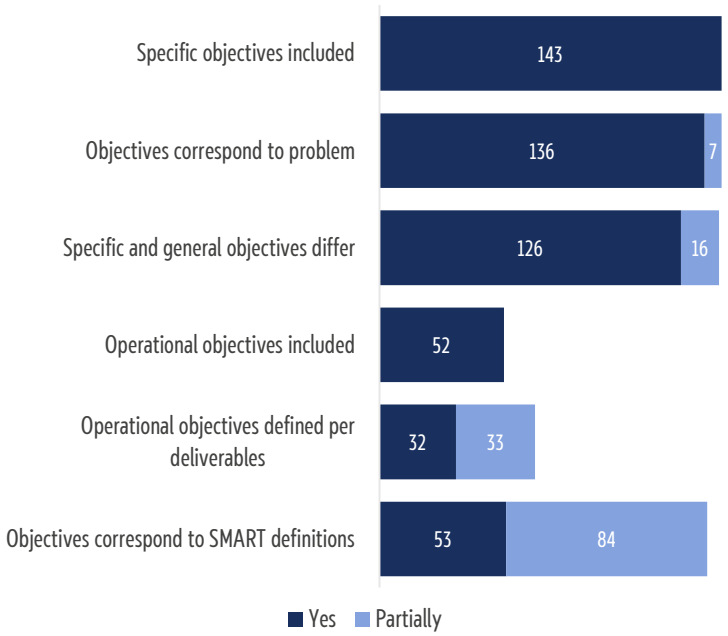
After analysis of the problem, the IA should define general and specific objectives. General objectives are 'Treaty-based objectives that the policy aims to contribute to'.[71] Specific objectives identify the goals of the policy initiative more specifically, often relating to several proposed measures to address a problem.[72] They should be distinct from the general objectives.

After identifying the preferred policy option – after the analysis of potential impacts – the IA should develop operational objectives, as recommended by the Better Regulation Toolbox. Operational objectives should be 'defined in terms of the deliverables of specific policy actions'.[73] As such, they are typically option-specific. Specific and especially operational objectives are not only relevant to the ex-ante IA of an initiative, but also in view of future effective monitoring and evaluation, as the initiative and its outcome will be measured in relation to them.

Consequently, clear objectives and deliverables of the preferred option should be specified in an IA, by relevant indicators.[74] Furthermore, the Better Regulation Toolbox also stipulates that objectives should be S.M.A.R.T. (i.e. specific, measurable, achievable, relevant and time-bound).[75]

During the review period, the average score for policy objectives reached 3.3, marking an **improvement** from 3.1 observed during the previous period. Notably, IMPA analysts observed that 100 % of the appraised IAs included specific objectives (see Figure 5).

Figure 5 – Assessment of the objectives in the appraised IAs



Source: IMPA, EPRS

95 % of IAs contained objectives corresponding to the problem, while the remaining 5 % corresponded only partially. Around 88 % of IAs included specific objectives that were distinct from the general one(s), and around 11 % were partially distinct. Specific objectives were not distinct from the general objective in only one case.

[71] Better Regulation Toolbox, 2023, Tool #15, p. 110.

[72] ibid. Specific objectives should be 'broad enough to allow consideration of all relevant policy alternatives without prejudging a particular solution, i.e. the specific objectives are part of the intervention logic: problem – drivers – specific objectives – policy options.'

[73] ibid.

[74] ibid: Operational objectives 'should not, therefore, be reported in the same place in the IA report as the general and specific objectives, but reported in the section referring to monitoring and evaluation'.

[75] See Better Regulation Toolbox, 2023, Tool #15, pp. 110-111.

As in the previous review term, the **most problematic** issues observed concern **operational objectives** (a mere 36 % of IAs analysed included operational objectives) and defining them in terms of the deliverables of specific policy actions (22 % of all IAs analysed). As mentioned, this dimension is especially important in measuring the outcome of the initiative. These observations correspond to the RSB's recommendations 'to link them [objectives] more clearly to key performance indicators when defining the future monitoring and evaluation arrangements'.[76] Furthermore, the RSB recommended expressing the objectives in smarter terms[77] and IMPA also found that objectives corresponded fully to S.M.A.R.T. criteria in only 37 % of cases. In 84 IAs (59 %), the objectives partially corresponded and 4 % were not considered to satisfy the S.M.A.R.T. criteria.

Good practice

The IA accompanying the proposal laying down measures for a high level of public sector interoperability across the Union (see 'Interoperable digital public services in the EU', EPRS, European Parliament, 2023) presents operational objectives, including potential indicators that appear relevant to the achievement of the specific objectives. These indicators include, for instance, the extent to which: a multi-level governance is established and functional; public administrations work together to develop interoperability solutions and the use of recommended solutions; public administrations share and reuse existing solutions in developing digital public services. Furthermore, the indicators are complemented by corresponding data sources and by specific targets to monitor the achievements over time.

However, compared to the previous review, there have been positive developments on setting objectives. The share of IAs that included operational objectives has increased (from 29 % in the previous review to 36 %), as well as the share of IAs fully complying with the S.M.A.R.T. criteria (from 30 % to 37 %).[78]

Range of options considered

According to the BRG, an **IA should consider a wide range of policy options, identify the most relevant for further assessment and describe the key aspects of the policy options retained**.[79] Furthermore, the policy options should be closely linked to the problem drivers, the problems and the defined objectives, as a clear logic should support the intervention.[80]

The Better Regulation Toolbox specifies that 'the design of possible policy options should always consider the option of changing nothing and use this as the benchmark, referred to as 'baseline', against which the policy options should be compared'.[81] It also stresses the importance of a clear and well-defined baseline, as it facilitates the assessment of the effects of the policy measures.[82]

An encouraging finding during the period under review is that a **clear majority of the IAs (around 87 %) defined the baseline sufficiently**. The baseline was partially explained in around 11 % of the IAs and the baseline was not adequately described in 2 %.

Relating to the BRG requirement to include a wide **range of alternative policy options**, the assessment concludes that 79 % of the IAs provided at least three alternative policy options in

76 RSB, Annual report 2023, p. 18.

77 ibid.

78 IMPA, Appraising the quality of the European Commission's impact assessments, 2019, p. 8.

79 Better Regulation Guidelines, 2021, p. 32; Better Regulation Toolbox, 2023, Tool #16.

80 Better Regulation Toolbox, 2023, Tool #16, p. 115.

81 Better Regulation Toolbox, 2023, Tool #60, p. 540.

82 ibid., p. 541.

addition to the baseline. This figure appears to **correspond to the level of the previous review** (79 %).[83] During this period, the IAs presented two policy options in 19 % and only one alternative policy option in 2 % of the cases. During the previous review term, 17 % of the IAs included two policy options and 4 % only one policy option.[84]

Despite the vast majority of IAs presenting **multiple policy options**, it appears that this does **not guarantee that all the IAs concerned offer real alternatives**. In a number of cases,[85] the policy options were 'built around each other', contrary to the Better Regulation recommendations.[86] According to Tool #16 of the Better Regulation Toolbox, this kind of policy option should be avoided, as it hampers impact analysis and creates a bias in favour of measures included in all policy options.[87] In these cases, the choice of policy options is in fact more limited. Tool #11 points out that 'the options should present alternative ways of meeting the specific objectives to differing degrees'.[88]

In line with the Better Regulation requirements, **policy options should be 'sufficiently well developed** to allow you to differentiate them based on their performance in achieving the identified objectives'. Moreover, the policy options 'clearly not responding to the problems or objectives or only for the sake of having additional choices' should not be presented.[89] The assessment indicates that around 66 % of the analysed IAs offer realistic alternatives, while 28 % included only partially realistic alternatives and around 6 %[90] presented unrealistic alternatives. Given that the previous review[91] reported 49 % of the IAs included realistic, 43 % partially realistic and 8 % not realistic alternatives, it seems that there was **positive development during the review period. However, as one third of the IAs do not entirely present realistic alternatives, further efforts are still needed** to improve the quality of the formulation of the policy options for the sake of transparency and objectivity of the analysis. This was also emphasised in the previous review.[92]

The BRG require that the content of the **policy options should be described with sufficient detail** to inform decision-making effectively, including an explanation how they differ from the baseline and other options.[93] During the period under review, an improvement can be seen in the way IAs present policy options. The content of the policy options was set out in an entirely clear and balanced manner in around 64 % of the IAs, and was only partially clear in 30 %. The presentation was insufficient in 6 % of cases.[94] A **substantial improvement in quality is observed**, as the previous review found a clear and balanced presentation of the policy options in only 37 % of the IAs.[95]

The BRG recommend that IAs include non-regulatory options, 'unless already ruled out or an obligation for legal action exists'.[96] During the review period, non-regulatory options were presented in around 47 % of the IAs.

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83 IMPA, Appraising the quality of the European Commission's impact assessments, 2019, p. 9.

84 ibid.

85 For example: Revision of Directive 2010/40/EU on the deployment of intelligent transport systems, EPRS, European Parliament, 2022.

86 Better Regulation Toolbox, 2023, Tool #16, p. 120.

87 ibid.

88 Better Regulation Toolbox, 2023, Tool #11, p. 71.

89 Better Regulation Toolbox, 2023, Tool #16, pp. 115, 117.

90 For example: The revision of the Schengen Borders Code, EPRS, European Parliament, 2022.

91 IMPA, Appraising the quality of the European Commission's impact assessments, 2019, pp. 9-10.

92 ibid., p. 10.

93 Better Regulation Toolbox, 2023, Tool #16 - How to identify policy options, p. 118.

94 For example: Fit for 55 package: Energy from renewable sources, EPRS, European Parliament, 2021.

95 IMPA, Appraising the quality of the European Commission's impact assessments, 2019, p. 9.

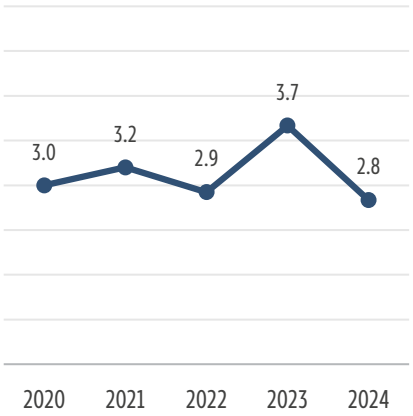
96 Better Regulation Toolbox, 2023, Tool #11, p. 71.

The quality of the options' section was considered satisfactory in almost a half of the 143 IAs (49 %), while it was good in 31 % and very good in 4 %. Quality was poor in 13 % and very poor in around 3 % of the IAs.

The **overall average score for the policy options in the review term was satisfactory (3.2), showing some positive progress** compared to the previous review. According to the 2019 quality report,[97] the average quality score of the policy options was 'right below the satisfactory level' (2.9). However, during this review, some variation in quality can be seen (see Figure 6). Average annual quality was poor (although close to the satisfactory level) in 2022 and 2024. It appears that this drop in quality concerns IAs in the second half of 2022 and the first half of 2024.

Even though a positive evolution can be seen in some aspects of the options' presentation and formulation, **further effort is needed**, particularly in the range of real alternatives. The RSB also made critical comments on the quality of the options' definition. The RSB has systematically flagged in its successive annual reports that the options' section was one of the weakest areas in first submission draft IAs. For example, in its 2023 annual report, the RSB considered the options section the weakest quality element in all first submission draft IAs, drawing attention in particular to a limited range of feasible options and options designed to support a preferred option.[98]

Figure 6 – Trend in average quality of the range of options dimension



Note: 1 - Very poor, 2 - Poor, 3 - Satisfactory, 4 - Good, 5 - Very good.

Source: IMPA, EPRS

Assessment of impacts

The identification and assessment of the most significant impacts is a core task of every IA. According to the BRG, 'an impact assessment is about gathering and analysing evidence to support policymaking'.[99] **The IA should assess the economic, environmental and social impacts for each specific case in an integrated and balanced way** and using both qualitative and quantitative analyses,[100] in line with the principle of proportionality.[101] The scope and depth of the analysis should be proportionate and consistent with the importance and type of the initiative, as well as with the nature and magnitude of the expected impacts. The effort invested in data collection, the depth of analysis, the extent of quantification and thereby choice of analytical methods should correspond to the likely magnitude of impacts.

The Parliament has repeatedly asked for attention to be paid to impact assessment. A key example is its 2022 resolution underscoring the need for better regulation and simplification, taking economic, environmental, gender and social impacts into account in an integrated and balanced

97 IMPA, Appraising the quality of the European Commission's impact assessments, 2019, pp. 10, 28.

98 For example, see RSB annual reports during the review period of this study 2020, 2021, 2022, 2023.

99 Better Regulation Guidelines, 2021, p. 30.

100 IIA BLM, paragraph 12.

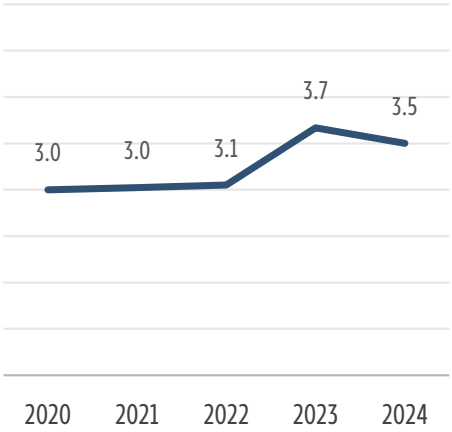
101 Better Regulation Toolbox, 2023, Tool #18, p. 136.

way.[102] In addition, the Parliament's 2023 resolution on EU regulatory fitness and subsidiarity and proportionality calls on the Commission to develop a more integrated approach to sustainability that would better take into account the interplay of the economic, social and environmental impacts of EU policies and legislation. Parliament considers equal attention to the evaluation of these impacts, as well as the development of additional tools to assess social and environmental impacts with respect to the Green Deal policy and the UN's Sustainable Development Goals, should be ensured.[103]

Other relevant direct and indirect impacts should also be assessed. These can vary between fundamental rights, gender equality, territorial and other impacts the Commission deems relevant, depending on the initiative or policy area. As highlighted in the BRG, the analysis should also involve the systematic consideration of relevant sustainable development goals and – if feasible – how the initiative contributes to their implementation; impacts on non-EU countries; and on essential security interests of the EU (including resilience against hybrid threats). Analysis should also check conformity with the 'do no significant harm' and 'digital by default' principles.[104] All IA reports should systematically consider and report potential impacts on fundamental rights as well as on SMEs and competitiveness.

