

Regulatory Scrutiny Board

Annual report 2025



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REGULATORY SCRUTINY BOARD

Annual Report 2025

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Foreword by the Chair



Rytis Martikonis
Chair

This report covers the tenth year of operation of the Regulatory Scrutiny Board, and the first year of the mandate of the second von der Leyen Commission. Whereas evaluations constituted most of the scrutiny work in the first part of the year, impact assessments of planned interventions increased in the second half of 2025. All in all, the Board scrutinized a total of 57 files, 25 impact assessments, 22 evaluations (including 3 fitness checks) and 10 resubmitted reports. The rate of initial negative opinions for impact assessments was 56% and 41% for evaluations, while the 10 files resubmitted for a second opinion obtained positive opinions with reservations, testifying to the improved quality of the resubmitted reports.

Initiatives related to the European Union's strategic autonomy were of particular importance as well as the Multiannual Financial Framework package.

In its scrutiny work, the Board consistently emphasized the fundamental importance of evidence-based analysis of policy problems and design of corresponding responses. The Commission has established a framework to handle data and Artificial Intelligence but further efforts are needed to enhance the collection and usage of data to obtain robust evidence for EU policy-making. The special feature of the report makes several observations and recommendations in this regard.

As well as performing its core function of assessing the quality of impact assessments, fitness checks and evaluations, the Board continued to provide advice to Commission services at early stages of preparation: 38 upstream meetings took place during 2025. The collaborative nature of quality assurance as well as the strong commitment to better regulation and continuous efforts of Commission services should be recognised.

Two new members — Dr Emmanuelle Maincent and Ms Doriane Givord-Strassel — joined the Board from the Commission services, respectively at the end of 2025 and beginning of 2026. These appointments were to replace two Board members who left during the year, Dr Dorota Denning and Mr James Morrison. I would like to thank both for their outstanding contributions to the Board's work and, on behalf of the Board, wish them well in their new assignments.

As ever, I am grateful to the colleagues of the Board secretariat for their dedicated support over the past year.

1

The Board



The Board has a central and precisely defined role in the Commission

The Regulatory Scrutiny Board (the 'Board') was set up as part of the Commission's 2015 renewed better regulation agenda to scrutinise the drafts of all impact assessments, fitness checks and a selection of evaluations. It reports on its activities to the President of the Commission and to the Commissioner in charge of Economy and Productivity, Implementation and Simplification. Following the decision of the President of the Commission P(2022) ⁽¹⁾, the composition of the Board has been increased by two to a total of nine members – the Chair, four Commission officials (the 'internal members') and four temporary agents ('the external members') – in order to reinforce the Board's operations and pay particular attention to competitiveness impacts.

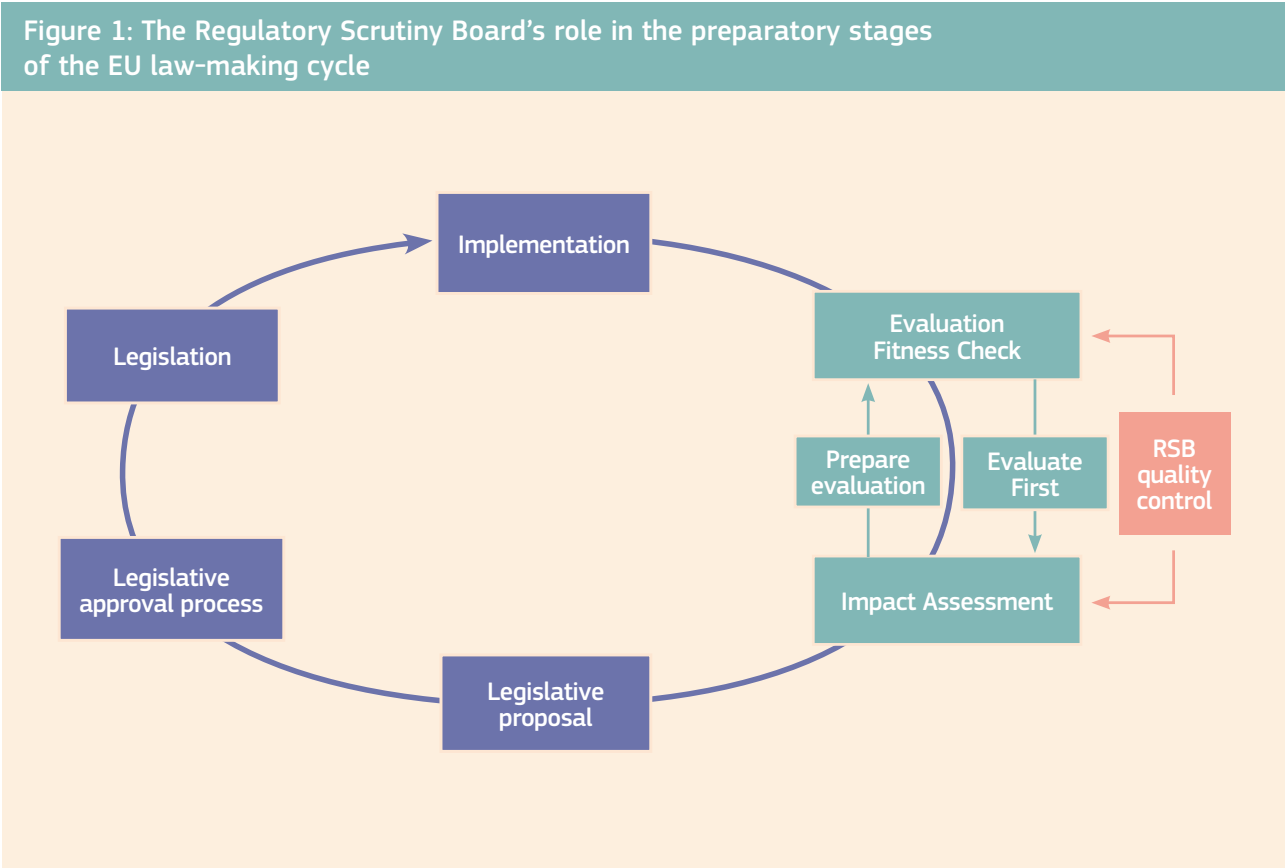


Figure 1 shows how the Board's internal quality control function fits within the Commission's preparatory processes of the EU law making cycle to make sure that the Commission proposals are based on clearly defined problems and on the best available evidence, are coherent and proportionate and take into account the full range of options and stakeholder views.

(1) In the first part of 2025, the Board was composed – from left to right – of Mr Rytis Martikonis (Chair), Mr Philippe Mengal, Ms Arianna Vannini, Dr Marek Havrda, Dr Alexander Gemberg-Wiesike, Mr James Morrison (Director), Dr Rolf Hoijer and Dr Dorota Denning (not in picture).

**Through its opinions,
the Board provides
independent quality control
within the Commission**

Within its mandate as an internal, independent and objective quality control and scrutiny body, the Board neither seeks nor takes instructions from any internal or external actor, performs its task independently and prepares its opinions autonomously. It acts during the internal Commission phases preceding the preparation of new legislation and is designed to ensure that Commission impact assessment and evaluation reports are of high quality, providing the best available evidence allowing informed decision making (see [Box 1](#)).

The Board's role is analytical

The work of the Board supports the implementation of the Commission's better regulation commitments. The Board cannot and does not question the political objectives presented in the impact assessments accompanying draft proposals – that role belongs solely to the College of Commissioners – but instead, the Board focuses on the quality of evidence, analysis and the logic of intervention. The Board assesses the files submitted to it objectively and on the basis set out in the better regulation guidelines and toolbox (for more details on the Board's functioning see [Box 2](#)).

The Board issues different types of opinions on draft impact assessments, fitness checks and evaluations, with recommendations for improvements (for more details, see [Box 3](#)).

**The Board provides
upstream advice**

The Board members also provide advice via internal upstream meetings with Commission services at the early stages of the preparation of evaluations, fitness checks and impact assessments.

**Given the Board's
internal role, its opinions
are published only with the
final impact assessment**

During the Commission's internal policy preparation process, the Board shares its opinions only with the Commission departments responsible for the preparation of the proposal. This is the logical consequence of the quality assurance role of the Board. Once a legislative proposal has been drafted by the Commission service and adopted by the College of Commissioners, there is full transparency on the Board's assessments and all its opinions are published, together with the proposal and final impact assessment. Similarly, the opinions for evaluations are published together with the finalised evaluation.

BOX 1: THE REGULATORY SCRUTINY BOARD AT A GLANCE

- The Board is an internal Commission quality control body set up to ensure the quality of all impact assessments and fitness checks and selected evaluations.
- The Board consists of nine members who serve three years – four are externally recruited and five drawn from within the Commission.
- The Board acts independently in carrying out its duties and neither seeks nor takes instructions from any internal or external stakeholders.
- The Board issues opinions on the quality of draft impact assessments, evaluations and fitness checks based on standards set out in the Better Regulation guidelines and toolbox.
- The Board does not take a view on the political objectives or advisability of initiatives: that role rests solely with the College of Commissioners.
- The Board's opinions are published when an initiative has been adopted by the College of Commissioners, to protect the candour of the internal Commission preparatory processes and in line with the working procedures of the Commission.