The persistent difficulties in transparently selecting and assessing the most significant impacts led to the overall average quality of **this dimension remaining one of the weakest** among the different dimensions covered under this review, with a score **slightly above the satisfactory range**. The RSB also underlined the quality component in its successive annual reports. In its 2023 annual report, the RSB states 'the analysis of impacts continued to provide challenges, although a slight improvement in overall scores was observed'.[105] The analysis of impacts and the comparison of options and proportionality were the greatest analytical challenges for first submission IAs scrutinised by the RSB in 2023.

Figure 7 – Trend in average quality of the assessment of impacts dimension



Note: 1 - Very poor, 2 - Poor, 3 - Satisfactory, 4 - Good, 5 - Very good.

Source: IMPA, EPRS

The analysis shows **the economic impacts** of the retained policy options of the proposed legislative initiatives were **assessed in a more systematic way than social and environmental impacts and has been carried out to a higher standard**. This picture appears to have remained relatively **stable over the last 12 years**, as the numbers provided in the 2015 and 2019 reviews were similar.[106] As the RSB noted in 2022, economic impacts continue to represent the most frequent category of those

[102] European Parliament resolution of 7 July 2022 on Better regulation: Joining forces to make better laws.

[103] European Parliament resolution of 23 November 2023 on European Union regulatory fitness and subsidiarity and proportionality – report on Better Law-Making covering 2020, 2021 and 2022.

[104] BRG, 2021, p. 32

[105] RSB, Annual report 2023, p. 20.

[106] Based on the 2015 review, economic impacts were assessed in 95 %; social impacts in 88 % and environmental impacts in 79 % of relevant cases. The 2019 review notes economic impacts were assessed in 98 %, social impacts in 91 % and environmental cases in 84 % of relevant cases.

assessed in draft reports, followed by social and environmental impacts, which was broadly in line with the pattern observed in previous years.[107]

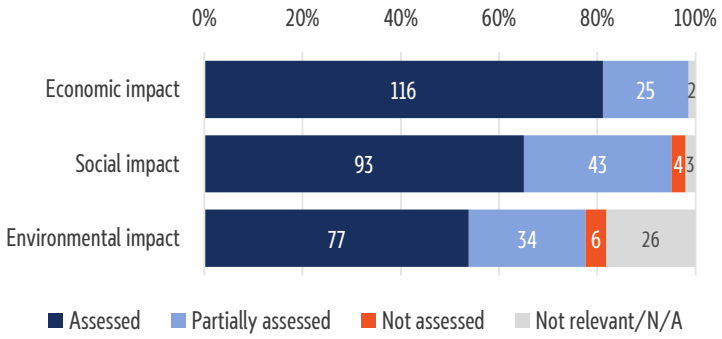
During the term under review, economic impacts were assessed in almost 99 % of cases, with the analysis found insufficient in 18 % (compared to 21 % in the previous review term). Social impacts were assessed in 95 % of all relevant cases, but analysis was considered insufficient in 30 % of those (as in the previous review term). Environmental impacts were assessed in 78 % of cases with further assessment deemed necessary in 24 % of those (compared to 31 % in the previous review term).[108] The number of cases where the three mandatory impacts (economic, social, environmental) were considered as not fully assessed appears to have slightly decreased for economic impacts, and increased for environmental impacts.

A four-point differential compared to the previous review term is observed for the number of impact assessments that include assessment of social impacts (95 % in the current review term compared to 91 % in the previous review term). At the same time, the number of cases in which environmental impacts were analysed is lower compared to the previous review term (78 % compared to 84 %). In a number of cases, the initial appraisals of Commission IAs also identified the need to consider social and environmental impacts, where they were presumably relevant to the case at hand and should have been assessed. More specifically, an analysis of social impacts was considered necessary in 3 % of IAs, and of environmental impacts in 4 % of IAs. Following the Commission's specific focus on environmental and social issues in its political guidelines for 2019-2024,[109] a more consistent approach was taken in the ex-ante assessment of these impacts, compared to the previous review term.

With regard to environmental impacts, the 2019 communication on the European Green Deal underlines that 'all EU actions and policies should pull together to help the EU achieve a successful and just transition towards a sustainable future', living up to a green oath to 'do not harm'.[110] However, only following the 2021 BRG revision was assessment of the preferred option in IAs expanded to cover analysis of the 'do no significant harm' principle. To ensure consistency with the principle, Tool #36 of the Better Regulation Toolbox includes a non-exhaustive list of questions to guide the Commission's work. Although, it is too early for a final assessment of the 'do no significant harm' principle at EU level, the present analysis shows 23 % of the IAs considered the principle as part of their analysis. It was not considered in 38 % of cases.

Figure 8 shows the share of IAs where the three mandatory impacts were assessed ('yes'), assessed 'partially', should have been assessed but were not

Figure 8 – Assessment of the economic, social, and environmental impacts in appraised IAs



Source: IMPA, EPRS

[107] RSB, annual report 2023, p. 21.

[108] IMPA, Appraising the quality of the European Commission's impact assessments, 2019.

[109] U. von der Leyen, Political Guidelines for the next European Commission 2019-2024.

[110] European Commission, The European Green Deal, COM(2019) 640.

('no'),[111] or were considered not relevant/not applicable (N/A) to the specific policy field/legislative initiative.

A number of other potentially relevant impacts were identified as part of the Commission's legislative initiatives, however without a consistent depth of analysis (or an analysis at all). One such example is **territorial impacts**.[112] In response to the 2018 Task Force on Subsidiarity, Proportionality and 'Doing Less More Efficiently' recommendations, the Commission amended its BRG and Toolbox, recognising the impacts of EU legislation may differ across local and regional levels and for public authorities. In parallel, in its 2022 resolution on better regulation, Parliament welcomed the Commission's intention to strengthen territorial impact assessments and underlined the importance of territorial impact assessments for the European Committee of the Regions (CoR) (including rural, urban and cross-border impact assessments).[113] A CoR opinion issued in 2021 called on the Commission to ensure that inception impact assessments and impact assessments include, inter alia, an evaluation of the potential territorially differentiated impacts of each legislative initiative.[114] Despite calls from key actors for territorial impacts to be considered whenever possible, territorial impacts were addressed in only 15 % of the 143 IAs appraised – **a slight improvement**, nevertheless.[115] They were partially addressed in 17 % and were not considered relevant in 26 %.

Parliament has regularly called for assessment of **gender equality related impacts**.[116] In its resolution of 10 March 2022 on gender mainstreaming in the European Parliament, Parliament stressed the importance of gender IAs in the design of legislative proposals and for gender-responsive evaluation of legislative initiatives. Parliament regretted that gender impacts are rarely addressed in Commission IAs.[117] Commission President von der Leyen's 2019-2024 political guidelines stressed the importance of 'A Union of equality' with a particular focus on gender equality.[118] However, gender related impacts were (partially) addressed **in only 7 % of the IAs** (see Figure 9). In 93 % of cases, gender equality related impacts were assessed as relevant but were not addressed.

111 For example, environmental impacts (including impacts on sustainable development and the SDGs, as well as on third countries (non-EU companies) are not part of the analysis of the IA regarding improvement of corporate sustainability reporting. According to IMPA's initial appraisal, environmental impacts seem to have been completely excluded, although this initiative is part of the European Green Deal and aims to reach the UN SDGs. For details, see Improving of corporate sustainability reporting, EPRS, European Parliament, 2021.

112 Better Regulation Toolbox, 2023, Tool #34, pp. 298 ff.

113 European Parliament resolution of 7 July 2022 on Better regulation: Joining forces to make better laws, paragraph 44.

114 Committee of the Regions, Opinion factsheet on Better Regulation, CDR-4071-2021, paragraphs 27, 38-44, 49.

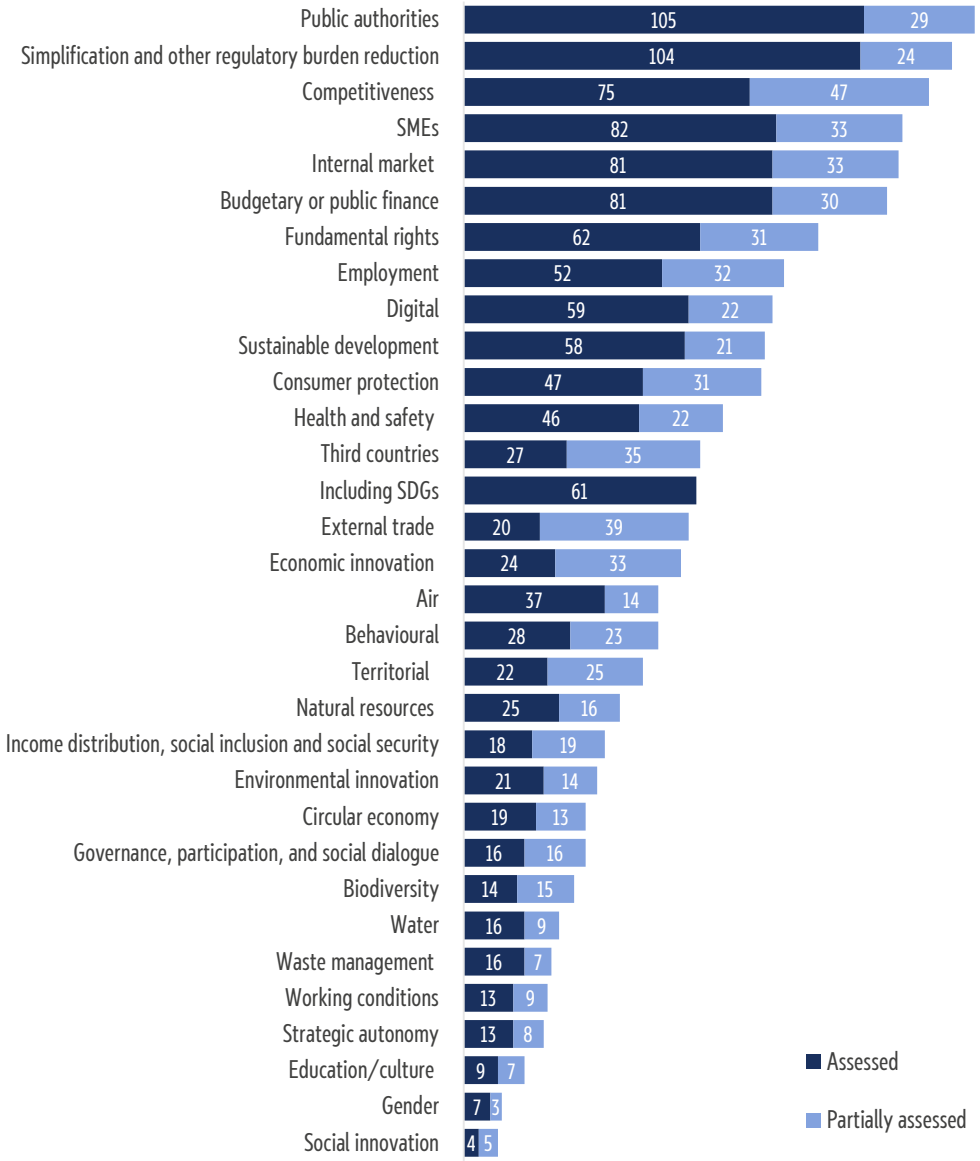
115 Territorial impacts were found to have been addressed in only 15 (11 %) of the total of 132 IAs appraised in the previous review term.

116 European Parliament resolution of 30 May 2018 on the interpretation and implementation of the Interinstitutional Agreement on Better Law-Making, 2018, paragraph 15.

117 European Parliament resolution of 10 March 2022 on gender mainstreaming in the European Parliament – annual report 2020, paragraph 38.

118 U. von der Leyen, Political Guidelines for the next European Commission 2019-2024, p. 11.

Figure 9 – Frequency of impacts



Source: IMPA, EPRS

The Commission's 2021 Better Regulation communication[119] further commits to promote the **'digital by default'** principle in forthcoming EU legislation as an important tool to support digital transformation. Digital aspects are to be considered at all stages of the policy cycle.[120] According to Tool #28 of the Better Regulation Toolbox, the assessment of the preferred option in impact assessments needs to cover the analysis of the 'digital by default' principle which means that the preferred option should allow for delivering services digitally, thus be digital-ready. When performing the analysis of the policy options, modelling digital impacts with the support of the JRC's

[119] European Commission, Better regulation: Joining forces to make better laws, COM(2021) 219.

[120] Policy design, IAs, stakeholder consultations, policy implementation, and monitoring and evaluation.

modelling competence centre should be considered.[121] The digital-ready impact questions listed in Tool #18 can give guidance on important digital-ready impacts. **Of the IAs appraised, 29 %** considered the 'digital by default' principle.[122] As highlighted above in relation to the 'do no significant harm' principle, the two principles were only introduced in the 2021 revision of the BRG. It is therefore not possible to compare the whole of the review period.