BOX 2: HOW THE BOARD PROCESS WORKS

- During the early preparatory stages of an impact assessment, the relevant Commission services(s) can ask the Board to have an upstream meeting. The department provides a copy of the 'call for evidence', which sets out the problem, proposed options and main expected impacts, as well as the outline/timeline for the public consultation and any studies. The meeting is an opportunity for the department to outline their intended methodological approach and to seek the informal, upstream advice from the Board members on any likely weaknesses of the analysis, thereby allowing for adjustment of the file's problem definition, intervention logic, option structure, evidence gathering and methodology prior to the formal submission to the Board.
- Once the Commission service has finalised its work on the draft impact assessment, it is formally submitted to the Board, normally four weeks before the Board meeting. All Board members read the full document and jointly produce an impact assessment quality checklist (IAQC) using the criteria in the better regulation guidelines and toolbox, identifying any weaknesses, inconsistencies or lack of clarity in the report. The checklist is sent to the relevant Commission service(s) which can provide a written response to the Board before the Board meeting. Board members study any additional information provided in the written response to the checklist and take this into account when asking questions at the Board meeting. In some cases, the Chair may decide to submit certain matters to the Board for decision by Written Procedure.
- The process is the same for evaluations. The Board produces an evaluation quality checklist (EQC) and, after discussion in the Board meeting, the Board issues an opinion. There is also a possibility to have an upstream meeting for evaluations.
- Board meetings are normally held on Wednesdays. Commission service(s) are informed at the beginning of the Board meeting that the Board has examined the impact assessment submitted and any written reply provided to the IAQC and that its opinion will be based solely on this information while taking into account any further information provided during the course of the subsequent discussion. Board meetings last about one hour per file and are followed by a discussion among Board members to determine collectively the nature of the Board's opinion to be issued (see Box 3). The opinion is normally submitted to the Commission service on the following days.
- During the entire process, the Board is supported by its secretariat. The secretariat plans and organises the Board meetings and provides drafts for the minutes of upstream meetings, the IAQCs or EQCs, and opinions.

BOX 3: TYPES OF OPINION(S)

For impact assessments, there are three types of Board opinion:

POSITIVE:

The Board is satisfied that the draft impact assessment meets the standards set out in the better regulation guidelines and toolbox. Comments in the opinion are advisory, and the file may proceed.

POSITIVE WITH RESERVATIONS:

In some cases, the draft impact assessment is largely satisfactory, but some key weaknesses remain and should be fixed. In other cases, there are significant weaknesses, but the department has provided convincing responses to the quality checklist in the discussion with the Board and has clearly indicated where they would make the necessary changes to the report. In both cases, the draft impact assessment must be amended to take account of the Board's comments set out in the opinion. Only then can the file proceed.

NEGATIVE:

The draft impact assessment is not satisfactory and falls short of the standards set out in the better regulation guidelines and toolbox. The file requires substantial revision. It must be resubmitted for a second opinion once the indicated changes have been made. To facilitate a satisfactory follow-up in case of an initial negative opinion, the Secretariat-General immediately organises meetings of the cabinets and services concerned to address the issues identified in the Board's negative opinion. In most cases, the resubmitted file has been sufficiently improved to address the Board's concerns and will be given a second opinion positive or positive with reservations. In very few cases, the resubmitted text may still contain fundamental deficiencies in meeting the standards set out in the better regulation guidelines and toolbox that have not been satisfactorily addressed. In these cases, the Board issues a **SECOND NEGATIVE OPINION**: The Commissioner for Economy and Productivity, Implementation and Simplification then decides whether and in what form it may proceed.

For evaluations and fitness checks, there were only two types of Board opinions until the end of 2023: positive or negative. At the beginning of 2024, the Board decided to introduce the 'positive with reservations' opinion type also for evaluations as this allows for more nuanced feedback to be provided. While there is no obligation to do so, after a negative opinion the relevant Commission service can submit a revised report of the evaluation / fitness check for a second opinion to the Board. So far, the Board has never given a second negative opinion on an evaluation.

1.1 The work of the Board in 2025

In 2025, the political cycle shaped the Board's activities

The second von der Leyen Commission started on 1 December 2024 and the year 2025 was its first full year in office. The year 2025 saw significant geopolitical shocks and economic tensions, enhanced by the increased weaponization of dependencies. The Commission strives for a more independent and secure Europe with 2024-2029 priorities, ranging from defence and security to sustainable prosperity, democracy and social fairness. Following the recommendations of the 2024 reports of both Professor Letta⁽²⁾ and Professor Draghi⁽³⁾ to make Europe more competitive, the Commission adopted the 'Competitiveness Compass'⁽⁴⁾, translating the reports into practical steps for the five years of the mandate. Moreover, the Commission published 'A simpler and faster Europe: Communication on implementation and simplification', setting out a vision for an implementation and simplification agenda. These priorities of the second von der Leyen Commission shaped the initiatives submitted to the Board in 2025.

(2) 'Much more than a market', April 2024 - <https://www.consilium.europa.eu/media/ny3j24sm/much-more-than-a-market-report-by-enrico-letta.pdf>

(3) 'The Future of competitiveness', September 2024 - https://commission.europa.eu/document/download/97e481fd-2dc3-412d-be4c-f152a8232961_en

(4) 'A competitiveness Compass for the EU', COM(2025)30 - https://commission.europa.eu/document/download/10017eb1-4722-4333-add2-e0ed18105a34_en

More files were scrutinised in 2025 compared to 2024

In 2025, the Board issued a total of 57 opinions (Table 1). This is sizeably more than in 2024, the year of transition from one legislative cycle to the next, but it remains below the average of preceding years. 22 out of these were evaluations (EVs) and fitness checks (FCs), slightly more than in 2024. The number of impact assessments submitted to the Board grew significantly, concurrently with the beginning of the von der Leyen Commission’s second mandate. In 2025, the Board scrutinised 25 impact assessments (IAs), including 7 on the proposals for the next Multi-annual Financial Framework (MFF), compared to only 3 in 2024 (Table 1). It also scrutinised 10 files resubmitted after having received a first negative opinion (7 Impact Assessments and 3 Evaluations).

Table 1: Opinions issued by the Board in 2025

	First Opinion	Second Opinion
IAs	18	7
IAs MFF	7	-
EVs	22	3
Total	47	10

There were only two positive opinions

In 2025, the Board gave positive opinions on two evaluations. The largest share of submitted reports received a positive opinion with reservations. Seven impact assessments received opinions without qualification (see box 4).

BOX 4: MFF PROPOSALS

The ‘Political Guidelines for the next European Commission 2024-2029’ call for the next EU long-term budget (MFF 2028-2034) to be more focused, simpler and more impactful. The Better Regulation Tool #9 acknowledges that *‘the special case of preparing a new multiannual financial framework is a unique process requiring a specific approach as regards scope and depth of analysis’*. As the architecture of the MFF 2028-2034 was meant to be significantly different from the structure of the MFF 2021-2027, the impact assessment submitted to the Board lacked several key components. The Board thus exceptionally decided to issue ‘Opinions without qualification’. Therefore, seven opinions related to the next MFF impact assessments are not included in the statistics analysed in this annual report.

In 2025, the share of negative opinions for impact assessments was higher than in the years 2016-2023, with the exception of the two outlier years 2019 and 2024 with very few impact assessments during the transition from one legislative cycle to the next.

Table 2: Overview of Board regulatory scrutiny work by year, 2016-2025

Year	Cases	Negative first opinions		Negative second opinions	
Impact assessments					
2016	60	25	42 %	2	8 %
2017	53	23	43 %	1	4 %
2018	76	21	28 %	1	5 %
2019	1	1	100 %	0	0 %
2020	41	19	46 %	1	5 %
2021	83	31	37 %	4	13 %
2022	70	24	34 %	0	0 %
2023	50	21	42 %	0	0 %
2024	3	2	67 %	0	0 %
2025	18*	10	56 %	0	0 %
Evaluations and Fitness Checks*					
2016+	7				
2017	17	7	41 %	0	0 %
2018	11	3	27 %	0	0 %
2019	17	8	47 %	0	0 %
2020	13	4	31 %	0	0 %
2021	15	3	20 %	0	0 %
2022	8	0	0 %	0	0 %
2023	8	4	50 %	0	0 %
2024	19	10	53 %	0	0 %
2025	22	9	41 %	0	0 %

- At the time of finalising the report, not all impact assessments with a first negative opinion had been resubmitted; second negative opinions are mentioned under year of second opinion
- Resubmission of evaluations after a first negative opinion is optional
- + in 2016, evaluations received opinions without qualifications
- * The Board scrutinised 25 impact assessments, out of which seven received an opinion without qualification

Regarding evaluations, the Board selected 15 evaluations for 2025. It scrutinised 19 and 3 fitness checks, which was similar to previous years:

Table 3. Evaluation Scrutiny 2025 vs 2019-2024

	2019	2020	2021	2022	2023	2024	2019-2024	2025
Selected evaluations per year*	21	11	12	6	13	30	16	15
<i>% of total evaluations and fitness checks</i>	<i>39 %</i>	<i>22 %</i>	<i>24 %</i>	<i>24 %</i>	<i>42 %</i>	<i>94 %</i>	<i>39 %</i>	<i>23 %</i>
Scrutinised evaluations and fitness checks	17	13	15	8	8	19	13	22
<i>% of total evaluations and fitness checks</i>	<i>31 %</i>	<i>27 %</i>	<i>31 %</i>	<i>32 %</i>	<i>26 %</i>	<i>59 %</i>	<i>33 %</i>	<i>34 %</i>
Presented as planned	8	5	7	1	4	13	6	6
Delayed from previous years	9	8	8	7	4	6	7	16

* excluding evaluations that were removed from the list of selected evaluations

More Board meetings were held in 2025 than in 2024

The Board held 21 Board meetings, out of which three meetings dedicated specifically to the MFF proposals, given the urgency (See **Box 4**). This is in line with the period 2020-2023, where there were between 20 to 27 meetings per year while in 2024, during the transition from one legislative cycle to the next, there were fewer Board meetings (16).

For two urgent files submitted in December 2025, the Board scrutinised the files applying a written procedure, so that the opinion could be delivered a few days after the submission of the files.

1.2 Outreach and advisory activities

Outreach activities

In 2025, Board members participated in 12 meetings or events with external stakeholders.

Furthermore, the Annual Report for 2024 was presented at the 7th RSB Annual Conference on Regulatory Scrutiny on 22 May 2025, which was attended by over 200 participants. The focus of the conference was on evaluations, building on the 2024 Annual Report's special feature. The conference included a first panel discussion on the issues identified by the Board through its scrutiny work of evaluations for the period 2019-2024. In a second panel, the discussion focused on the challenges and recommendations for EU evaluations for the following years.

In addition, the Board conducted an internal 'outreach' exercise with some Commission services. Board members attended their internal management meetings, which provided an opportunity to explain the Board's work and answer questions.

Upstream meetings continued

The well-established practice of the Board holding 'upstream meetings' with Commission services upon their demand to get targeted advice at early stages of the preparation of the impact assessments and/or evaluations continued in 2025. 38 meetings concerning 39 files took place between Board members and the responsible Commission services.

The Board identified some key lessons learned, which could help improve the quality of the files to be submitted for scrutiny (see **Box 5**).

BOX 5: LESSONS LEARNT FROM THE 2025 UPSTREAM MEETINGS

Firstly, **key elements of the impact assessment/evaluation should be provided**: for the Board to be able to advise a Commission service on the preparation of an impact assessment report, it is important that, prior to the meeting, the Commission service has already sufficiently analysed the problem(s) and defined a preliminary intervention logic with a proper articulation of the links between the identified problems, their drivers, their consequences and the corresponding specific objectives. Although all the details of the policy options are not necessarily known at this stage, their outline and the underlying evidence should be put forward. Finally, the methodological approach to assessing the main impacts should be provided. If a modelling tool is to be used, a sufficient explanation of the model should also be provided, together with the data, evidence and underlying assumptions that will be used as input.

Secondly, **the upstream meeting should be planned adequately**: the upstream meeting should take place early enough to enable the Commission service concerned to consider and incorporate all the relevant advice expressed in the meeting. For example, if it appears from the upstream meeting that an intervention logic should be revised or the chosen methodology revisited, there still needs to be sufficient time for the service concerned before finalising the impact assessment/evaluation report. On the other hand, if an upstream meeting takes place too early in the process, the key elements listed above may not yet be sufficiently defined. Consequently, the advice the Board members may be able to give is likely to be limited.

It seems that upstream meetings are sometimes requested only after an external contractor has finished a procured study. At this point in time, it may be too late to amend major flaws in the report. If an external contractor is tasked to contribute to the process with a study, for the upstream meeting to be most useful, it should be requested before the tender specifications are finalised.

Thirdly, **the RSB 2024 Annual report's special feature on evaluations**⁽⁵⁾ reflects the lessons learned from Commission evaluations scrutinized during the period 2019 – 2024. In this special feature, the Board made recommendations on the drivers impacting the overall quality of evaluations, on the issues specific to the five Better Regulation evaluation criteria as well as on the most problematic quality components the Board has encountered.

Finally, **advice received in the upstream meetings should be made use of**: the main underlying issues for a negative opinion are often already identified in the upstream meeting, yet are not sufficiently addressed in the report. The minutes of the upstream meetings are a valuable source of information in this respect.

(5) Regulatory Scrutiny Board — European Commission: https://commission.europa.eu/law/law-making-process/regulatory-scrutiny-board_en

2

Observations and challenges in impact assessments and evaluations in 2025

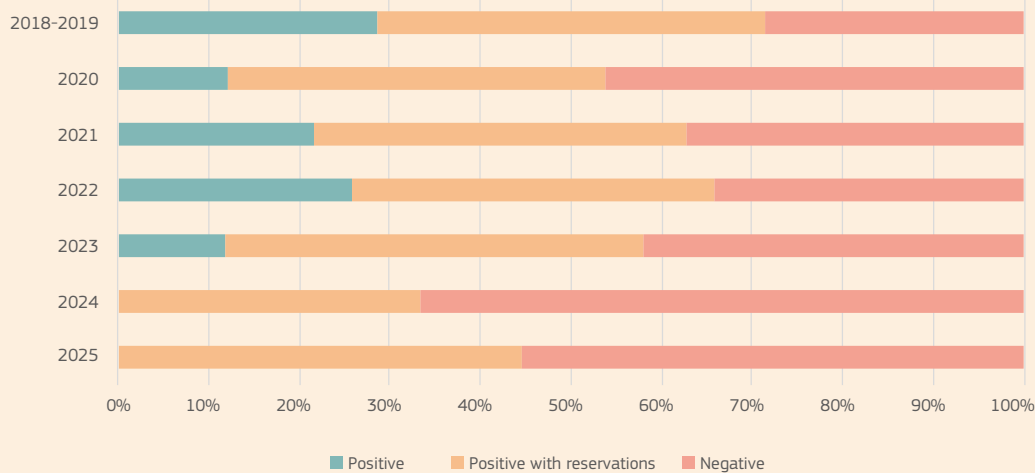
2.1 Impact assessments

2.1.1 Observations and challenges

The Board tracks the quality of scrutinised impact assessments based on two broad sets of indicators:

- The share of opinions that received a 'positive', 'positive with reservations' or 'negative' opinion type.
- The monitoring of 13 quality components, tracking the quality of different aspects⁽⁶⁾

Figure 2: Types of opinion for impact assessments at first submission per year



No 'positive' opinion...

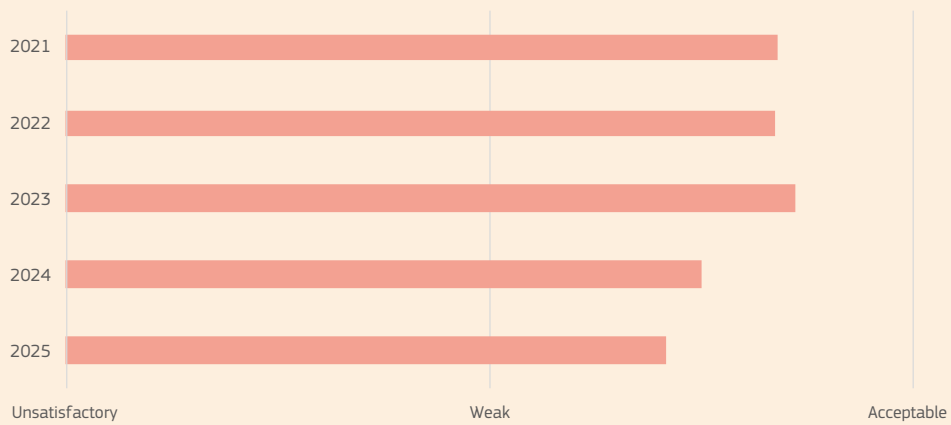
Regarding the first indicator (the share of 'positive' opinions), the Board did not give any positive opinion in 2025, while in previous years between 12 to 29% of the opinions were positive. In 2025, more than half of the impact assessments received a first 'negative opinion' (56%). All the remaining opinions were positive with reservations (44%) (see [Figure 2](#)). On the other hand, the Board has issued no second negative opinions, (i.e. negative opinions for a resubmitted impact assessment) since 2021.

... which is also reflected in lower average quality scores

The 13 quality components are intended to monitor the quality of different aspects of impact assessments over time. Each aspect is not necessarily equally important in every file, and calculating an average of them may not capture the full picture. Nevertheless, for illustrative purposes, it is arithmetically possible to calculate an average value, as shown below. This shows that the higher rate of negative opinions ([Figure 2](#)) also corresponds to lower values for the individual quality components.

(6) An 'average quality score' can be calculated by taking the sum of each score per variable and dividing it with the number of variables (13), in that case, each variable (or quality component) has implicitly the same weight. The above scores refer to first submission opinions. The 13 quality variables are the same as presented in [Figure 4](#). The RSB quality indicators and elements are set out in more detail in annex. It is a system developed to provide a structure for RSB analysis, to monitor work and to better advise services preparing future reports. It does not exhaustively describe or determine the considerations of the Board.

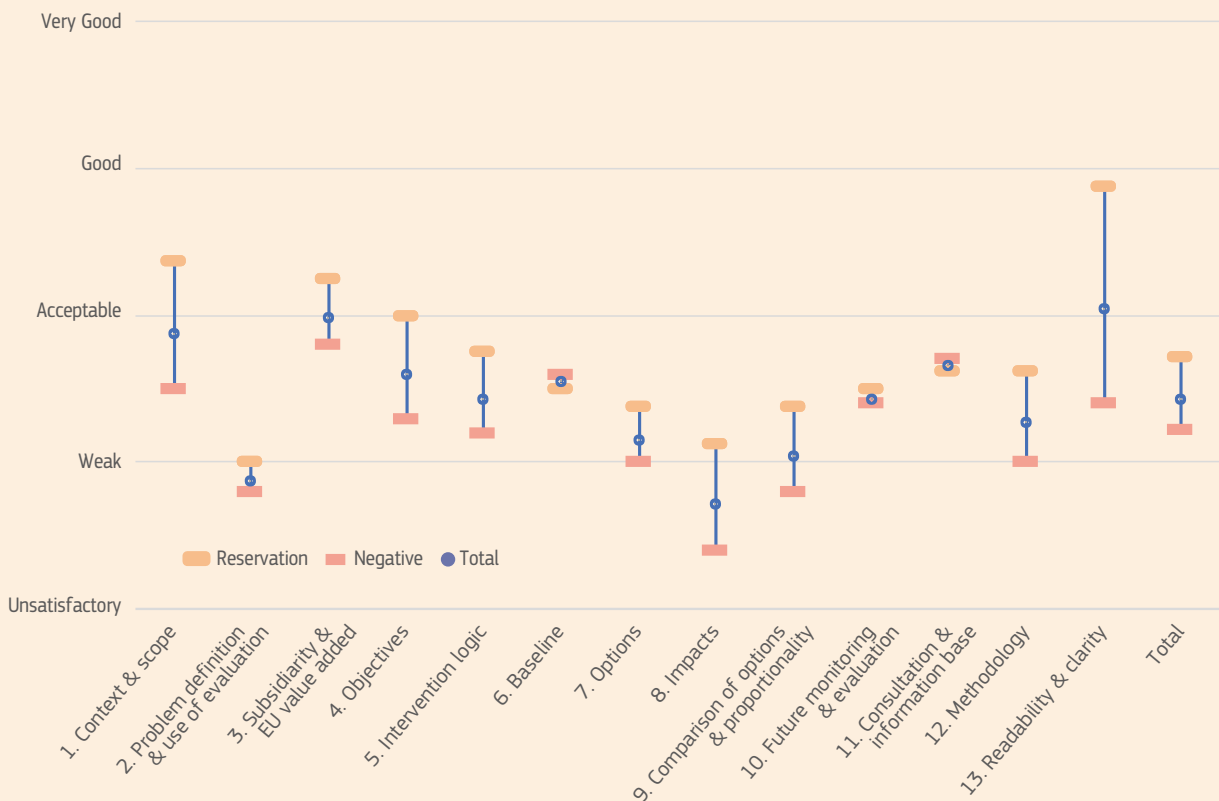
Figure 3: Average quality of impact assessments at first submission per year



Readability and clarity together with subsidiarity and EU value added were the strongest parts

Looking at the quality of impact assessments by quality component allows a more nuanced picture of the quality observed in 2025. Like in previous years, the quality components ‘subsidiarity and EU value added’ and ‘readability and clarity’ (criteria 3 and 13 in Figure 4), are the ones that received overall the highest quality scores.