The findings of the 2019–2024 review of the 'assessment of impacts' dimension of the IAs show there is **still room for improvement** in the implementation of the BRG and Toolbox. The analysis confirms the need, identified by the Commission in its stocktaking report, to secure a balance between the depth of the analysis of a varying set of impacts on the one side, and the readability and transparency of the IA on the other.[123] The findings also concur with the RSB that 'the assessment of impacts can be constrained by limited data availability and raise analytical challenges, nevertheless, there is clear scope to further improve on this key part of an impact assessment, including by making better use of the dedicated assessment tools provided in the new Better Regulation toolbox'.[124] The Board further noted the identification and assessment of significant impacts, in line with the principle of proportionate analysis, is a core task of every impact assessment.[125]

As in previous years, the RSB 2023 annual report[126] highlighted that the **analysis of impacts is among the elements which pose the greatest analytical challenges**. Although there was a slight improvement on quality scores compared to the ones for 2022, these quality elements continued to receive the lowest quality markings. In line with the findings of previous RSB reports, the 2023 report draws attention to 'the omission of certain impacts in the analysis, lack of or reliance on single sources of evidence, an unbalanced inclusion of stakeholder feedback, lack of depth and rigor of impact analyses as well as a lack of acknowledgement of uncertainties'.[127]

As in the past, this review echoes the RSB's concerns and reiterates the need for the Commission to duly justify which impacts it analyses, to what extent, and to explicitly indicate whether one of the aforementioned compulsory impacts is not relevant or why other potentially relevant impacts are not assessed.

SMEs/Competitiveness

The BRG require **IAs to assess the impacts of initiatives on SMEs and competitiveness**. The Better Regulation Toolbox (Tool #18) states that regardless of whether impacts are relevant for a given initiative, it remains necessary to report on specific impacts, such as those on SMEs and competitiveness, in all IAs – and to justify a lack of further assessment.[128]

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121 Models are currently used to quantify environmental, economic, and social impacts of policy options but could be extended to questions of digital transformation. See also Tool #61 and the Commission's modelling inventory MIDAS.

122 For example, in line with the 'digital-by-default' principle, the IA accompanying two proposals (COM(2023 752 and COM(2023) 753) on passenger rights stresses the importance of the use of digital products and solutions in reimbursement processing and improved information for passengers. For details, see Improving passenger rights, EPRS, European Parliament, 2024.

123 To properly assess the appropriate level of analysis in relation to the magnitude of the expected impacts, the communication on stocktaking also highlights the relevance of the quality and availability of data, timing and resources to conduct balanced and comprehensive IAs.

124 RSB, Annual report 2022, p. 17.

125 RSB, Annual report 2023, p. 42.

126 ibid, p. 19.

127 ibid, p. 20.

128 Better Regulation Guidelines, pp. 33 and 35. Better Regulation Toolbox, 2023, Tool #18, p. 141.

The Better Regulation Toolbox states[129] that the 'SME Test must be performed and reported more systematically in all IA reports, where proportionate'.[130] The IA report should indicate the degree of relevance of the initiatives to SMEs (not relevant, relevant or highly relevant), and the assessment should be proportionate to that degree of relevance.[131]

The Commission stressed the need for a 'more systematic and proportionate application of the SME test' in its communication on better regulation.[132] Several Parliament resolutions demand the same, such as the 16 December 2020[133] and 7 July 2022 resolutions.[134]

In around 57 % of the IAs appraised, impacts on SMEs were comprehensively assessed, while impacts were only partially assessed in 23 %. Contrary to the BRG, the impacts on SMEs were not assessed in around 13 % of the IAs. These findings present **mixed trends compared to the previous review**. While the previous review report indicated that impacts on SMEs were assessed in 89 % of all relevant cases, the level in this review is slightly lower (87 %). Another observation relates to the number of IAs that did not address impacts on SMEs. In the previous review report, the share was 11 %, whereas in the current review it is 13 %. However, a positive development is noted in the quality of SME assessments. The share of IAs where the impacts were comprehensively assessed was bigger than those where they were only partially assessed compared to the previous review (48 % and 41 %).[135] A full SME Test was performed in 59 % of IAs analysed here, where impacts on SMEs were assessed in more depth. This shows a clear increase from the previous review term when the respective figure was 28 %.[136]

129 Better Regulation Toolbox, 2023, Tool #23, p. 184.

130 Better Regulation Toolbox, 2023, Tool #23 – The SME Test. It contains four steps: 1) identification of affected businesses, 2) consultation of SME stakeholders, 3) assessment of the impact on SMEs, and 4) minimising negative impacts on SMEs. An SME filter process, announced in the SME Strategy for a sustainable and digital Europe, is applied to all initiatives requiring an IA and helps identify initiatives that are important for SMEs. If the initiative is not relevant for SMEs, the test is limited to step 1.

131 Better Regulation Toolbox, 2023, Tool #11, p. 72; Tool #18, p. 141, 145; and Tool #23, p. 184.

132 European Commission, Communication on Better Regulation: Joining forces to make better laws.

133 European Parliament resolution on A new strategy for European SMEs.

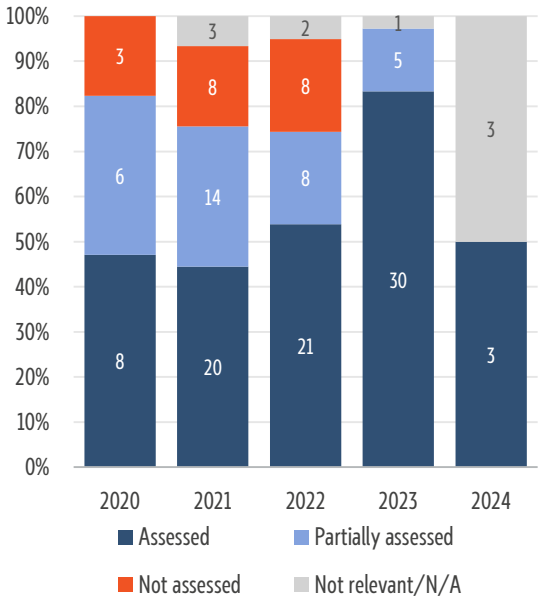
134 European Parliament resolution on Better Regulation: Joining forces to make better laws.

135 IMPA, Appraising the quality of the European Commission's impact assessments, 2019, p. 12.

136 ibid.

When considering the assessment of the SME dimension within the five-year review term, around 19 % of the IAs did not address impacts on SMEs in 2020-2022, while all IAs explained the relevance of the impacts on SMEs (relevant or non-relevant) and assessed those considered relevant in 2023 and 2024 (see Figure 10). This positive development is likely linked to a new compulsory competitiveness check in all IAs, introduced in the Commission's long-term competitiveness strategy in March 2023, which also comprises impacts on SMEs.[137] Furthermore, the Commission increasingly focuses on the importance of improving the business environment for SMEs by reducing regulatory obstacles and administrative burden, in line with the 'think small first' principle.[138] While the RSB in the first years of the term under review frequently pointed out that the analysis on SMEs was not sufficiently developed, it reported an improvement in this respect in its 2023 annual report.[139]

Figure 10 – Assessment of impacts on SMEs by year



Source: IMPA, EPRS

The Better Regulation Toolbox provides several guiding tools for assessment of impacts on **competitiveness**.[140] For example, Tool #21 requires that IAs assess whether initiatives are likely to have significant impacts on sectoral competitiveness and whether further analysis is needed. It provides advice on qualitative screening, quantifying impacts and mitigating measures.

Nonetheless, the IAs appraised often lacked proper assessment of the competitiveness dimension and some IAs did not consider this aspect at all. The 2019 review report found impacts on competitiveness were considered in 67 % of the IAs and 32 % of these IAs assessed these impacts insufficiently.[141]

During the period under review, some 52 % of the IAs appraised assessed impacts on competitiveness in detail, while the assessment was only partial in 33 %. Impacts on competitiveness were not relevant in 6 % and 9 % of the IAs did not address and explain the relevance of the competitiveness dimension. It appears there is **room for improvement in the quality of the analyses**, given the number of IAs that only partially assessed competitiveness.

137 European Commission, communication on Long-term competitiveness of the EU: looking beyond 2030.

138 See for example: European Commission, communication on An SME Strategy for a sustainable and digital Europe, and communication on SME Relief package.

139 RSB, Annual reports 2020 (p. 21), 2021 (p.22), 2022 (p. 17, 22), 2023 (p. 23-24).

140 Such as: Tool#21 on sectoral competitiveness; Tool#23 on the SME Test, Tool#24 on competition.

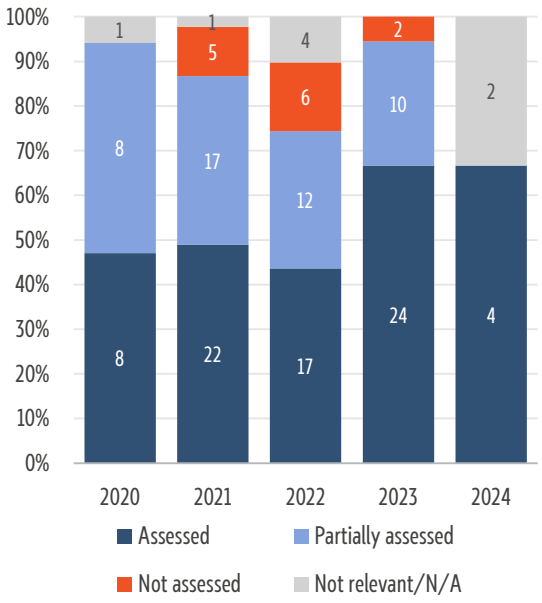
141 IMPA, Appraising the quality of the European Commission's impact assessments, 2019, p. 13.

The RSB has drawn attention to often underdeveloped assessments of impacts on competitiveness or a lack of analysis. For example, the RSB 2022 annual report notes the analysis of competitiveness issues featured among the most frequent recommendations in the Board's opinions.[142]

Nevertheless, a positive trend in the assessment of the competitiveness dimension is observed in this review. The **share of the IAs that assessed impacts on competitiveness in detail increased** from around 47 % in 2020-2022 to 67 % 2023-2024.

This increase in 2023-2024 appears to result from the Commission's renewed focus on competitiveness and a growth-promoting regulatory framework.[143] The new competitiveness check requirement, added to the Better Regulation Toolbox (appendix),[144] aims to provide an integrated competitiveness analysis and greater visibility for the competitiveness dimension in all IAs. It covers the four key competitiveness elements: cost and price, innovation, SMEs and international competitiveness.

Figure 11 – Assessment of impacts on competitiveness by year



Source: IMPA, EPRS

Some 39 % of the IAs in 2023 (all during the second half of the year) and 83 % in 2024 included a dedicated competitiveness check annex. Even though the requirement to include a competitiveness check enhances progress in the competitiveness assessment, **more attention could be paid to the quality of analysis**. The RSB 2023 annual report considered that, while the IAs included increasingly comprehensive assessment of competitiveness, the analyses were not always sufficiently meaningful and the full potential of the competitiveness check is not therefore used.[145]

Simplification and other regulatory implications

Simplification and burden reduction, in particular for SMEs, are key von der Leyen Commission **objectives** and are also reflected in the Commission IAs' increasing focus on these issues throughout 2019-2024. Previous Commissions already worked on both objectives, as illustrated for instance by the High-Level Group on administrative burdens in EU law ('Stoiber group'),[146] active between 2007 and 2014, and by instruments such as REFIT, the REFIT platform and, more recently, the Fit for

142 RSB, Annual reports 2020 (p. 21), 2021 (p. 22), 2022 (p. 22).

143 See for example: European Commission communication on Towards a more resilient, competitive and sustainable Europe and communication on Long-term competitiveness of the EU: looking beyond 2030.

144 Better Regulation Toolbox, 2023, Tool #11, pp. 81-82. Better Regulation Toolbox - Appendix: Competitiveness check.

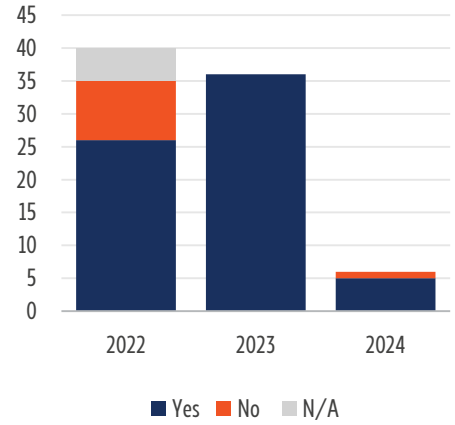
145 RSB, Annual report 2023, pp. 23-24, 38-42. The RSB was tasked in its revised mandate (December 2023) to pay special attention to the impacts on competitiveness.

146 European Commission, The High Level Group on Administrative Burdens – Questions and Answers, press memo, 14 October 2014.

Future Platform.[147] In March 2023, the Commission's long-term competitiveness communication[148] set the target of reducing burdens associated with reporting requirements by 25 %.

In line with this longstanding priority, the simplification principle was considered in more or less detail in a large majority of the IAs reviewed (only about 10 % did not mention it). However, there was an important 'upgrade' in the effort on reducing regulatory burden when Commission President Ursula von der Leyen announced the introduction of a **'One in, one out' (OIOO) approach at EU level** at the beginning of her first mandate in September 2019. Until then, the Commission and most experts had consistently questioned the feasibility of targeted regulatory cost reduction at EU level.[149]

Figure 12 – Does analysis consider OIOO? By year of publication



Source: IMPA, EPRS

In 2019, in her mission letter[150] to Maroš Šefčovič President von der Leyen wrote '... the Commission will develop a new instrument to deliver on a "One In, One Out" principle. Every legislative proposal creating new burdens should relieve people and businesses of an equivalent existing burden at EU level in the same policy area. We will also work with Member States to ensure that, when transposing EU legislation, they do not add unnecessary administrative burdens'.

In the following years, the Commission developed an implementation tool and prepared guidance on how to implement the OIOO principle at EU level, published in the context of the **2021 BRG revision**. Tool #59 of the Better Regulation Toolbox is dedicated to the implementation of OIOO in Commission IAs, in combination with Tools #56, #57 and #58 (which relate to typology of costs and benefits, methods for assessing costs and benefits and the EU Standard Cost Model, respectively). The new Tool #59 states that IAs systematically need to: a) consider whether a new proposal would have significant cost implications for businesses and citizens, and b) report on the expected additional administrative costs (or cost savings) under the preferred option(s).