Figure 4: Quality of impact assessments at first submission by quality component, 2025



Regarding the ‘readability and clarity’ component, the Board observed that all the cases with a first opinion ‘positive with reservations’ received on average a score close to ‘good’ quality. Preparing clear and easily accessible impact assessment reports is not self-evident, considering the technical and scientific nature of many initiatives. In this respect, the Board also noted that although only a limited number of services requested a derogation to the limit on the number of pages, services tended not to respect the recommended length set in the Commission’s better regulation guidelines (40 pages for impact assessments, 50 pages for evaluations), even though this is an essential element that facilitates the effective use of impact assessment and evaluation reports by decision-makers.

Regarding the ‘subsidiarity and EU value added’ component, the Board observed that the overall quality score was at an ‘acceptable’ to ‘good’ level for opinions ‘positive with reservations’. However, draft reports that received a ‘negative’ opinion often showed deficiencies in the demonstration of the necessity and added value of the EU action. In the corresponding opinions, the Board recommended better explaining why the objectives of the initiative could not be sufficiently achieved by Member States acting alone and substantiating this with evidence.

Several quality components show sufficient quality scores overall

As illustrated in [Figure 4](#), the quality components ‘context and scope’, ‘objectives’, ‘intervention logic’, ‘baseline’, ‘consultation and information base’, and ‘future monitoring and evaluation’ received on average weak to acceptable quality scores.

A clear presentation of the policy context, including the links to existing legislation and planned initiatives and a clear identification of the issues that fall within the scope is an essential element for a high-quality report, as it sets the scene for the development of a clear intervention logic as well as a dynamic baseline scenario. In 2025, like in previous years, the Board flagged serious contextual and scope issues, predominantly in several negative opinions, while reports that received an opinion ‘positive with reservation’ generally had a sufficient quality.

While in most of the scrutinised reports the definition of the objectives and of the intervention logic was generally of an acceptable quality, the related quality components were problematic in several reports receiving negative opinions. In these cases, these weaknesses often occurred together with other deficiencies, such as unclear problem definition, a limited identification of problem drivers or policy options unlikely to deliver on the specific objectives. In the corresponding opinions, the Board recommended establishing a clear and consistent hierarchy of objectives, expressing objectives in a SMART⁽⁷⁾ manner, coherently using them when comparing the effectiveness of the policy options and linking these objectives more clearly to key performance indicators when defining the future monitoring and evaluation arrangements. While the 2025 statistics on the latter quality component do not indicate any major deviations from the 2022-2023 quality findings, the recommendations made by the Board in its previous report, such as making better use of best practices presented in the better regulation toolbox, remain relevant.

(7) Specific, Measurable, Achievable, Relevant and Time-bound

For the analysis of impacts and comparison of policy options to be meaningful, there is a need for a baseline scenario that is sufficiently robust. As in previous years, the Board observed in several opinions either ‘negative’ or ‘positive with reservations’ that the baseline (see [criteria 6 in Figure 3](#)) was not dynamic enough, not sufficiently taking account of the expected impacts of parallel or recently adopted initiatives, technological evolution and/or market developments. As a result, in these cases, there was no appropriate benchmark established for comparison.

Regarding the ‘consultation and information base’ quality component, the Board found that the quality was comparable to the years 2022–2023. Several draft impact assessments that initially received a ‘negative’ opinion had deficiencies, such as not presenting the diverging or dissenting views of different stakeholder groups in a sufficiently transparent, granular and balanced manner or not paying sufficient attention to the non-representativeness of the feedback received. The Board also observed that several public consultations received only a limited number of responses, often those of a highly technical or scientific nature.

The problem definition, the design of policy options, their impacts, their comparison, and the methodology used were the weakest quality elements...

As in previous years, in 2025, on average the quality components ‘problem definition and use of evaluations’, ‘design of policy options’, ‘analysis of impacts’ and ‘comparison of options and proportionality’ received the lowest scores. This largely explains why a large share of impact assessments received a negative opinion at first submission stage

The component ‘problem definition and use of evaluation’ was an issue for all opinions positive with reservations and for all negative opinions. The average value for this quality component was significantly lower in 2025 than in 2023. In 2025, this quality was on average lower than weak for the files that got negative opinions at first submission stage, and on average weak for those obtaining a positive opinion with reservations. In comparison, in 2023, the same quality component was close to good for positive opinions, between weak and acceptable for positive opinions with reservations, and weak only for negative opinions. The Board noted that for some files, it was not clear what were the problems to be solved. In addition, in certain cases, it seemed that the problem tree had been designed to justify a particular policy option (‘retro-engineering’).

The identification of the problem drivers or root causes was also insufficient in many files. The poor quality of the problem (driver) definition impacts the quality of the whole impact assessment: getting the problem definition right is essential since it lays the groundwork for other essential quality components and for presenting a clear and consistent intervention logic. Furthermore, it is important that the preceding evaluation, if it exists, is of good quality and related findings are adequately used in the problem definition, including by concisely explaining any identified underlying regulatory or market failure(s) and the magnitude of the problem(s). In several cases, the Board found that the problem definition was not supported by robust evidence.

The definition of policy options was, on average, a weak quality component across all impact assessments which received a negative opinion in 2025 (see [criteria item 7 in Figure 4](#)). Options were often not designed in a way that clearly brought out the available policy choices and trade-offs. Regarding impact assessments labelled positive with reservations, on average, the score for this quality component was acceptable. As in previous years, the most common deficiencies included a too limited range of feasible options, “strawman” options designed to support a preferred option or not sufficiently reflecting on alternative combinations of options, thereby limiting the choice for policy makers. In several cases, the description of the policy measures was not clear enough to understand what exactly was intended to be done and in consequence what the impacts would be.

The quality component ‘impacts’ score for first submissions receiving a negative opinion was the lowest of all. In line with the findings presented in previous Board annual reports, deficiencies were often caused by the following: omission of certain impacts in the analysis; (over)reliance on opinion data; presentations of stakeholders’ feedback which were not balanced; analyses of the impacts lacking depth and/or rigour; uncertainties not being acknowledged. This seems to indicate that in several cases, data collection and analysis were given insufficient attention by the services preparing impact assessments, despite the approach recommended in the Better Regulation Guidelines.

The Board observed very limited changes as regards the quality component ‘comparison of options and proportionality’ (see [criteria item 9 in Figure 4](#)). The quality standards required by the Better Regulation Guidelines were in a number of cases not adequately met by the first submission reports. This resulted in weak scores for many draft impact assessments, irrespective of whether they received an ‘negative’ or ‘positive with reservations’ opinion. Some draft reports typically did not provide a clear comparison of all options in terms of effectiveness, efficiency and coherence. Frequently, the cost-benefit or multi-criteria analyses did not allow for a solid comparison of options and justification of the preferred set of measures. Frequently, the analysis of compliance with the principle of proportionality – including the commitment to legislate only where and to the extent necessary – was not sufficient. There were also instances where the Board raised concerns about the analysis and justification of the choice of the preferred option.

For the methodology component, quality scores were reported weak on average for impact assessments that received a negative opinion. In several cases, the Board recommended significantly improving the explanation of the underpinning methodological approach. It requested that reports should better present the level of overall confidence in the modeling as well as the most relevant assumptions underpinning the models. It also asked to indicate more explicitly how robust, credible and accurate the modelling results were. The quality of data and evidence was also pointed out as an area for improvement (see also the [special feature in chapter 3](#) on Challenges of evidence base for impact assessments).

2.1.2 Observed quality difference of resubmitted files

The ultimate objective of the scrutiny process is to ensure that the final impact assessment report that accompanies the legislative proposal for College decision is 'fit-for-purpose' and allows evidence-based decision-making. The scrutiny process takes place ahead of the presentation of the final impact assessment and adoption of the legislative process; this allows for deficiencies identified in the Board's opinion to be addressed prior to finalisation.

The Board's scrutiny is associated with an improved quality of impact assessments

For files having received a negative opinion in the first instance, the Board's quality monitoring system tracks the evolution of the quality components of the draft impact assessments when the draft report is submitted for the first time, and when a second submission is assessed. This evolution comparing 2025 with the preceding years is presented in **Figure 5** below.

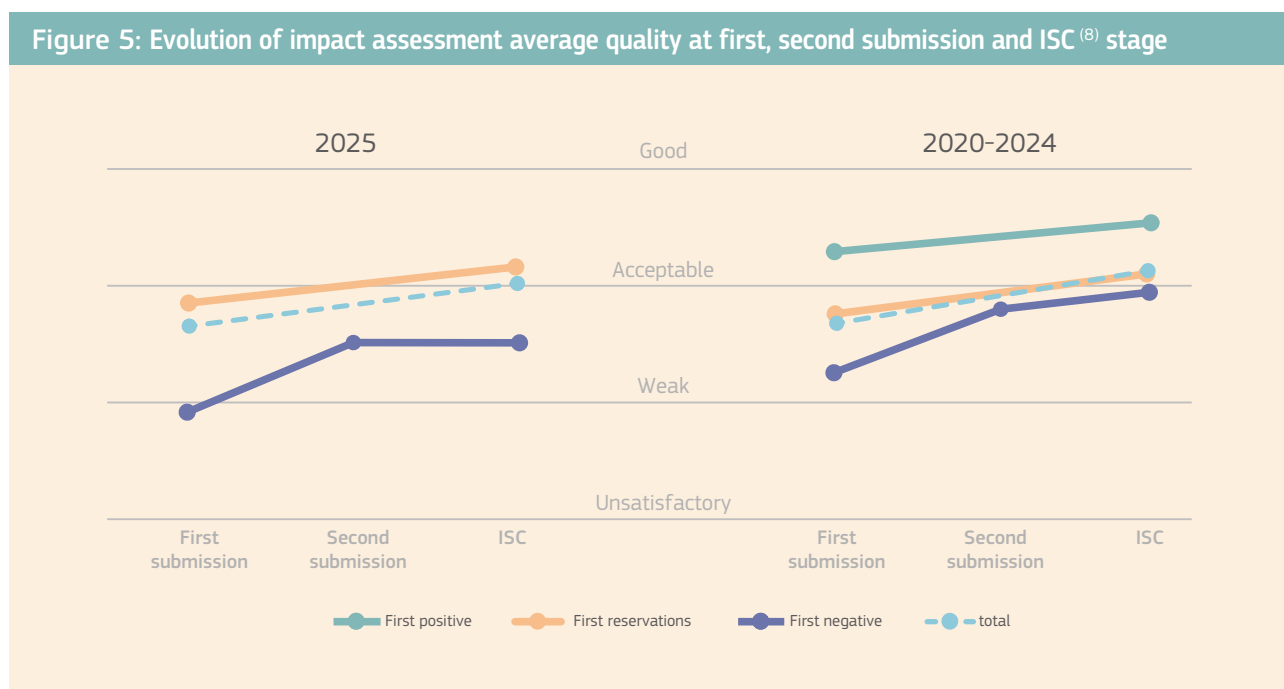


Figure 5 shows that at ISC stage all scrutinised impact assessments on average have an overall acceptable quality level and thus can be considered as 'fit for purpose'. The greatest improvement continued to take place between the first and second submission of draft impact assessments that received an initial negative opinion. This confirms the key role of the Board in ensuring that impact assessments are improved to the degree necessary to make them fit for purpose.

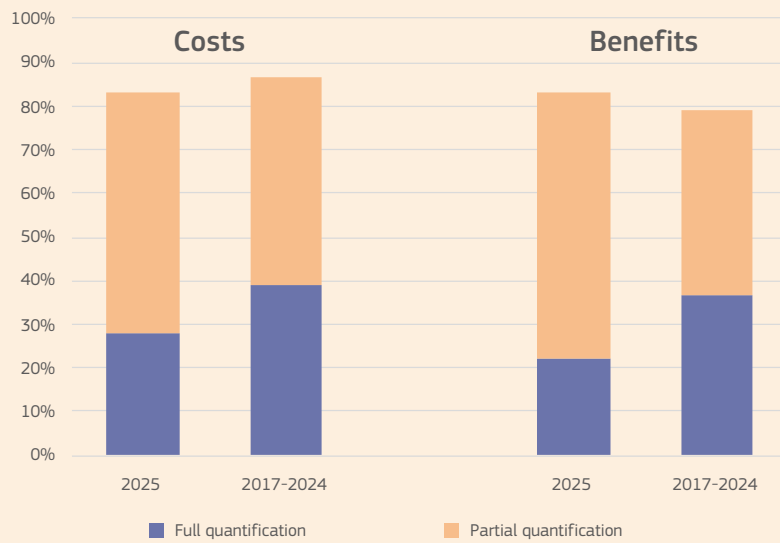
2.1.3 Quantification of impacts

Quantification remains a challenge

As **Figure 6** shows, the full quantification of the costs and benefits remained a challenge in 2025. While the Board acknowledges that, in certain specific cases, costs and benefits cannot be quantified, it underscores the need to quantify both costs and benefits to the extent possible and in a proportionate manner.

(8) At ISC stage, the Secretariat-General checks that the opinions of the Board are taken into account

Figure 6: Quantification of costs and benefits in draft impact assessments 2025 vs 2017-24



2.2 Evaluations: observations and challenges

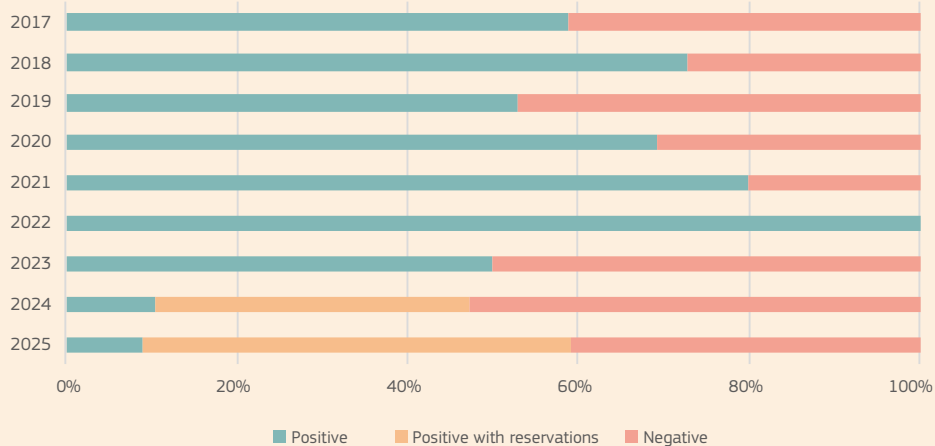
2.2.1 General observations

In 2025, the Board scrutinised 22 evaluations and fitness checks of existing legislation, compared to 19 in 2024. The Board again concentrated on spending programmes which made up more than half of all scrutinized evaluations, like in 2024.

Compared to 2024, there was a lower rate of negative opinions in 2025

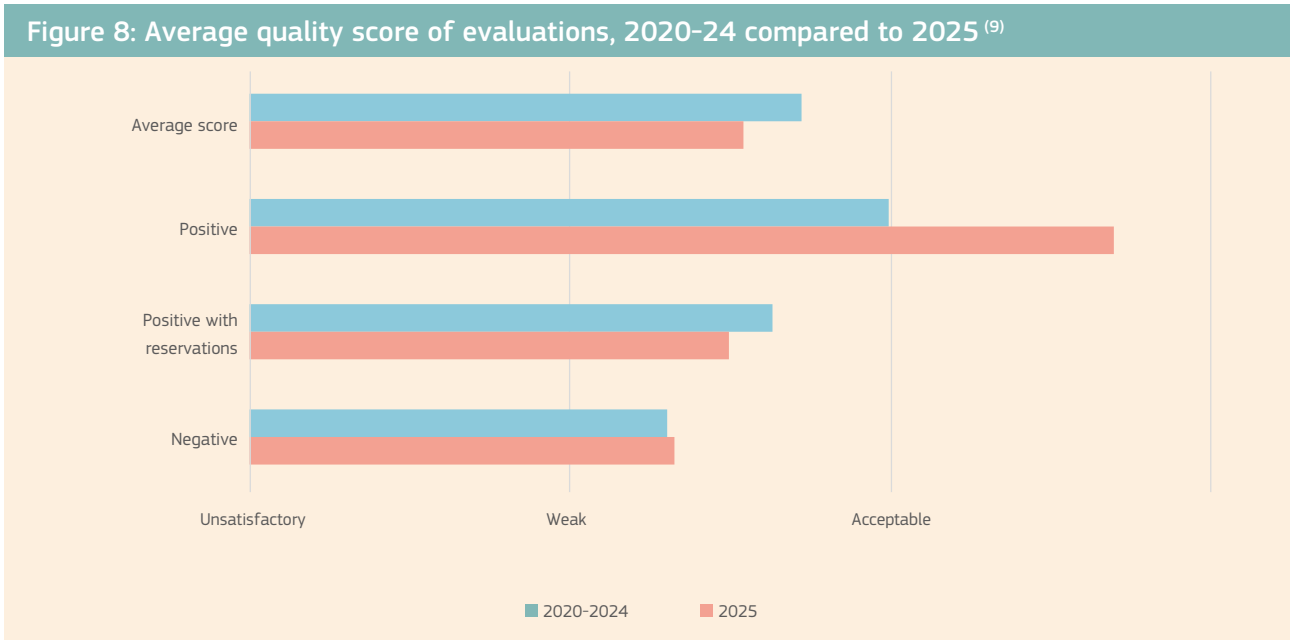
In 2025, 41% of the evaluations scrutinised (9 out of 22) received a negative opinion, which is a lower proportion than in 2024, when 53% of the evaluations scrutinised (10 out of 19) received a first negative opinion (see [Figure 7](#)).

Figure 7: Share of positive, positive with reservation, negative opinions for evaluations, 2017- 2025



The average quality score was low

The average quality score for the 2025 selected evaluations was below the 2017-2024 average (see [Figure 8](#)). It seems that the main challenges identified in the special feature of the 2024 annual report dedicated to evaluations persist.



2025 confirmed the previous observations on the high difference of scores between quality components

Evaluations are complex exercises. A good evaluation must address many aspects in the right way in the specific circumstances of the evaluated intervention, while considering the appropriate proportionality of the analysis. The Board's opinions in 2025 confirmed its previous observations on the high variability of scores of quality components.

Several quality components for evaluations performed well ...