Based on the cost (and benefit) estimates provided in the IA, the second OIOO step is defined as 'offsetting new burdens resulting from the Commission's proposals by reducing existing burdens in the same policy area'.[151] Therefore, IAs cover the first (ex-ante) part of OIOO implementation (the 'One in' of new administrative costs for business and citizens), done by the IA author DG(s). The second part, offsetting costs 'in the same policy area', is an entirely separate exercise, conducted by the Secretariat General of the Commission, once a year, in the framework of the annual burden

147 European Commission, webpage Fit for Future Platform (F4F) - 2021-2024 [last accessed 3 December 2024].

148 European Commission, Long-term competitiveness of the EU: looking beyond 2030, COM(2023) 168.

149 European Commission, Overview of the Union's efforts to simplify and to reduce regulatory burdens, (SWD(2017) 675), chapter 4. See also E. Golberg, The jury is still out on One-in-One-Out, *The Regulatory review*, February 2020. Doubts were also expressed after the introduction of OIOO, see for instance: H. Xanthaki, The 'one in, one out' principle: A real better lawmaking tool?, Policy Department for Citizens' Rights and Constitutional Affairs, European Parliament 2023; B. Pircher, EU Better regulation: Creating a playing field for businesses at the expense of social and environmental policies, Arbeiterkammer Wien, 2024.

150 U. von der Leyen, Mission letter to the Vice-President-designate for Interinstitutional Relations and Foresight, 10 September 2019.

151 'New burdens' as defined in Tool #58 (EU Standard Cost Model).

survey. Consequently, the **following observations on the implementation of the OIOO concept concern the cost calculations reported in the IAs between 2022 and 2024, not the offsetting of costs**.[152]

Following a pilot project in 2021,[153] where 10 IAs started applying the OIOO tool, application became systematic for all IAs presented under the Commission's 2022 work programme. It seems, however, that a transition period applied to IAs published (even late) in 2022, probably owing to the process starting long before the systematic application date, as the average duration to conduct an IA is about one year.[154]

For the 10 2021 pilot IAs analysed by IMPA, considerable variation appears in the application, as the RSB acknowledged.[155] Cost calculations in these files were presented case by case with partial/selective quantifications, rather similar to previous practice. In particular, reported cost categories appeared to vary, without sufficient (or, in some cases, any) explanation of the applied estimation methods. Benefits appear to be quantified less frequently than costs in IAs, with the risk of an even more imbalanced cost/benefit analysis, as the Commission's analysis of the OIOO pilot also highlighted in the 2021 annual burden survey.

Similar observations apply to the IAs published towards the end of 2022 and after, although by then, the majority of appraised IAs did comply with the now mandatory OIOO application, featuring at least an overview of relevant administrative costs under the preferred option in Annex 3. **By 2023 and 2024, all but one[156] IA reported on administrative costs for business and citizens under the OIOO principle** (see Figure 12).

Appraisals of the IAs considered in this review frequently found featured cost categories were **not transparent**, notably as regards the 'business as usual costs' referred to in Tool #59. This tool specifies that all direct and indirect, one-off and recurrent compliance costs (adjustment costs and administrative costs) should be estimated 'to the extent that this is feasible'. However, IAs do not always explain when and why this is or might not be feasible. Furthermore, the **distinction between cost categories**, namely adjustment costs (expected to be compensated to the greatest possible extent) and administrative costs (to be offset), was not always clear.[157]

The RSB states that in 2023, during the interservice consultation following an IA's first submission, quantification of costs for OIOO increased by 29 % and deems this 'sufficient', but it does not define what 'sufficient' exactly means in this context.[158] **IMPA data confirms that quantification of costs has generally increased since 2022, which could indeed be linked to the requirement to implement OIOO (but could also be a result of the general objective to quantify more)**. As noted, IMPA appraisals often found that distinctions between the quantified costs were not evident in the

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152 The implementation of the offsetting is briefly indicated in Tool #59, without precise criteria how to determine 'the same policy area' following an 'offsetting hierarchy', ranging from 'the remit of each DG' to the broadest possible EU policy area, the headline ambitions of the Commission work programme. The Annual Burden Survey 2022, pp. 15-16 and 27-31, suggests the latter was used.

153 European Commission, Annual burden survey 2021, pp. 11 and 21-25.

154 See, for instance, the absence of OIOO in the IA accompanying the proposal on Euro 7, published in November 2022, prepared throughout a complex IA process that started in 2018, see the initial appraisal Updating Euro emission standards (Euro 7), EPRS, European Parliament, 2023.

155 RSB, Annual report 2021, p. 11.

156 The IA accompanying the proposal on Europe's 2040 climate target and path to climate neutrality by 2050.

157 Commission services use an internal online calculator, developed for the purpose of OIOO, which is not public. Parliament has called on the Commission to make it publicly accessible (European Parliament resolution of 7 July 2022 on Better regulation: Joining forces to make better laws). The Commission's Annual burden survey 2021 features a – difficult to read and mostly empty – screenshot of this calculator in Annex II, without further information.

158 RSB, Annual report 2023, pp. 26-27.

IAs and therefore could not be checked. The Commission's own (laconic) appreciation of the challenges of the OIOO implementation confirms the clear need for full transparency in cost calculations for OIOO: 'often the distinction between administrative and adjustment costs may be subject to interpretation, in particular for initiatives that are, by their very nature, of an administrative character'.[159]

Given the gradual, and at times opaque, application to date, it is **too early for a final assessment of the OIOO implementation at EU level.** On the one hand, the increased use of cost quantification observed in IAs following the introduction of the OIOO approach in 2022 may indicate **greater awareness of and attention is paid to cost effects on citizens and businesses of new proposals**, which would be very useful. On the other hand, both the complexity of the exercise – as admitted by the Commission – and the **lack of transparency** affecting the proper use and scrutiny raise **questions about the effectiveness, efficiency and added value of OIOO at EU level**, where IAs are characterised by the integrated approach and balanced cost/benefit assessment of the Better Regulation framework.

The **Parliament's July 2022 resolution on better regulation expresses a number of concerns regarding OIOO**.[160] First, Parliament noted that the OIOO approach was introduced without prior consultation or an IA. Second, it warned of the risk of 'mechanical or mathematical' decision-making that could lead to deregulation or 'no-regulation' and prevent the adoption of social, environmental or consumer protection standards. Third, Parliament highlighted the need for transparency and proportionality and reiterated its request to maintain a balance between qualitative and quantitative impact analysis, assessing cost and benefits alike. It may be added that considerable administrative burden results from Member States' 'gold-plating' EU legislation, which is excluded from OIOO – as are administrative costs deriving from new EU proposals for public authorities.

Impacts on third/developing countries and the SDGs

Article 208 TFEU stipulates that the EU implement a development cooperation policy with the primary aim of reducing and ultimately eradicating poverty. It constitutes the legal basis of the policy coherence for development (PCD) concept, which 'aims at minimising contradictions and building synergies between different EU policies and through which EU and its Member States seek to take account of development objectives in policies that are likely to have an impact in developing countries'. Furthermore, according to the revised BRG, better regulation relies on several key concepts, one of which is a **comprehensive approach. In relation to third countries and EU development policy**, this means that **SDGs need to be 'incorporated' in policymaking**, and if EU internal policies are expected to have significant impacts on third countries, these need to be assessed and presented transparently.[161]

To confirm this, the Commission claimed that the lasting commitment to the UN SDGs constituted 'an overriding political priority' for the von der Leyen Commission of 2019-2024[162] and pledged to include links to the SDGs throughout evaluation and impact assessment.[163] Reference to the SDGs – notably Tool #19, together with Tool #35 on identifying impacts on developing countries, were among the **new/revised elements** included in the latest version of the BRG and Toolbox.

The Better Regulation Toolbox indicates how to use the indicators of identified SDGs in different sections of the IA reports (problem definition, objectives, baseline, impact analysis and the

159 European Commission, Annual burden survey 2022, p. 33 (endnote 50).

160 European Parliament resolution of 7 July 2022 on Better regulation: Joining forces to make better laws, paragraphs 83, 85 and 86.

161 Better Regulation Guidelines, 2021, pp. 5-6.

162 See European Commission, webpage Policy coherence for development.

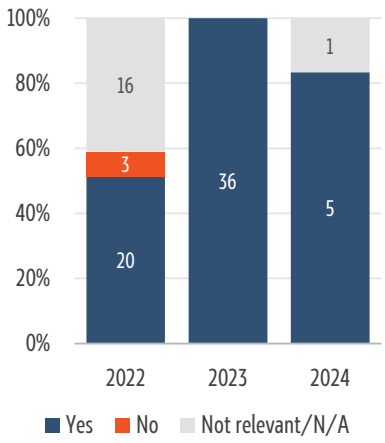
163 European Commission, Better regulation: Joining forces to make better laws, p. 15

monitoring arrangements). In addition, Annex 3 of an IA report has to include a table identifying relevant SDGs and explain progress towards the identified SDG targets for the preferred option. The Better Regulation Toolbox also stipulates, when screening indicates that impacts on developing countries are expected to be significant, 'it is essential to ensure that the external dimension of the EU initiative is considered from the very start'.

Moreover, regarding developing countries and PCD, the Parliament, and particularly its Committee on Development (DEVE), aims to strengthen the coordination, accountability, and transparency of PCD. It repeatedly calls for PCD to be consistently applied in all relevant proposals. In its latest resolution on PCD,[164] the Parliament declared its commitment to enhance its own PCD work.[165] It called for a systematic analysis of how PCD is addressed in the Commission's IAs and urged the Council and the Parliament, as co-legislators, to carefully assess the impact on developing countries of their amendments in relation to the Commission's legislative proposals.

Following the 2021 BRG and Toolbox revision, the Commission started including analysis of SDGs in IAs at the beginning of 2022. IMPA analysts observed that roughly half of the IAs in 2022 considered SDGs, while starting from 2023, all IAs reviewed consistently took this requirement into consideration (Figure 13).

Figure 13 – SDGs considered in Commission IAs 2022-2024



Source: IMPA, EPRS

In the meantime, the **situation regarding policy coherence for development and impacts on third/developing countries has not evolved to the same extent regarding the SDGs**.[166] While a number of EU internal policy initiatives have substantial impacts on third countries, these impacts are seldom analysed substantially. Roughly 43 % of all analysed IAs considered impacts on third countries to some extent and around 11 % explicitly mentioned developing countries, but the analysis often appears superficial. For instance, analysis in the IA accompanying the proposed EU talent pool regulation, which includes measures specifically targeting third/developing countries, was found not sufficiently in-depth. The initial appraisal of the Commission's IA draws attention to the lack of analysis regarding the risks of brain drain, ethical recruitment issues, potential impacts in relation to gender equality and diversity, equal treatment of persons with disabilities and the unique challenges faced by asylum seekers.[167] Likewise, the IA on the 2040 EU climate target does not analyse the potential impacts of different EU climate target levels on third or developing countries, and does not place them in the context of EU's international commitments towards developing countries and PCD. The IA does not discuss what impacts the projected increased EU needs for raw and rare materials will have on third countries (for instance, impacts

164 European Parliament resolution of 14 March 2023 on Policy Coherence for Development.

165 E. Pichon, Understanding Policy Coherence for Development, EPRS, European Parliament, 2023.

166 For further analysis of how the PCD principle is operationalised by the Commission, see: K. Eisele and I. Ioannides, Assessing policy coherence for development across internal and external EU policies: A call for action - Ex-post evaluation', EPRS, European Parliament, November 2024.

167 Establishing an EU Talent Pool, EPRS, European Parliament, 2024.

related to increased mining, changes in labour conditions and changes affecting local communities).[168]

Finally, the political guidelines for the Commission starting in December 2024 underline the need for a more systematic approach to assessing the impact of EU laws on non-EU countries and the need to provide more targeted support to help them adjust to and benefit from these laws.[169] This may lead to **growing relevance of ex-ante assessment of these impacts**.

Monitoring and evaluation

Monitoring and evaluation are essential components of effective policy-making. In the IIA BLM it is recognised as one of the tools for better law making. The implementation of monitoring and evaluation provisions contribute to ensuring that the legislative text achieves the intended outcome and contributes to evidence-based decision making.

The BRG stress the importance of monitoring and evaluation, mentioning that 'full benefits of an EU intervention will only be delivered if the policy is implemented and applied properly'.[170] In this line, the 'evaluate first' principle reinforces this approach integrating evaluation requirements at the beginning of the policy-making process. Therefore, **IAs should include specific monitoring and evaluation arrangements to determine what needs to be monitored, how to measure and how to collect data**. In this respect, considering that 137 (around 96 %) of the IAs appraised included monitoring provisions and 121 (around 85 %) included evaluation provisions, it is possible to conclude that these obligations have **generally been respected in the current review term**. These numbers are very **similar to the previous review term** in which 96 % of the IAs appraised included monitoring and evaluation provisions.[171]

In line with Better Regulation Toolbox Tool #41, indicators are essential to evaluate whether an initiative has been successful in achieving the intended results or whether it needs revision. To the extent possible, all indicators ('Relevant, Accepted, Credible, Easy and Robust') should be linked to the preferred option of the IA and to the operational objectives of the initiative. During the 2019-2024 Commission term, the vast majority of IAs included monitoring and evaluation requirements supported by relevant indicators. Nevertheless, in 45 (around 31 %) of the IAs appraised, the monitoring and evaluation indicators were found to be only partially relevant in relation to the objectives pursued. This figure is slightly above the previous review term, when it was 28 %. Therefore, standardising data collection and ensuring consistent reporting across Member States remains a challenge, given that several of the IAs assessed did not include operational objectives and the indicators included were vague and a timeline was missing.