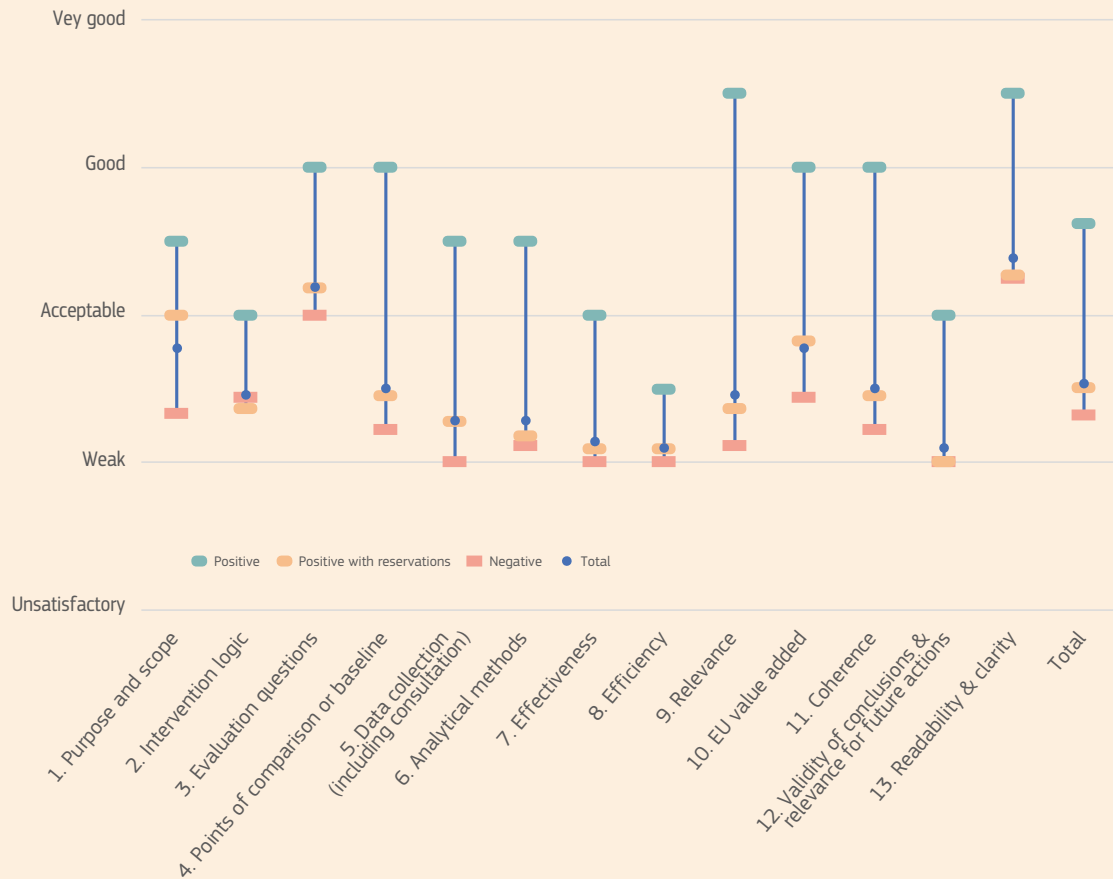
As already observed in 2023 and 2024, out of the 13 quality components assessed by the Board and presented in [Figure 9](#), two components performed overall well: 'evaluation questions' and 'readability and clarity'.

... while others had an average score of 'weak' or 'unsatisfactory'

By contrast, the quality components 'intervention logic', 'point of comparison', 'data collection', 'analytical methods', 'effectiveness', 'efficiency', 'relevance' and 'validity of the conclusions' overall received a (worse than) weak average quality score. This was the case for both opinion types 'positive with reservations' and 'negative'.

(9) The above scores refer to first submission opinions.

Figure 9: Quality of evaluations at first submission by quality component, 2025



The Board observed the lowest average quality scores for the quality component ‘effectiveness’, ‘efficiency’, ‘validity of conclusions and relevance for future actions’ as well as ‘analytical methods’. All reports having received a first negative opinion had a weak or unsatisfactory score on those components, and the evaluations having received an opinion positive with reservations also had weak score on these components.

The quality of the evaluations suffered from weaknesses in the quality of the evidence, data and underlying analytical methods

Evaluations are complex exercises. A good evaluation needs to get many aspects right in the specific circumstances of the evaluated intervention while taking into account the need for appropriate proportionality of the analysis and adhering to legal requirements regarding timing. The Board’s initial opinions from 2024 confirmed an observation of previous years on the high variability of scores of quality components. Looking at the overall quality of evaluations at quality component level provides some insights as to why evaluations received a positive, positive with reservations or a negative opinion.

In some opinions, the Board found that the conclusions did not adequately reflect the analysis of the evidence presented (and often lacked such analysis) or lacked a critical assessment of the robustness of the lessons learned. The Board also considered that the lessons learned from some evaluations did not inform possible future actions or were not adequately grounded in evidence stemming from the preceding analysis. It is also obvious that poor methodological design does not allow for drawing valid conclusions. As the component 'validity of the conclusions and relevance for future actions' is essential for future informed decision-making, it was one of the main reasons (together with other poorly performing quality elements) for the Board's negative opinions.

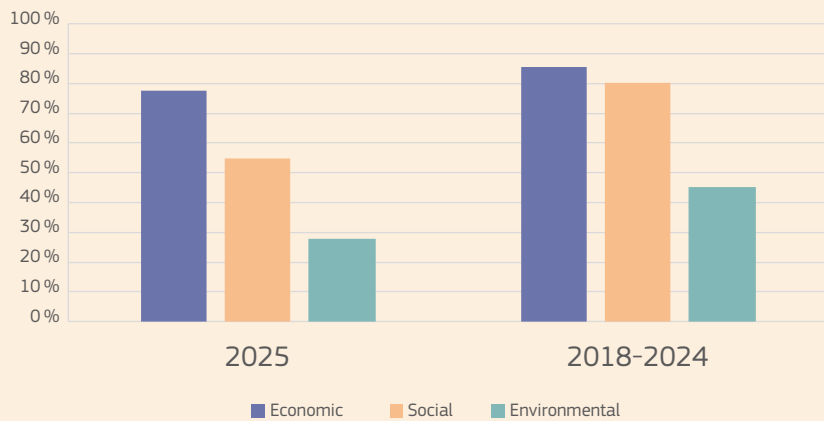
The quality component on 'Data collection (including consultation)' was another component with a weak score overall as well as a challenge for evaluations that received a positive opinion with reservations. A weak evidence base was often the consequence of a deficient monitoring system, not providing relevant data for causal analysis of benefits. Without a sufficient evidence-base built on observational data, many evaluations relied largely on opinion data, often from non-representative, self-selected samples of beneficiaries. Insufficient data was also directly linked to poor methodological design reflected in the overall low scores on 'analytical method'. The Board observed that the causal links between the intervention and observed effects were not clearly established while the reports failed to report on the absence of causality and were not explicit about the related limitations. Besides, evaluation reports neither sufficiently explained assumptions, estimates and calculations nor provided the limitations of their evidence base.

Additionally, the components 'effectiveness' and 'efficiency' overall had a weak average score. In several opinions, the Board noted that the analysis of effectiveness and efficiency was underdeveloped as regards the causal attribution of benefits to the evaluated intervention. The 'efficiency' quality component was weak for all evaluations, irrespective of the type of opinion. In several opinions, it was found that evaluations had not sufficiently developed the analysis of the potential for cost reduction, regulatory burden reduction or simplification. The Board requested more robust evidence that the administrative costs were not unduly high compared to the benefits. In several opinions, it was found that the reports did not rely on quantified indicators and measurable comparison factors for their analysis of effectiveness or did not sufficiently take into consideration the complexity of the context (e.g., various procedures, EU regulations, or national rules). It was also found in some reports that the justifications for the conclusions and lessons learned on effectiveness were insufficient or that the effectiveness analysis suffered from data limitations.

2.2.2 Types of impacts assessed and quantification of costs and benefits in evaluations

The Board monitors which types of impacts are, to some extent, assessed in the scrutinised evaluations. **Figure 10** shows that the three generic types of impacts (economic, social and environmental) were assessed in the scrutinised evaluations. The order was in line with the observations of previous years.

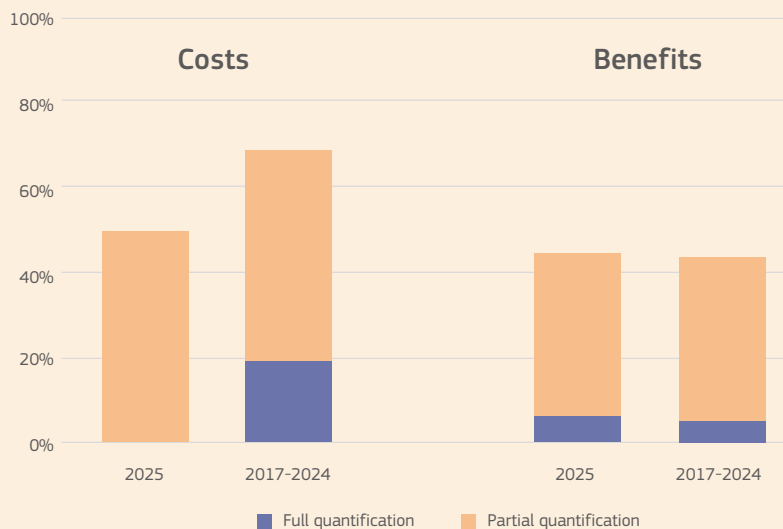
Figure 10: Types of impacts assessed in evaluations — 2025 compared to 2018-2024



Quantification of costs and benefits in evaluations

The level of overall quantification is lower in 2025 for costs, when compared with the 2018-2024 average for scrutinised evaluations (**Figure 11**).

Figure 11: Quantification of costs and benefits in scrutinised evaluations, 2025 vs 2017-2024



While in 2025 the quantification (at least partial) of both costs and benefits in impact assessments exceeded 80 %, the quantification in evaluations was below 50 %. The quantification of costs and benefits in impact assessments is modelled building on many assumptions. The quantification in evaluations should reflect the costs and benefits which have materialized and have been captured by data generated through monitoring and evaluation systems. The lack of quantifications in many evaluations may suggest deficiencies in these systems.

BOX 6: THE BOARD'S REPORTING AND MONITORING SYSTEM IN 2026 — UPCOMING CHANGES

With a view to simplifying its operations and based on years of experience and critical analysis of the added value of the current system, the Board decided to modify its monitoring and reporting system, to remove certain elements which were not bringing practical learnings and to focus on the key elements that are used for an interpretation and/or may trigger a decision. The corresponding modification of the IT tool started at the end of 2025 and will become effective in 2026 to support the drafting of the Annual Report 2026. The Annual report 2025 is therefore based on the current system.

2.3 Conclusions

In 2025, the Board issued a negative opinion for 56 % of the first submissions of relevant impact assessments and for 41 % of the evaluations and fitness checks. For impact assessments in particular, as in previous years, the 'problem definition', 'design of options', 'analysis of impacts' and 'comparison of options and proportionality' were the weakest quality components, even though these quality components reflect the core elements for an impact assessment to be fit for purpose. For evaluations and fitness-check reports, the quality components 'effectiveness', 'efficiency', 'validity of conclusions and relevance for future actions' as well as 'analytical methods' had the weakest scores overall.

While in principle the Better Regulation Guidelines and Toolbox provide sufficient overall guidance, the Board identified a need for reflecting how these systematic quality deficiencies could be better addressed. This should include looking into how services could better identify, obtain and use data, and apply appropriate methods to generate the necessary evidence. It would also involve making better use of internal expertise and ensuring the quality of procured external studies, bearing in mind that the analysis must be proportionate.

The Board also offered advice to Commission services through internal outreach activities as well as upstream meetings. In this context, the Board noted that upstream meetings with Commission services responsible for impact assessment or evaluation/fitness check reports may be a powerful tool to improve the quality of the reports, provided they meet a number of requirements in terms of scheduling, preparation and follow-up.

Finally, recurring weak scores in certain essential quality components point to the need to refocus the Better Regulation framework on core elements, thus increasing agility in view of the Commission's needs to act in response to emerging priorities. This should further enhance the quality of impact assessments, evaluations and fitness checks and allow for a more efficient use of resources.

3

Special features – Challenges of evidence base for impact assessments

3.1 Introductory remarks

In October 2024, the European Court of Justice ruled that EU legislators must produce ‘*and set out clearly and unequivocally the basic data on the basis of which [legislation is] adopted and on which the exercise of their discretion depends. When adopting a legislative decision, they must have ‘sufficient information to enable them to assess the proportionality’ of a given measure.* Furthermore, at the end of 2025, the Ombudswoman highlighted the importance of the evidence-based principle even in cases of urgency when finding that the ‘Commission should establish a procedure to ensure that the urgent preparation of legislative proposals still complies with the principles of a transparent, evidence-based and inclusive law-making process’.

This special feature focuses on the importance of data as an essential element for providing the necessary evidence on which to base policy decision-making, by building on the Board’s scrutiny work over recent years, in particular of Commission’s impact assessments. They are primary tools for decision-makers as they aim to provide them with the necessary evidence, which should stem from a systematic analysis of data, based on methods that can be scrutinized.

Observational data as an essential element for building evidence base for policy making

When building an evidence base, several types of data are needed (See [Box 7](#)). This special feature underscores the importance of observational data, the use of which could be enhanced. In light of digitalisation across the whole society and economy, the use of observational data, more and more digitally available, brings huge opportunities for evidence-based policy making.

BOX 7: EVIDENCE, OBSERVATIONAL AND OPINION DATA

According to the Better Regulation Tool #4 ‘*Reliable evidence is the cornerstone of ‘better regulation’... Reliable evidence is based on the appropriate method to collect, interpret, process and transform data and information*’

Tool # 67 on ‘*Data identification for evaluation and impact assessment*’ states that ‘*Stakeholder consultations provide **data on opinions**. Data from markets, balance sheets of firms, registries (health, social security, unemployment) etc. are observational data. **Observational data** can be micro (having records for every single individual or firms, etc.) or macro (as in national accounts aggregating data over a specific group). Data on opinions complement observational data. These two types of data are complementary but not substitutes.*’ Furthermore, observational data contribute to democratic policymaking by taking account of situations relevant to all stakeholders, including those who may be underrepresented.

Both observational and opinion data are necessary. The BRT underlines that ‘*Data needs to be relevant in respect to: (a) the impact assessment and evaluation criteria (b) the specific intervention logic. Therefore, using ‘the data that we have’, however tempting it is in a situation where evidence is limited, this should be assessed in view of its usefulness. The best data for impact assessments and evaluations is linked to the policy objectives and intervention logic.*’

Various observational data are already used in the Commission’s impact assessments and evaluations. Besides data provided by Eurostat, micro data (e.g. at the firm level) are increasingly being used, often with the support of the JRC. Additionally, modelling tools, which work with observational data, have been developed by the JRC and other Commission services (See [MIDAS^{\(10\)}](#), the *Modelling Inventory and Knowledge Management System of the Commission*).

(10) Explore MIDAS by departments | Modelling Inventory and Knowledge Management System of the European Commission (MIDAS): <https://web.jrc.ec.europa.eu/policy-model-inventory/explore/>

On observational data stemming from digital footprints

Widespread digitalisation in many operations and processes has the possibility to provide a wealth of data (see [Annex 4](#) for examples). This, coupled with increased possibilities for analysing data, including through artificial intelligence (AI), has resulted in major transformations across all domains, what and how data are used. Data ranging from satellite imagery data, anonymized credit card transactions and mobile operator information to corporate files in public registries, tax statements and extensive public sector administrative records including microdata etc. on the one hand, and advanced AI-powered analytics on the other hand are transforming how evidence can be generated, analysed and interpreted. Many sources of data, such as administrative microdata, are increasingly becoming accessible to researchers and evaluators (see [Annex 4](#) for illustration). The importance of accessing and better exploiting data is also reflected in recent proposals from the Commission, building on initiatives established since 2020 ⁽¹¹⁾, which aim inter alia at scaling up access to data, while complying with data protection rules.

3.2 Observations from the scrutiny work of the Board

The Board found that the use of observational data in impact assessments and evaluations is in need of improvement

Based on its scrutiny work over the last years, the Board observed that many reports lacked a clear identification of the necessary evidence. The Board noted that though data, including observational data, may have been available, they were often not sufficiently used to develop the necessary evidence. At times data used were not the most relevant and often methods and tools used to analyse the data were neither the most appropriate nor sufficiently used to perform the needed analysis.

As a result, the evidence necessary to respond to the key questions defined in the Better Regulation Guidelines and to assess the initiatives proposed was frequently not sufficiently developed. Two examples in 2025 where data and evidence were used to strengthen the (final) impact assessment are the proposed revision of the carbon border adjustment mechanism (CBAM) ⁽¹²⁾ and the resubmitted proposal for a Market Integration Package in the context of the Savings and Investment Union (SIU) strategy ⁽¹³⁾.

(11) E.g. 'A European Strategy for Data', COM(2020)66 — <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0066>;

'Data Union Strategy – Unlocking data for AI', COM(2025)835 — <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52025DC0835>.

(12) Impact Assessment Report SWD(2025)988 on a proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2023/956 as regards the extension of its scope to downstream goods and anti-circumvention measures, COM(2025)989 — [https://ec.europa.eu/transparency/documents-register/detail?ref=SEC\(2025\)989&lang=en](https://ec.europa.eu/transparency/documents-register/detail?ref=SEC(2025)989&lang=en)

(13) Impact Assessment Report SWD(2025)943 on a proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) No 1095/2010, No 648/2012, No 600/2014, No 909/2014, 2015/2365, 2019/1156, 2021/23, 2022/858, 2023/1114, No 1060/2009, 2016/1011, 2017/2402, 2023/2631 and 2024/3005 as regards the further development of capital market integration and supervision within the Union, COM(2025)943 — [https://ec.europa.eu/transparency/documents-register/detail?ref=COM\(2025\)943&lang=en](https://ec.europa.eu/transparency/documents-register/detail?ref=COM(2025)943&lang=en)

More specifically, the Board observed the following elements on the use of data and the related analytical methods:

The causal links between the identified problems and their problem drivers on the one hand and, on the other hand, between the problems and their consequences in terms of resulting costs posed a challenge. Similarly, the causal links between the policy measures considered and the expected benefits (*i.e. tackling the problem drivers to solve/mitigate the problems*) commonly lacked robust underlying evidence based on observational data. These issues, coupled with the fact that uncertainties were generally not clearly acknowledged, hampered the comparison of the effectiveness and efficiency of the policy options, despite modelling efforts.

Frequently, the analysis of the impacts, including the main benefits and costs, was not well substantiated by evidence. As a result, estimates were not sufficiently robust. Moreover, the reports did not systematically present the complete methodology utilized, including the input data used in modelling and underlying assumptions. The limitations stemming from the methods and the underlying data were not always identified, clearly communicated, and reflected in the conclusions of the analysis.

The data related to the costs were not always sufficient for establishing a complete account of the compliance costs for all groups of stakeholders. As a result, it was not possible to estimate both the aggregate and the marginal costs accruing to different stakeholders (including citizens and businesses) and to compare the efficiency of the policy options.

Many impact assessments relied mainly on evidence based on opinion data. The opinion data was used notably to overcome evidence gaps for assessing the causal links between the problems, the problem drivers as well as lack of evidence regarding the effectiveness of the policy measure proposed.

BOX 8: LIMITATIONS OF OPINION DATA

Collecting ways of stakeholders' views, including through open public consultations, is an indispensable part of democratic policy-making.

However, whereas opinion data provide important information, they cannot serve as a substitute for evidence based on observational data. Taken alone, opinion data is insufficient to build a solid evidence base for an impact assessment. Moreover, when opinion data is used it requires careful consideration of limitations and biases such as sampling errors, response errors, and cognitive biases. Contributions received represent the views of those that responded. Respondents to public consultations are self-selecting and are not a representative sample of the EU population.