168 Europe's 2040 climate target and path to climate neutrality by 2050, EPRS, European Parliament, 2024.

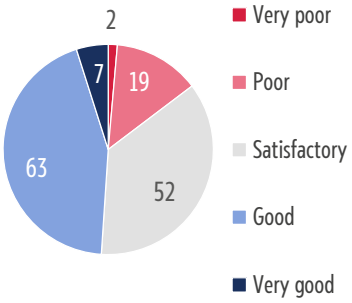
169 U. von der Leyen, Europe's choice, Political guidelines for the next European Commission 2024-2029, p.28.

170 Better Regulation Guidelines, 2017, p. 9

171 IMPA, Appraising the quality of the European Commission's impact assessments, 2019, p.21.

Monitoring and evaluation was one dimension that scored better in the previous review term, largely within the 'good' range, and this trend has continued. **Monitoring and evaluation continues to be amongst the best scoring dimensions** with a majority of IAs being considered 'good'. As Figure 14 shows, 63 of the IAs scored 'good',[172] and 7 'very good'.

Figure 14 – Quality of the IAs on the monitoring and evaluation dimension



Source: IMPA, EPRS

The Commission and the Parliament share the view that monitoring and evaluation is an essential part of an IA. Parliament's resolution[173] of 30 May 2018 on the interpretation and implementation of the Interinstitutional Agreement on Better Law-Making states under paragraph 50 that 'the three institutions will monitor the implementation of the new IIA jointly and regularly, at both the political level through annual discussions and the technical level in the Interinstitutional Coordination Group; whereas monitoring at the political level includes regular discussions in the Conference of Committee Chairs'.

It is therefore relevant to include monitoring and evaluation provisions in the legislation itself. In accordance with the IIA BLM and in line with the 'evaluation first' principle, embedding review clauses – i.e. review, evaluation, monitoring and reporting provisions – into legislation is a common practice today.[174] The Parliament is bound to uphold the principles of better law-making, notably the effective use of ex-ante impact assessment and ex-post evaluation during the entire legislative cycle. For that reason, the Parliament monitors the transposition, implementation and enforcement of EU law and EU programmes.[175]

Stakeholder consultation

Under its sixth political priority 'A new push for European democracy', the Commission is committed to promoting the participation of Europeans and civil society in policymaking activities and to ensuring the transparency and the legitimacy of the policymaking process.[176] **Stakeholder consultation is an important element of the Commission's IA process**.[177] As reflected in the Interinstitutional Agreement on Better Law Making, the three institutions recognised that public and stakeholder consultation is integral to well-informed decision-making and to improving the quality of law-making.[178] The European Court of Auditors contributed to the review of the Commission's stakeholder consultation procedure with a dedicated special report, issued in 2019, where it noted that the European Commission's consultations were generally of a high standard.[179] The same report

[172] See as example Digital euro, EPRS, European Parliament, 2024.

[173] European Parliament resolution of 30 May 2018 on the interpretation and implementation of the Interinstitutional Agreement on Better Law-Making.

[174] N. Hahnkamper-Vandenbulcke, Review clauses in EU legislation adopted during the second half of the ninth parliamentary term (January 2022-September 2024), EPRS, European Parliament, 2024.

[175] ibid.

[176] Better Regulation Toolbox, 2023, Tool #51, p. 444.

[177] The importance of stakeholder consultations to prepare EU legislation is also stated in Article 11 TEU, and Protocol 2 on the application of principles of subsidiarity and proportionality.

[178] Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making, 2016, paragraph 19.

[179] European Court of Auditors, Special report no 14/2019: 'Have your say!': Commission's public consultations engage citizens, but fall short of outreach activities, 2019, p. 47.

identified some shortcomings, such as on outreach activities, and insufficient focus on monitoring and assessment of public consultation. The Commission established a streamlined system, including: feedback to the 'call for evidence' document targeting the broader public (for IAs, but also for politically important initiatives without an IA, evaluations of broad public interest and fitness checks); and targeted stakeholder consultations.

For legislative initiatives underpinned by an IA, the BRG recommend holding open stakeholder consultations targeting the broader public at different stages of the procedure. At the initial stage, the Commission solicits feedback on the inception impact assessment[180] via the 'call for evidence'. Secondly, the Commission has an obligation to run a 12-week open public consultation on all new legislative proposals and evaluations. Both the call for evidence and the public consultation are published on the 'Have your say' portal.[181]

In addition to public consultation, the Commission also carries out targeted stakeholder consultation focused on specific groups of stakeholders and experts. Tools used include, for instance, targeted online surveys, focus group meetings, workshops, and interviews. Whether open or targeted, the Commission's interaction with stakeholders is subject to strict transparency standards.

In the context of the IA process, stakeholder engagement is governed by a well-defined set of general principles and minimum standards in the BRG.[182] **Results of stakeholder consultations should be reported in the IA in a transparent and detailed manner, including dissenting views**. Stakeholders' views should be broken down into categorised. Different stakeholder views should be reported systematically throughout the report. IAs must contain a dedicated annex summarising the main features and outcomes of the consultation activities undertaken for an IA.

An EPRS report[183] summarising the work undertaken by the Parliament in IA and European added value during 2022, noted that, on the basis of the initial appraisals carried out in 2022, stakeholder consultations were among the IA aspects found to be the strongest.

The average quality of stakeholder consultation in the Commission's IAs reviewed was found to be 'good'.[184] The review shows the Commission respected the minimum standard of the compulsory 12-week open public consultation in 81 %) of IAs, continuing the positive trend for broader stakeholder involvement already noted in the previous review term.[185] However, **views expressed by different stakeholder groups are not always presented clearly and systematically** (e.g. there is no systematic differentiation between preferences expressed by the different stakeholder groups). In a number of cases, the IA could have better reflected insights from the consultation activities, particularly regarding the analysis/choice of policy options and their potential impact. The results of stakeholder consultations were reported in the IA in a fully transparent and detailed manner in 68 % of the IAs assessed, whereas their presentation was deemed only partially transparent and detailed in 29 %. In only 3 % of IAs was the presentation considered not to be

[180] Inception Impact Assessments aim to inform citizens and stakeholders about the Commission's plans, to allow them to provide feedback on the intended initiative and to participate effectively in future consultation activities. Citizens and stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to make available any relevant information that they may have, including on possible impacts of the different options.

[181] European Commission, https://ec.europa.eu/info/law/better-regulation/have-your-say_en.

[182] See Better Regulation Guidelines, 2021, pp. 14-15.

[183] W. Hiller, European Parliament work in the fields of Impact Assessment and European Added Value - Activity Report for 2022, p. 10

[184] In particular, the 'stakeholder consultation' dimension has been assessed as 'very good' in 16 cases, 'good' in 62 s, 'satisfactory' in 55, and 'poor' in 10 cases, with an average score of 3.6 points out of 5. See Figure 1.

[185] During the previous review term, the formal minimum standard of the compulsory 12-week open public consultation was upheld in 82 % of cases.

transparent. During the previous review term, consultation results were found to be presented in a fully transparent and detailed manner in only 51 % of the IAs, whereas in 41 % their presentation was deemed only partially transparent and detailed. In 8 % of cases, the presentation was not considered transparent.[186]

These observations suggest that **room for improvement persists when it comes to representativeness and transparent and detailed reporting on the use of stakeholder input** to Commission IAs, confirming the findings of the most recent RSB report. More specifically, the RSB stressed in its 2023 report that some IAs did not present 'contradictory views of different stakeholder categories in a sufficiently transparent, granular, and balanced manner or did not pay sufficient attention to the non-representativeness of the stakeholder feedback received'.[187]

The present review agrees with the importance of developing awareness-raising action to better communicate with and manage stakeholder expectations, as identified in the Commission's stocktaking exercise.[188] The European Parliament's 2022 resolution on Better Regulation called all EU decision-makers to take stakeholders' input into account and ensure effective follow-up in the ensuing decision-making processes, involving affected stakeholders and ensuring the participation of vulnerable groups.[189] The European Parliament also welcomed 'the Commission's efforts to consolidate the consultation process, the commitment to report on each public consultation within eight weeks of its closure and the commitment to more actively publicising consultations in order to reach more citizens, stakeholders, including SMEs, and local and regional authorities'. Finally, the Parliament's 2023 resolution on EU regulatory fitness and subsidiarity and proportionality, invited the Commission to evaluate the possibility for the EU to involve national parliaments at an earlier stage of the legislative procedure, more specifically when consultations take place.[190]

Supporting data and analytical methods used

The quality, availability and transparency of data supporting the analysis of the IA are **essential elements for the evidence-based analysis of potential impacts**. The Better Regulation Toolbox states that 'reliable evidence is a cornerstone of "better regulation"'.[191] The Toolbox provides a description of different types of data to be used in IAs. It also indicates how to integrate these data, as well as organise and plan data collection.[192] Ideally, the data need to be linked to the policy objectives and intervention logic.[193] Analytical methods used in the IA, including modelling, need to be described in the IA in a dedicated annex according to the BRG and Toolbox.

The Better Regulation Toolbox states that 'underlying data, statistics, information, expert contributions, and stakeholder views should all be referenced, as well as documented transparently

186 IMPA, Appraising the quality of the European Commission's impact assessments, 2019, pp. 19-20.

187 RSB, Annual Report 2023, p. 18

188 European Commission, Stocktaking report on the Commission working methods for monitoring and implementation of EU law, SWD(2023) 254.

189 European Parliament resolution of 7 July 2022 on Better regulation: Joining forces to make better laws.

190 European Parliament resolution of 23 November 2023 on European Union regulatory fitness and subsidiarity and proportionality – report on Better Law-Making covering 2020, 2021 and 2022.

191 See Better Regulation Toolbox, 2023, Tool #4, p. 20.

192 ibid. See also Tool #67.

193 See Tool #67.

... '[194] Assumptions underlying the analysis, uncertainties and limitations should be explained transparently,[195] as well as methods and models used, if appropriate.[196]

When modelling or other analytical methods are used in an IA and the analysis in the IA relies on them, a **separate annex should be included that describes these models and analytical methods and how they have been applied in the analysis of the IA**.[197] The Better Regulation Toolbox states 'all models that make a substantial contribution to the assessment of policy options in an IA have to be described in the publicly accessible Modelling Inventory and Knowledge Management System of the Commission (MIDAS)'.[198] IAs need to assess all relevant impacts qualitatively and quantitatively where possible.[199]

Data shows that the **average quality of this dimension in the IAs under review is satisfactory, a steady improvement compared to the previous review term**. A majority of the appraised IAs (97 %) were rated as 'very good', 'good' and 'satisfactory' for the dimension related to the quality of data, research, and analysis. In the majority of IAs reviewed (75 %), data sources were found relevant, reliable and publicly accessible. Some 82 % of the IAs were considered to provide an entirely clear explanation of the assumptions and limitations of the analysis, whereas this was found only partially clear in 16 % of the cases.

In its initial appraisals, IMPA identified some issues regarding the lack of **transparency** of information, including supporting studies that are not available. For instance, in 57 % of cases, the commissioned **supporting studies** were publicly available at the time of writing the initial appraisals. However, this was not the case in 23 % and only partially so in 10 % of the IAs (10 % did not indicate whether they rely on external supporting studies). In some cases for example, supporting studies are well referenced, but not hyperlinked and cannot be easily traced by internet search. It is therefore not clear whether the supporting studies were publicly available at the time of publication of the IA. Similar issues were identified in the previous review term. The co-legislators, other stakeholders or the public need access to the specific research supporting an IA, to check be able to check its statements and conclusions.

The analytical methods and models used in the appraised IAs vary considerably. In 74 %, the IA used cost/benefit analysis, cost-effectiveness analysis, sensitivity analysis, multi criteria analysis or other analytical methods. Similar to the previous review term, **cost/benefit analysis predominated. Modelling** was used in 57 % of the IAs reviewed. However, issues regarding full transparency and availability of the analytical methods and models used were identified. For instance, not all data sources are referenced and publicly available in several cases. In addition, not all models are explained, publicly available or reported in MIDAS.[200]

194 ibid, Tool #11, p. 67.

195 See Better Regulation Toolbox, 2023, Tool #4, p. 25 and Tool #11.

196 On transparency, see Tool #61, p. 548, and on analytical methods Tools #62, 63, 65 and 66.

197 Better Regulation Toolbox, 2023, Tool #11, p. 80.

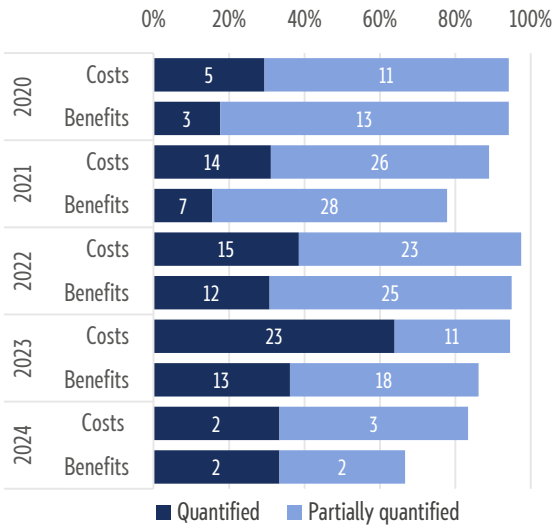
198 Better Regulation Toolbox, 2023, Tool #61, p. 550. See also Better Regulation Guidelines, 2021, p. 33. See Modelling Inventory and Knowledge Management System of the European Commission (MIDAS).

199 Better Regulation Guidelines, 2021, p. 33.

200 As a good example see Europe's 2040 climate target and path to climate neutrality by 2050, EPRS, European Parliament, 2024, p. 11.

Quantification of expected costs and benefits makes the impacts of an initiative more tangible and comparable.[201] The vast majority of assessed IAs provided quantitative data (99 %, compared to 90 % in the previous review term). Figure 15 shows whether IMPA deemed IAs to have (partially) quantified costs and benefits, by year. Evidence shows a consistent year-over-year increase in the share of IAs that quantify costs: from 29 % in 2020, 31 % in 2021, 39 % in 2022, and 64 % in 2023 – **costs are quantified in 42 % of the IAs appraised**. In the remainder, costs are typically partially quantified (52 %) and 6 % did not quantify costs at all. While Figure 15 shows **a rise in the share of IAs that quantify benefits between 2020 and 2023**, they remain quantified in only 26 % of appraised IAs, partially quantified in 60 %. Benefits were not quantified in 8 % and could not be quantified in 6 % of cases.

Figure 15 – Quantification of costs and benefits by year of publication IA



Source: IMPA, EPRS

The latest RSB annual report states:[202] 'Overall quantification of costs is closer to the average of the previous years but remains still at relatively high levels. However, benefits are not quantified to the same extent when compared to 2022'.[203] Nevertheless, the RSB acknowledges there are considerable differences in supporting data availability depending on the subject matter and policy area.[204] Some RSB opinions underlined the need to quantify both benefits and costs, especially those relevant to the OOIO approach.[205] Consequently, **improvements to how impacts are quantified are needed in future**.[206]

Follow-up to the Regulatory Scrutiny Board opinion

An analysis of how the comments expressed in RSB opinions were followed up in the final version of the IA is part of any IMPA initial appraisal. This aspect helps trace the evolution of the IA drafting process and complements the Commission's own internal check of the draft IA, conducted by the RSB at an early stage[207] in the procedure. In particular, this shows **whether (and to what extent) RSB suggestions for revision of any problematic parts of the draft IA were taken on board when finalising the IA**. However, this can only be deduced indirectly, by thoroughly comparing all parts of the final IA with the RSB opinion(s) published at the same time, because the draft IAs are not publicly

201 RSB, Annual report 2018, p. 35.

202 See also W. Hiller, European Parliament work in the fields of Impact Assessment and European Added Value, Activity report for 2022, EPRS, European Parliament, p. 12.

203 RSB, Annual report 2023, p. 24.

204 See also European Commission, Quantification in Commission Impact Assessments and Evaluations, Report of the RSB/SG/JRC Working Group [undated].

205 RSB, Annual report 2023, p. 24.

206 See Better Regulation Guidelines, 2021, p. 33: '... It will not be possible to quantify impacts in all cases, but it is expected (in the context of the "one in, one out" approach and for REFIT initiatives) that systematic efforts will be made to do so, to the extent that this is proportionate ...'.

207 RSB, Annual report 2023, p. 21. See in this context also p. 38 below.

available at any stage of the procedure (or afterwards) – despite Parliament's call to make them available to the co-legislators.[208]

Irrespective of this caveat, IMPA initial appraisals complement the RSB's scrutiny work in two ways: by drawing attention to aspects that are particularly important to Parliament and by further conveying the Board's messages where necessary, i.e. in cases where the final IA has not taken them into account.[209] The added value of this work benefits not only Members of Parliament and the wider public, but is also noted by the RSB, which stated in its 2018 annual report that it used IMPA initial appraisals to assess its own work.[210]

The RSB issues **three main types of opinion on draft IAs: 'positive', 'positive with reservations' and 'negative'**. The latter imply a rejection of the draft IA, which has to be improved and resubmitted for a second opinion, before the corresponding legislative proposal can go forward. The IIA BLM notes 'Impact assessments are a tool to help … reach well-informed decisions and not a substitute for political decisions within the democratic decision-making process'.[211] The RSB has a supporting role to improve the quality of IAs, but no veto power to block or suspend political decisions to proceed with a file. During the reporting period for this review, a total of 205 opinions were issued on different versions of the 143 IAs appraised by IMPA. **At first submission, 61 (43 %) of the 143 IAs received a negative opinion** and thus had to be resubmitted. At the other end of the quality spectrum, a positive opinion does not usually express fundamental criticism, but still contains some indications for improving the IA before its publication. Of the 143 IAs analysed, **19 received a first positive opinion – with 13 % representing a low percentage rate. Most of the RSB opinions at first submission were 'positive with reservations' (63, i.e. 44 %)**.

The 'positive with reservations' category was introduced in 2016, when the Commission considered the choice between a negative or a positive opinion 'too binary'. In most cases, these opinions indicate 'significant shortcomings' and, thus, significant need to revise a draft IA. As noted in IMPA's previous review,[212] the quality of an IA receiving a 'positive with reservations' opinion can vary considerably, but in many cases seemed to be closer to a negative than to a positive opinion.[213] This impression was reinforced by the RSB's admission that when under time pressure 'the Board sometimes gives a conditional stamp of approval to work that still needs substantial improvement in some important respects, on the understanding that listed shortcomings are appropriately addressed'.[214] Given that acute time pressure on the EU legislative process increased during the 2019-2024 legislature, **IMPA paid particular attention to 'positive with reservations' opinions**, notably if issued as a second opinion following a first negative opinion, which happened for 46 of the 61 IAs that received an initial negative opinion (75 %). Figure 16 shows how the RSB opinion categories are divided for the IAs reviewed.

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208 European Parliament resolution of 7 July 2022 on Better regulation: Joining forces to make better laws, paragraph 82.

209 See Claudio Radaelli, 'Halfway through the Better Regulation strategy of the Juncker Commission: What does the evidence say?' *Journal of Common Market Studies*, 2018, Volume 56, Issue S1, pp. 85-95.

210 RSB, Annual report 2018, pp. 21-22.

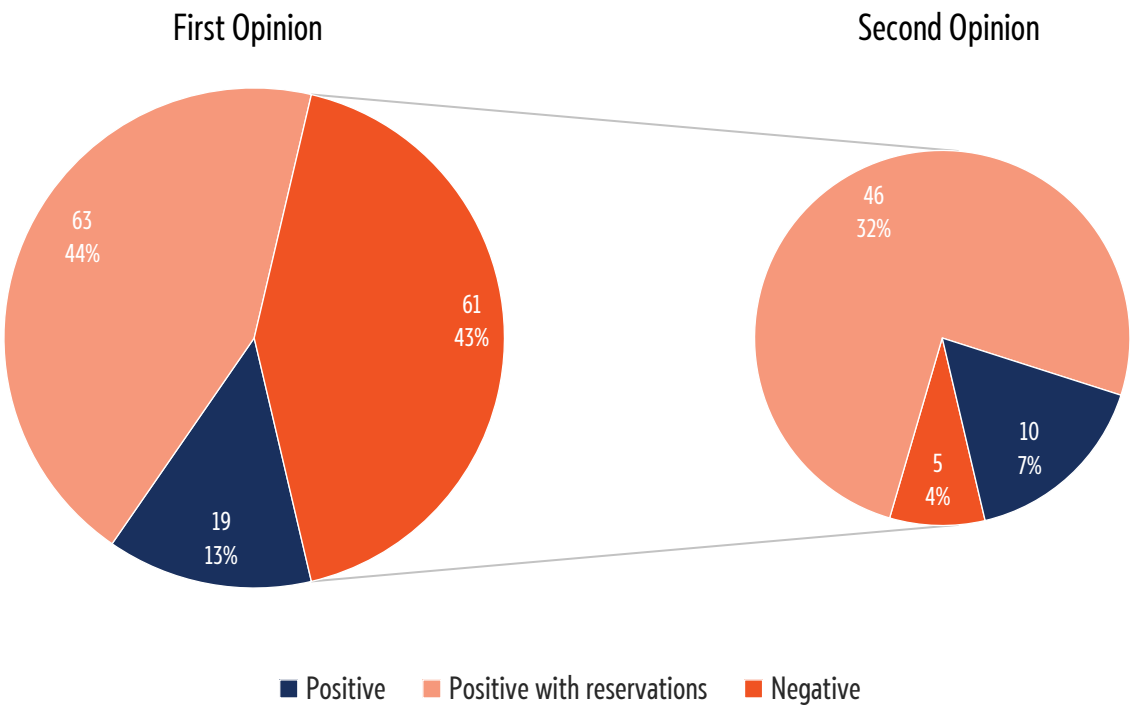
211 IIA BLM, paragraph 12.

212 IMPA, Appraising the quality of the European Commission's impact assessments, 2019, pp. 22-23.

213 It is important for the sake of transparency to state precisely in the proposal when a 'positive with reservations' opinion was issued (and not label it as a 'positive' opinion, which occurred for instance in the proposal on harmonised river information services (RIS) (COM(2024)33).

214 RSB, Annual report 2018, p. 10.

Figure 16 – All issued RSB opinions on appraised IAs, by first and second submission



Source: IMPA, EPRS

As can be seen in Figure 16, among the 143 appraised IAs between 2019 and 2024, five received **two consecutive negative opinions,** one in 2021 and four in 2022.[215] According to the BRG, a second negative RSB opinion 'will be final, unless exceptional circumstances require otherwise'.[216] In any case, the Commission must explain publicly why it puts a proposal forward despite two negative RSB opinions, usually in the proposal's explanatory memorandum. While the Commission adopted two proposals despite receiving two negative RSB opinions in the sample of IAs under the previous review, the requirement (in principle) for a positive RSB opinion on the draft IA for an initiative to go forward was not respected in all of the above-mentioned double-negative cases in this review. The proposals were put forward despite a double RSB rejection. Interestingly, the **justifications** to do so and how the Commission addressed this challenge varied considerably: in only one case (the initiative on equal pay for equal work), the core text of the rejected IA was modified and improved, then exceptionally resubmitted a third time to the RSB, which gave a final (third) positive opinion (the IMPA initial appraisal found, however, that RSB comments were taken on board only 'partially'). In another case, Annex 1 to the IA provided clarification of changes to the IA addressing RSB comments to a certain extent, and the explanatory memorandum provided the justification to proceed (the initiative on the Union secure connectivity programme). In a third case, the proposal diverted from the preferred option of the (rejected) IA, making it more flexible for Member States to implement (the initiative on energy performance of buildings). Finally, in two cases, instead of

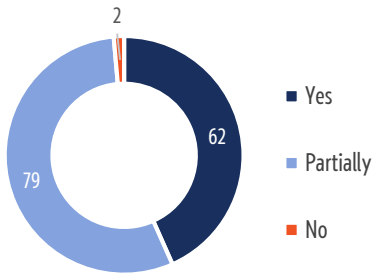
[215] This concerned the IAs accompanying 1) the proposal to strengthen the application of the principle of equal pay for equal work or work of equal value between men and women through pay transparency and enforcement mechanisms (2021); 2) the proposal on combating violence against women and domestic violence (2022), 3) the proposal on the energy performance of buildings (recast); 4) the proposal establishing the Union Secure Connectivity Programme for the period 2022-2027; and 5) the proposal on the Corporate Sustainability Due Diligence and amending Directive (EU) 2019/1937 (2022).

[216] Better Regulation Toolbox, 2023, Tool #3, p. 19.

modifying the IA, a new staff working document, labelled 'Follow-up to the second opinion of the Regulatory Scrutiny Board' was added to the proposal, to provide evidence and explanation (the proposals on combating violence against women and on due diligence).[217] While case-by-case **flexibility is understandable** in this context, for scrutiny purposes, recourse to these options should remain exceptional and **not replace the provision of 'fit for purpose' IAs**.

In conclusion, **IMPA data used for this review shows 87 % of draft IAs were either rejected (negative opinion) or in need of substantial re-drafting (positive opinion with reservations) when they first reached the RSB**. All but five (double negative, see above) of the rejected IAs received better feedback at their second submission to the RSB, but 46 still needed 'significant' improvement after this second quality check, as the resubmitted draft IAs only received a positive opinion with reservations (and only 10 received a simple positive opinion at second submission). During the reporting period, the number of initially rejected IAs remained at a relatively stable (high) level in the busiest years – 2021 (15), 2022 (19) and 2023 (16). Together with the IAs receiving a positive with reservations opinion, the overall quality both at first and second submission stage appears impressive. Data also suggests that slightly less negative first opinions led to more positive with reservations opinions (15 to 23 in 2021) and vice versa (19 to 13 in 2022). These two categories clearly outnumbered positive opinions throughout the legislature (a balanced 16 to 16 issue of both in 2023, and four positive opinions).

Figure 17 – Does the IA integrate the RSB recommendations?



Source: IMPA, EPRS

The **follow-up to RSB recommendations was, on average, one of the weaker dimensions appraised by IMPA, and found to be in the lower satisfactory area (3.3)**. A positive finding is that most of the Commission IAs scrutinised by IMPA explained transparently in Annex 1 – albeit to varying degree of detail – how they considered they had addressed the RSB recommendations for improvement, as required by the BRG. However, after checking the final IAs, IMPA found that compliance with the RSB recommendations on substance was often 'partial', i.e. while not ignoring them, also not fully implementing them. Of the 143 IAs, 79 note (55 %) the final IAs addressed the RSB's comments 'partially', while 62 (43 %) were found to have addressed them more comprehensively. Only two final IAs[218] were found to have not taken the comments into account.

It thus appears that considerable room for improvement remains on the full take-up of RSB criticism and recommendations. In particular, the follow-up appears to have been less thorough for positive with reservations opinions, where – as noted above – the need for improvement to the draft IA to make the IA fit for purpose was often significant.

While a limited follow-up to RSB criticism can be justified,[219] the RSB itself expressed concern in 2019 that positive with reservations opinions 'did not lead to corrections that the Board had

[217] They address the lack of evidence the RSB had criticised in the second negative opinion and update parts of the rejected IAs by providing, inter alia, a revised baseline, problem definition, cost assessment and/or preferred option (in SWD(2022) 61 and SWD(2022) 42).

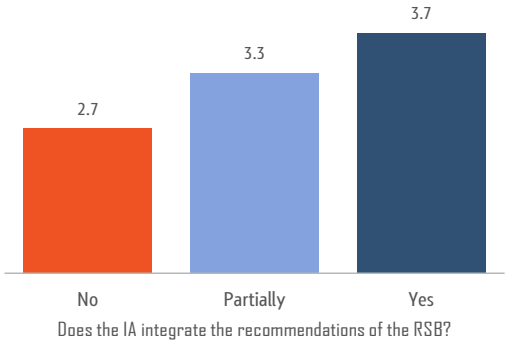
[218] The IAs on Energy performance of buildings (recast) and on Updating the crypto assets regulation and establishing a pilot regime for distributed ledger technology.

[219] In some cases, the IAs provided indication as to why certain RSB requests were not fully taken into account in the final IA, but in most instances this had to be deduced from IMPA's analysis, as it was not spelled out. Reasons for limited modifications could be, for instance, proportionality considerations, time constraints or political decisions.

expected to see' and announced the need for more 'follow-up'.[220] Since then, this follow-up work seems to have intensified. The RSB recently emphasised a distinction in quality at first and second submission of draft IAs.[221] More importantly in this context, it stressed that final IAs were further improved by **internal 'upstream' scrutiny** of the uptake of RSB recommendations after the second opinion and before publication. These internal, informal 'coaching' activities cannot be checked, as none are public or documented.

What can be said is that these activities seem to have contributed considerably to improving the overall quality of the final IAs: IMPA data shows that despite the high numbers of (very) critical RSB opinions at first submission and still many critical positive with reservations opinions even at second submission, the average overall quality score of the final IAs appraised by IMPA between 2019 and 2024 is well above the satisfactory level (see chapter on the assessment of impacts above). IMPA data also suggests a **positive correlation** in so far that as **IAs that integrate RSB comments more thoroughly obtained a higher overall average score (3.7) than those that did so only partially (3.3), or not at all (2.7)**. Notwithstanding this positive outcome, transparency of the follow-up and integration of RSB comments in an IA is important to informing policymakers and stakeholders of the reasoning and evidence base for a Commission initiative (including justifications why certain RSB remarks were not taken on board).

Figure 18 – Average IA quality score (1-5 scale) on integration of RSB comments



Source: IMPA, EPRS

This review assumes that the RSB and author DGs used the time between a second RSB opinion and the publication of a legislative initiative (with the accompanying IA) to improve the final IAs more effectively than in the past. Internal consultation activities were also possibly better structured than in the past. The **relatively stable average period[222] between final RSB opinion and IA publication suggests that generally, the whole IA process followed a more streamlined and structured pattern**.

This could also be linked to the RSB's increased focus on the **coherence of IA-work for similar or interlinked initiatives**. It is worth noting that the **focus of RSB quality checks varied** throughout the reporting period **to reflect evolving Commission political priorities**. For instance, in 2020 and 2021, following the 'Fit for 55' package IAs, the coherence (or lack thereof) between interlinked IAs became an RSB priority, while in 2022, following introduction of the new OIOO principle (see section above), there was increased focus on quantification (mostly of costs). Finally, in 2023, the Commission's 'renewed focus' on competitiveness led to a **revised RSB mandate** to 'pay special attention to the impacts on competitiveness'.[223] It is therefore generally useful to remember that in

[220] RSB, Annual report 2018, p. 43.

[221] See also for the following RSB, Annual Report 2023, pp. 16-17, 21-22 and 26.

[222] IMPA data shows that during the reporting period, the average number of days between the final RSB opinion and the publication of an initiative ranged from 96 to 127 days between 2020 and 2023 (for the 6 IAs published in 2024, it was 154 days). The overall average number of days between the final RSB opinion publication and that of the legislative proposal was 110 days.

[223] RSB, Annual report 2023, pp. 24 and 46. The competitiveness check and the SME test are also highlighted for RSB work in 2024, alongside the continuous 'upstream support meetings with the Commission services'.

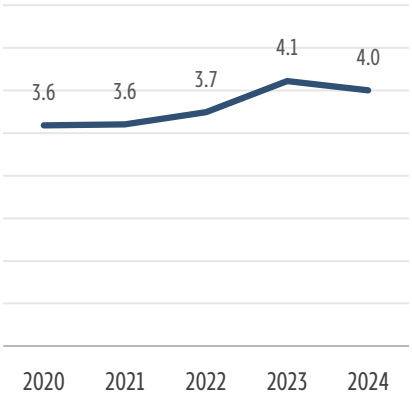
addition to better regulation criteria, other factors in the dynamic political environment can also determine the RSB's work (and priorities).

Coherence between the IA and the Commission's legislative proposal

While according to the IIA BLM, IAs are not a substitute for political decisions within the democratic decision-making process, they are considered a tool to help the three EU institutions reach well-informed decisions. The BRG also recognise the possibility that the College of Commissioners takes a different approach to the preferred policy option in an IA, but recommend that such situations should be explained in the proposal's explanatory memorandum.[224]

The last dimension analysed in any IMPA initial appraisal is therefore the IA's coherence with the legislative proposal. The **comparison of the IA with the proposal can provide insight as to whether and how the IA's conclusions were followed by the political decision-makers**. In IMPA appraisals this is checked by comparing the IA to the proposal in terms of overall coherence between the preferred course of action (or other key findings) of the IA and the proposed policy measures and by comparing monitoring and evaluation provisions presented in the IA to those described in the proposal. The Parliament considers that 'consistency between the explanatory memorandum and the impact assessment related to the same proposal is necessary'.[225]

Figure 19 – Trend in average quality of coherence between IA and legislative proposal dimension



Note: 1 - Very poor, 2 - Poor, 3 - Satisfactory, 4 - Good, 5 - Very good.

Source: IMPA, EPRS

The IMPA Unit scored the 'coherence of the legislative proposal with the IA' as 'good' and 'very good' in 69 % of appraised IAs; 'satisfactory' in 24 %; 'poor' in 7 %; and 'very poor' in one case. In this last case, however, the explanatory memorandum and recitals of the legislative proposal explain the policy choices made, notably the divergence from the IA (which received two negative RSB opinions).

The coherence between legislative proposals and the IA has not changed compared to the previous legislative term (71 % of proposals analysed are deemed 'coherent' with the IA in both), but the average 'coherence' score (3.8), however shows a **qualitative improvement (from 3.3) on the previous review**. The main conclusion for this dimension is that major diversions from the IA's findings, which appear to occur rarely, should be justified and clearly explained in the explanatory memorandum of the legislative proposal, as requested by Parliament,[226] so the co-legislators are fully informed about the line of action that has been pursued and the reasoning behind it.

[224] Better Regulation Guidelines, 2021, p. 36.

[225] European Parliament resolution of 30 May 2018 on the interpretation and implementation of the Interinstitutional Agreement on Better Law-Making, paragraph 42.

[226] Ibid.

3. Conclusions

The objective of the Ex-Ante Impact Assessment (IMPA) unit's initial appraisals is to become an integral part of Parliament's scrutiny of the executive, in line with the implementation of the IIA BLM, under which Parliament is committed to take full account of the Commission's IAs. Initial appraisals contribute to and support the consideration of a legislative proposal at parliamentary committee stage. This may inspire committees to invite the Commission to explain its assessment and the methodology used and to request further IA-related work.

Assessing a relatively high number of IAs based on standard criteria over five years provides an opportunity to use the compiled mass of comparable data and draw up a multiannual quality review of the IAs analysed. This third multiannual review not only assesses the strengths or shortcomings of different dimensions of IAs during one term, but also reveals trends through comparison with the previous review term, especially how the emphasis on certain dimensions has evolved or shifted over a longer period.

Based on the review undertaken in this study, **the overall average quality of the 143 IAs appraised is satisfactory, with an average score of 3.5** (on a scale from 1 to 5, corresponding to the perceived quality of 'very poor', 'poor', 'satisfactory', 'good', and 'very good'). This is an improvement compared to the overall average quality of IAs appraised during the previous review term (3.1).

Problem definition

A solid and evidenced-based problem definition constitutes a building block and reference framework for the whole IA. As in the previous review, the problem definition is **one of the best-scoring dimensions** in this study, with more than half of the sampled IAs rated 'very good' or 'good'. In an overwhelming majority of cases, it was found that IAs successfully identified the nature and scale of the problem, who is affected by the problem and how the problem would evolve without further EU intervention. Interestingly, over two thirds of the initiatives concerned a **revision of existing legislation**. In a majority of those cases (88 %), the evaluate-first principle was respected, although the Commission increasingly conducts the evaluation and the IA in parallel processes ('back to back'), rather than consecutively, as is in principle the rule. Due to time constraints, as many as 30 % of revisions were undertaken in a back-to-back process, which raises questions regarding the extent to which evaluation findings could be considered for the IA's design – particularly the problem definition.

Subsidiarity and proportionality

Over the review term, the average **quality reached the satisfactory level** – a steady improvement compared to the previous review term. The necessity for EU action was assessed in 95 % of all cases, compared to 98 % in the previous review term. Expected EU added value was assessed in 89 % of all cases, compared to 64 % in the previous review term. As in the previous review, the 'cost of non-Europe' provided for in the IIA BLM and called for by Parliament, was generally not analysed in the IAs appraised.

The Commission employed the **systematic use of a model template ('subsidiarity grid')** to assess subsidiarity and proportionality in IAs and legislative proposal explanatory memoranda, recommended by the Task Force on Subsidiarity, Proportionality and 'Doing Less More Efficiently', for politically sensitive and important initiatives. Of the IAs appraised 46 % were accompanied by a subsidiarity grid.

Proportionality was comprehensively addressed in a majority of IAs appraised (62 %) and less comprehensively in 24 %. Proportionality was not addressed in 14 % of the IAs. While proportionality was included in the Better Regulation Guidelines as a fourth criterion against which policy options

should be compared alongside efficiency, effectiveness and coherence, policy options were not compared against this criterion in 25 % of cases (compared to 32 % in the previous review term).

Objectives of the initiative

The average score for policy objectives reached 3.3 in this review, marking an **improvement** from 3.1 observed during the previous period. IMPA observed that 100 % of the appraised IAs included specific objectives, 95 % contained objectives corresponding to the defined problem, and the remaining 5 % included objectives that corresponded only partially. However, more effort is needed to ensure the inclusion of operational objectives in IAs, defined in terms of concrete policy deliverables, as they were missing in most cases to date.

Range of options considered

A substantial improvement is noticeable in the quality of presentation of the policy options. In 64 % of cases, the presentation was clear and balanced, compared to 37 % in the previous review. On the other hand, while a vast majority of IAs continue to provide multiple policy options, this does not always appear to ensure a wide range of feasible alternatives. In several cases, the policy options were built around each other, which limits the choice of options. During the term under review, 66 % of the IAs presented entirely realistic alternatives, which shows a clear improvement from the previous review, when the share of IAs providing realistic alternatives was 49 %. **Despite this positive evolution, further effort would be warranted**, given the importance of providing a choice of feasible alternatives for the objectivity and quality of the analysis.

Assessment of impacts

The identification and assessment of impacts was **one of the weakest dimensions** covered under this review, falling slightly above the satisfactory range, with an average score of 3.2. The analysis of impacts continued to pose challenges, mostly related to the persistent difficulties in transparently selecting and assessing the most significant impacts, in line with the principle of proportionate analysis. As was previously the case, this review identifies the need to duly justify which impacts are analysed, to what extent and to explicitly indicate whether one of the three mandatory impacts (economic, social, environmental) is not relevant or why other potentially relevant impacts are not assessed.

According to the IIA BLM and the Better Regulation Toolbox, the IA should assess the **economic, environmental and social impacts for each specific case in an integrated and balanced way**, using both qualitative and quantitative analyses, in line with the principle of proportionality. The Parliament has repeatedly asked for particular attention to be paid to IA. Its 2022 resolution on Better Regulation underscores the need for better regulation and simplification, taking economic, environmental, gender and social impacts into account in an integrated and balanced way. Parliament's 2023 resolution on European Union regulatory fitness and subsidiarity and proportionality calls on the Commission to better take account of the interplay of the economic, social and environmental impacts of EU policies and legislation.

As in the previous review term, the **assessment of impacts on SMEs and competitiveness** were often underdeveloped, something the Parliament has criticised in its resolutions. The improvement in the quality of the SME analyses and **the increase in the use of the SME Test can be observed in the present review term**. A positive evolution from 2023 onwards is seen in the assessment concerning both SMEs and competitiveness. Given the new requirement for a **compulsory annex on a competitiveness check in IAs** (including impacts on SMEs), introduced in the Commission's long-term competitiveness strategy, it remains to be seen how this recent positive trend evolves in terms of the quality of the competitiveness and SME assessment.

The revised Better Regulation Guidelines of November 2021 introduced a new tool to the set of instruments for simplifying and reducing the burden EU legislation: the **'One in, one out' (OIOO)**

approach. IAs need to systematically consider whether a new proposal would have significant cost implications for businesses and citizens and report on the expected additional administrative costs expected under an IA's preferred option(s). Following a transition period of gradual implementation, starting with 10 pilot IAs in 2021/2022, by the third quarter of 2022 nearly all IAs reviewed complied with the OIOO application. However, IMPA noted a **varied application and a lack of methodological transparency**, notably in terms of the definition and distinction of cost categories and quantified aggregates. Given the limited time of full application, it is **too early for a final assessment of the OIOO-implementation at EU level**. The Parliament has expressed concern about OIOO and the risk of 'mechanical or mathematical' decision-making or deregulation that could prejudice Parliament's capacity as co-legislator.

Monitoring and evaluation

Monitoring and evaluation remain core elements of policymaking aimed at assessing the performance and the impact of EU policies. During the term under review, **137 (around 96 %) of the IAs assessed included monitoring provisions and 121 (around 85 %) comprised evaluation provisions**. Moreover, the majority of the IAs were considered to have good monitoring and evaluation systems. The majority of IAs reviewed included monitoring and evaluation requirements supported by relevant indicators.

Stakeholder consultation

Stakeholder consultation is one of the dimensions that **scored better for the IAs reviewed, with an average score of 3.6 points**. While the average quality of this dimension in the IAs reviewed was found to be good, there is still **scope for improvement** with regard to the representativeness of different stakeholder categories as well as to the transparent and detailed reporting on the use of stakeholder input to Commission IAs.

This review agrees with the Parliament's 2022 resolution on Better Regulation, calling all EU decision-makers to take stakeholders' input into account and ensure effective follow-up in the ensuing decision-making processes, and welcoming 'the Commission's efforts to consolidate the consultation process, the commitment to report on each public consultation within eight weeks of its closure and the commitment to more actively publicising consultations in order to reach more citizens, stakeholders, including SMEs, and local and regional authorities'.

Supporting data and analytical methods used

The **average quality score is 'satisfactory'**, a **steady improvement compared to the previous review**. A majority of the appraised IAs (97 %) were rated as 'very good', 'good' and 'satisfactory' for the dimension on the quality of data, research, and analysis.

As in the previous review term, IMPA identified **issues regarding a lack of transparency of information, including the unavailability of supporting studies**. As regards the use of analytical methods (e.g. cost/benefit analysis, cost-effectiveness analysis, sensitivity analysis, multi-criteria analysis or other analytical methods) and models, the variety between the appraised IAs is considerable and has not changed significantly compared to the previous review term. **Issues were identified as regards the full transparency and availability of the analytical methods and models used**. In several cases, not all data sources are referenced and publicly available, and not all models are explained, publicly available or reported in the Modelling Inventory and Knowledge Management System of the Commission (MIDAS).

On quantification of costs and benefits, data shows a **consistent increase in the share of IAs that quantify costs**. Overall, costs are quantified in 42 % of the IAs appraised (partially in 52 % and 6 % did not quantify costs at all). The data shows an increase in the share of IAs that quantify benefits between 2020 and 2023. However, benefits are only quantified in 26 % of appraised IAs, partially

quantified in 60 %, and in 8 % benefits were not quantified. In 6 % of cases benefits could not be quantified.

Follow-up to the Regulatory Scrutiny Board opinion

The uptake of Regulatory Scrutiny Board recommendations to improve draft IAs was, on average, **one of the weaker dimensions appraised by IMPA**, scoring in the **lower satisfactory area** (3.3), a similar score to the previous review. A positive finding is that most of the IAs scrutinised by IMPA explained transparently how they addressed the RSB's comments, usually in Annex 1 to the IA. However, IMPA data shows that many final IAs addressed the comments only 'partially', even after 'positive with reservations' opinions, where the need for improvement to the draft IA was often significant to make the IA fit for purpose. Full transparency about the follow-up to the RSB's comments is important to informing policymakers and stakeholders of the reasoning and evidence behind a Commission initiative – including proper justification why certain RSB remarks might not have been taken on board.

Coherence between the Commission's legislative proposal and the IA' s preferred option

It appears that the coherence of legislative proposals with the IA **remained the same as in the previous review period**. Reasons for a partial lack of coherence varied from case to case and often concerned minor elements that did not put the preferred course of action into question. The quality of the 'coherence' element, however, **improved from an average 3.3 to 3.8 score** in the current review.

In **conclusion**, this quality analysis finds there has been a **positive evolution** – not only in the overall average quality of IAs, but also in several dimensions, which reflects the Commission's significant efforts in applying the better regulation rules and tools. At the same time, the study reveals shortcomings in certain parts of IAs, the improvement of which will need a careful and systematic approach in future IAs. This particularly concerns the assessment of impacts, the range of feasible options and elements such as the inclusion of operational objectives and the quantification of benefits. As regards full uptake of the RSB's recommendations in the final IA, the intensified upstream scrutiny of the RSB appears to have benefitted the quality of IAs reviewed and should therefore be maintained.

Negotiations on a renewed interinstitutional agreement on simplification and better law-making are approaching, as the **revision of the 2016 Interinstitutional Agreement on Better Law-Making** (IIA BLM) is part of the von der Leyen II Commission's political priorities. The Parliament and the Commission are also currently revising their **framework agreement** – a political momentum for closer cooperation. With this study, IMPA aims to contribute to this reflection and the institutions' joint effort to make better regulation activities, and in particular IAs, more effective and useful for policymakers and to improve the quality of EU law-making. This includes a more active exchange of information on upcoming legislative initiatives, as well as on cases where the Commission intends to present an initiative without an IA.

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Annex – List of the 143 initial appraisals of European Commission impact assessment reports reviewed

1	Review of the Benchmark Regulation	October	2020
2	Better cooperation against tax fraud and evasion	November	2020
3	Protection of workers from exposure to carcinogens or mutagens: fourth proposal	November	2020
4	Setting the 2030 GHG emissions reduction target	December	2020
5	Strengthening the digital operational resilience in the financial sector	December	2020
6	Adequate minimum wages	January	2021
7	Improving the common level of cybersecurity across the EU	February	2021
8	Establishing an EU single window for customs	February	2021
9	Data Act Governance	February	2021
10	Improving the resilience of critical entities	February	2021
11	Updating the crypto assets regulation and establishing a pilot regime for distributed ledger technology	March	2021
12	Establishing a computerised system for communication in cross-border civil and criminal proceedings (e-CODEX)	March	2021
13	Digital Services Act	March	2021
14	Trans-European energy infrastructure guidelines: Updating the current framework	April	2021
15	Improving roaming on public mobile telecommunications networks	May	2021
16	Updating the EU regulatory framework for batteries	May	2021
17	Establishing the new EU strategy on adaptation to climate change	May	2021
18	Digital markets act	May	2021
19	EU partnership on metrology	June	2021
20	Revising the Machinery Directive	July	2021
21	Tackling distortions of foreign subsidies	July	2021
22	Strengthening Europol's mandate	July	2021
23	Application of the equal pay principle through pay transparency measures	July	2021
24	Artificial intelligence act	July	2021
25	Improving corporate sustainability reporting	July	2021

26	Consumer Credits	October	2021
27	Improving the Schengen evaluation and monitoring mechanism	October	2021
28	Updating the framework for the safety of non-food consumer products on the internal market	October	2021
29	European green bond standard	October	2021
30	Establishing a framework for a European digital identity	October	2021
31	Fit for 55 package: Energy from renewable sources	November	2021
32	Fit for 55' legislative package: Strengthening the CO2 emission performance standards for new passenger cars and new light commercial vehicles	November	2021
33	Fit for 55' legislative package: ReFuel EU Aviation	December	2021
34	Fit for 55 package: Recasting the Energy Efficiency Directive	December	2021
35	Fit for 55' package: Revision of the Effort-Sharing Regulation	December	2021
36	Towards a new Generalised Scheme of Preferences regulation for developing countries	December	2021
37	Anti-money-laundering package	December	2021
38	'Fit for 55' package: Carbon border adjustment mechanism	January	2022
39	'Fit for 55': Revision of the EU Emissions Trading System	January	2022
40	Fit for 55' legislative package: Deployment of alternative fuels infrastructure	January	2022
41	Common chargers – Revision of the Radio Equipment Directive	February	2022
42	'Fit for 55' package: Fuel EU Maritime	February	2022
43	Fit for 55' package: Revising the Regulation on land use, land-use change and forestry (LULUCF)	February	2022
44	Fit for 55 package: revising the EU Emissions Trading System as regards aviation	March	2022
45	Review of the capital requirements framework	March	2022
46	Amending the rules governing the statute and funding of European political parties (recast)	March	2022
47	Transparency and targeting of political advertising	March	2022
48	Review of the Waste Shipment Regulation	April	2022
49	Solvency II review	April	2022
50	Minimising the risk of deforestation and forest degradation associated with products placed on the EU market and exported from the EU	April	2022
51	Environmental crime directive	April	2022

52	Improving working conditions in platform work	April	2022
53	Review of rules for alternative investment funds	April	2022
54	Digitalisation of cross-border judicial cooperation	April	2022
55	Revision of the Trans-European Transport Network (TEN-T) Regulation	May	2022
56	EU response to economic coercion by third countries	May	2022
57	The revision of the Schengen Borders Code	May	2022
58	Fit for 55: EU framework to decarbonise gas markets and promote hydrogen	May	2022
59	Combating violence against women and domestic violence	June	2022
60	Fit for 55 package: Reducing methane emissions in the energy sector	June	2022
61	Revision of Directive 2010/40/EU on the deployment of intelligent transport systems	June	2022
62	Fit for 55 package: Energy performance of buildings (recast)	June	2022
63	Review of rules on financial market data	June	2022
64	Setting ecodesign requirements for sustainable products	June	2022
65	Establishing the Union secure connectivity programme for the period 2023-2027	July	2022
66	Data Act	July	2022
67	Revising the EU geographical indications for wine, spirit drinks and agricultural products	September	2022
68	Tackling industrial emissions from large agro-industrial activities	September	2022
69	Consumer protection for the green transition	September	2022
70	Revision of the Central Securities Depositories Regulation	September	2022
71	Recasting the Long-Term Residents Directive	September	2022
72	Fluorinated greenhouse gases	September	2022
73	Corporate Sustainability Due Diligence	October	2022
74	Sustainable use of plant protection products	October	2022
75	Recasting the Single Permit Directive for third-country nationals	October	2022
76	Revision of the Construction Products Regulation	November	2022
77	Improving distance marketing of consumer financial products	November	2022
78	Further reduction of the ozone depleting substances	November	2022
79	Preventing and combating child sexual abuse	November	2022
80	Regulation on nature restoration	December	2022

81	Single Market Emergency Instrument	December	2022
82	Strengthening cyber resilience	December	2022
83	Establishing the European health data space	January	2023
84	Protection of workers from the risks related to exposure to asbestos at work	January	2023
85	Updating liability rules for defective products	January	2023
86	Interoperable digital public services in the EU	February	2023
87	Safeguarding media freedom and pluralism in the internal market (Media Freedom Act)	February	2023
88	Cleaner Air for Europe	February	2023
89	Revising the standards for surface water and groundwater pollutants	February	2023
90	Revising the Urban Wastewater Treatment Directive	February	2023
91	Harmonising certain aspects of insolvency law	February	2023
92	Packaging and packaging waste	February	2023
93	Updating Euro emission standards (Euro 7)	February	2023
94	Listing Act package	April	2023
95	Revising the Community Design Regulation and the Design Directive (recast)	May	2023
96	Classification, labelling and packaging of substances and mixtures	May	2023
97	EU critical raw materials act	May	2023
98	Certification of carbon removals	May	2023
99	Updating CO2 emission standards for heavy-duty vehicles	May	2023
100	Advance passenger information (API): Revising the rules	June	2023
101	Anti-trafficking in human beings	June	2023
102	Reducing exposures to third-country central counterparties	July	2023
103	EU Company law: Expanding and upgrading the use of digital tools and processes	July	2023
104	Promoting the repair of consumer goods	July	2023
105	Bank crisis management and depositor insurance	September	2023
106	Revision of the EU pharmaceutical legislation	September	2023
107	Revision of EU customs legislation	September	2023
108	Intellectual property: Regulation on standard essential patents	September	2023

109	Legislation for plants produced by certain new genomic techniques	September	2023
110	Soil monitoring and resilience in the EU	October	2023
111	Plant and forest reproductive material	October	2023
112	Compliance with flag state requirements	October	2023
113	Revision of the Waste framework directive	October	2023
114	Intellectual property: A revised framework for compulsory licensing of patents	October	2023
115	Stepping up toy safety	October	2023
116	Intellectual property: Revising legislation on supplementary protection certificates	November	2023
117	Maximum authorised weights and dimensions for certain road vehicles	November	2023
118	Open Financial Data implications	November	2023
119	Revision of the Victims' Rights Directive	November	2023
120	Transparency and integrity of environmental, social and governance rating activities	November	2023
121	European cross-border associations	December	2023
122	Introducing a European disability card and a European parking card	December	2023
123	Accounting of greenhouse gas emissions of transport services	December	2023
124	Combatting microplastic pollution in the EU: unintentional releases of plastic pellets	January	2024
125	Second revision of payment services in the EU	January	2024
126	Forest monitoring and resilience in the EU	January	2024
127	Alternative dispute resolution for consumers	January	2024
128	Digital euro	February	2024
129	Establishing an EU Talent Pool	February	2024
130	Combating late payment	February	2024
131	Defence of Democracy package	February	2024
132	Increasing the competitiveness of the intermodal transport	February	2024
133	Adapting liability rules to artificial intelligence	March	2024
134	Revision of the European Works Councils Directive	March	2024
135	Protecting animals during transport	April	2024

136	Circularity of vehicles: Design, production, end-of-life and waste management	April	2024
137	Reinforced quality framework for traineeships	July	2024
138	Improving passenger rights	September	2024
139	Europe's 2040 climate target and path to climate neutrality by 2050	September	2024
140	Revision of harmonised river information services	October	2024
141	Combating child sexual abuse and exploitation	October	2024
142	Revision of the Package Travel Directive	October	2024
143	EU Digital Travel application	January	2025

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This study provides an analysis of the quality of European Commission ex-ante impact assessments (IAs) published between December 2019 and November 2024, following their appraisal by the Ex-Ante Impact Assessment Unit (IMPA) of the European Parliamentary Research Service (EPRS). Drawing on a review of 143 initial appraisals of Commission IAs, the study analyses them according to quality criteria stemming from the Commission's Better Regulation Guidelines, European Parliament resolutions and the Parliament's Impact Assessment Handbook.

During the term under review, the average quality of Commission IAs has developed positively, and in several respects. This reflects the Commission's significant efforts to apply the better regulation rules and tools. At the same time, the study reveals shortcomings in certain parts of IAs, the improvement of which will need a careful and systematic approach in future, in particular the assessment of impacts, the range of feasible options, and elements such as the inclusion of operational objectives and the quantification of benefits. As regards the uptake of the Regulatory Scrutiny Board (RSB) recommendations in the final IA, the intensified upstream scrutiny of the RSB appears to have benefited overall IA quality during this review term and should therefore be maintained.

With this study, IMPA seeks to contribute to the joint effort to improve the quality of EU law-making. The aim is for the findings of the review to feed into the broader discussion on better regulation in the European Union, and impact assessment in particular.

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