The methods used to analyse data are essential for providing reliable conclusions

Frequently, when secondary evidence was used, the selection of concrete studies was not clearly explained, nor was the robustness of their results adequately assessed. This is a missed opportunity for enhancing the quality of impact assessments since a comprehensive review of existing evidence is essential for designing a meaningful monitoring and evaluation framework⁽¹⁴⁾. Such a synthesis would also help identify indicators, variables, data sources and methods which have been tested by the scientific and the evaluation communities.

The data collected must be analysed to turn them into useful evidence. Nonetheless, it is often difficult to know to what extent an observed change can be attributed to specific factors, including the policy initiative. As observed by the Board, the reliability of the conclusions of the analysis is determined by the quality of the evidence and in turn, by the quality and fit-for-purpose character of the underlying data and methodology.

Therefore, appropriate methods must be used to generate the evidence necessary for analysing in a proportionate manner the underlying problem drivers, deriving the intervention logic (ex-ante) and assessing the effectiveness of the initiative (ex-post). In this regard, Better Regulation Tool #68, 'Methods for evaluating causal effects' provides basic guidance on, among other things, experimental designs, regression discontinuity design, differences in differences, instrumental variables and matching methods.

In an impact assessment, the estimation of the benefits resulting from a regulatory intervention aiming at altering behaviours may be particularly challenging. It requires that the underlying evidence is sufficiently solid, and in this respect, cross-checking the robustness of the evidence is essential. Equally, the uncertainties concerning the extent to which the expected effects of an intervention reflect the underlying preferences and the observed behaviours must be transparently analyzed and communicated. As the expected benefits usually refer to states of the world that have not yet been attained (at least in a given context) and are often intended to be an alternative to market outcomes under the business-as-usual scenario, they cannot build on observed price signals that reflect underlying preferences and relative scarcities. In this context, Better Regulation Tool #69 'Emerging methods and policy instruments' provides a useful overview of the application of behavioural insights into a policy process.

(14) In this respect, it is important to note that the Board has observed that on average the [future] monitoring and evaluation component was assessed below acceptable (see e.g. 2023 Annual Report). This quality component has been rated among the weakest components of impact assessments which received positive opinions. A better ability to understand the benefits and costs and how they are causally related to the regulatory interventions is also critical for identifying obsolete and low added value rules, which – considering the objectives of simplification and regulatory burden reduction – should be considered for suppression.

3.3 Concluding remarks

Considering the principle of proportionality of the analysis as outlined in the Better Regulation Guidelines, continuous efforts should be made by those developing policy interventions to obtain evidence as robust as possible.

After a preliminary identification of problems to be tackled by the initiative and taking into account the key questions to be answered by an impact assessment, it is essential for Commission services to embark on developing a solid evidence base at an early stage.

Building on the intervention logic of the initiative, developing a solid evidence base involves (a) defining the evidence needs, (b) mapping of existing evidence and data sources⁽¹⁵⁾, (c) identification of evidence gaps and (d) addressing the gaps by additional data collection using appropriate combinations of methods for processing and analysing the data. In this context, building on the relevant parts of the Better Regulation Toolbox, it may also be useful to look at methods and tools developed elsewhere⁽¹⁶⁾ to reflect and propose an approach to services for assessing the robustness of the evidence and the suitability of the data and methods.

A synthesis of existing evidence through thorough desk research (literature review) is usually the first point of departure as it allows identifying the types of data, sources, and methods used in past evaluations and research. Latest advances in AI may help produce literature reviews, faster and more efficiently.

Monitoring and evaluation arrangements are essential elements of the impact assessment report. Building on those arrangements, which should not create an unnecessary or disproportionate administrative burden, the lead service should decide on the necessity of a data plan, after the adoption of each legislative text by the co-legislators. This should be done in cooperation with the relevant Commission services (e.g. JRC, ESTAT, chief economist units) and agencies. This plan should be based on an appropriate combination of methods, in line with up-to-date scientific knowledge, taking advantage of existing data sources, and advanced analytical methods. The proportionality of the analysis and the cost of collecting the data are to be duly considered.

When working with data and indicators, it is important to bear in mind the following considerations, as they may impact their quality: (a) whether the indicators and underlying data are a good proxy for the theoretical construct(s) in the intervention logic and whether the indicators cover all relevant aspects (are ‘fit for purpose?’). These are important questions impacting the validity of the data; (b) not all data may be accessible due to the confidential nature of certain data; (c) there may be systematic biases in certain data⁽¹⁷⁾; (d) certain data may be missing or may be incomplete for example when a certain type of event is not recorded systematically and (e) there may be issues linked to the consistency and standardisation of the data, for instance when administrative registers of Member States are the source.

Services often outsource supporting studies to contractors. When the contractors help with data collection and analysis, the required quality of the necessary evidence, the main data sources, the methods for data collection and the analytical methods to be used to produce such evidence should be defined by the Commission service. Outsourced studies should not replace the policy design work, including defining options, their assessment, and comparison. The JRC Competence Centre on Microeconomic Evaluation⁽¹⁸⁾ may provide more systematic advice and support.

(15) In this respect, data may be available from JRC, ESTAT, other relevant services and EU agencies

(16) Such as for example the THEARI framework described in ‘*Standards for evidence in policy decision-making*’ (https://osf.io/preprints/psyarxiv/fjwvk_v1) by Ruggeri, K., Lindezen, S., Wang, C., Papa, F., Riesch, J., & Green, J. (2020) or ‘*The Maryland Scientific Methods Scale*’ (<https://www.taylorfrancis.com/chapters/edit/10.4324/9780203166697-2/maryland-scientific-methods-scale-david-farrington-denise-gottfredson-lawrence-sherman-brandon-welsh?context=ubx&refid=1e6e60aa-e4d5-4884-972f-a41b86edae92>) by Farrington, D. P., Gottfredson, D. C., Sherman, L. W., & Welsh, B. C. (pp. 27–35 of *Evidence-based crime prevention*, Routledge (<https://www.taylorfrancis.com/books/edit/10.4324/9780203166697/evidence-based-crime-prevention-david-farrington-doris-layton-mackenzie-lawrence-sherman-brandon-welsh?refid=0b9b0f98-409c-4c8a-ae43-494ea28220cc&context=ubx>), 2003).

(17) For instance, a certain field is encoded only for successful candidates, dropouts are excluded from school registers, etc.

(18) **Microeconomic Evaluation** — https://knowledge4policy.ec.europa.eu/microeconomic-evaluation_en

A certain level of expertise and skills is necessary to enhance the use of both data and methods to generate a solid evidence base for the Commission's impact assessments. Building on the actions put forward in the context of the AI@EC communication, particularly those aiming at developing operational capacity to ensure the use of trustworthy AI technologies in the EC, Commission staff should continuously develop and acquire the relevant skills.

All in all, the guidance on data and methods provided in the Better Regulation Toolbox is useful but for it to more effectively support services when working on an impact assessment or an evaluation, it would benefit from being consolidated and made more operational. ⁽¹⁹⁾ Data collection aligned with the methods allowing to generate robust evidence, including a sampling strategy, is of key importance, providing corresponding details and examples in the Better Regulation Toolbox would be helpful for Commission services.

(19) For instance, a dedicated section on data, with a special focus on administrative and other data that can be retrieved from various sources, would be useful.

The Board expresses its great appreciation and deep gratitude to its former members who left in 2025

James Morrison and **Dorota Denning**



The Board welcomes the new Director
Doriane Givord-Strassel
who joined the team on 1 January 2026



The RSB team



Left to right: **Dr Rolf Höijer**, Member of the Board, **Sandra Van de Weyer**, Assistant, **Arianna Vannini**, Member of the Board, **Doriane Givord-Strassel**, Acing Chair and Director of the Board, **Dr Marek Havrda**, Member of the Board, **Claudia Di Dio**, Assistant, **Dr Alexander Gemberg-Wiesike**, Member of the Board, **Dr Emmanuelle Maincent**, Member of the Board, **Deirdre Hughes**, Assistant

The RSB Secretariat



Back row from left: **Ulrik Mogensen**, **Manol Bengyuzov**, **Hans Moons**, **Yianis Koutsikidis**, **Stefan Paduraru**, **Karolina Zalewska**, **Christoffer Branzén**, **Serge Le Gal**, **Zuzanna Targowska**
Front row from left: **Maria Gerolymatou**, **Mercedes De Miguel Cabeza**, **Marta Simon Martin**, **Antonina Cipollone**, **Ioana Cristina Condurat**, **Ima Gomez Lopez**, **Fabienne Corvers**, **Nikolaos Archontas**

ANNEX 1

Impact assessments and Evaluations 2025






















2025 Impact Assessments whose legislative act has been adopted by 1 March 2026:




The Board's opinions are published together with the impact assessment once the relevant legislative act has been adopted by the Commission.

Title	Opinion Submission 1	Opinion Submission 2	'Evaluate first' principle
Regulatory measure on ecodesign requirements for solid fuel local space heaters (review of Regulation (EU) 2015/1185)	ONGOING	ONGOING	Yes
Review of the Securitisation framework	●		Yes
Firearms Trafficking Directive	●	●	Not needed
Revision of the Drug Precursors Regulations	●		Yes
Sustainable Finance Disclosure Regulation (SFDR)	●	●	Yes
Train drivers' certification	ONGOING	ONGOING	Yes
Revision of Textile Labelling Regulation, harmonising physical and digital labelling and improving information conveyed to the consumer on textile and related products	ONGOING	ONGOING	Yes
Cyber Security Act review	●	●	Yes
IA on an Industrial Accelerator Act	ONGOING	ONGOING	Not needed
Grid Package	●		Not needed
Revision of EU legislation on registration, evaluation, authorisation and restriction of chemicals	ONGOING	ONGOING	Yes
Extension of the scope of the carbon border adjustment mechanism to downstream products and anti-circumvention measures	●		Not needed
Review of ESAs founding regulations and sectorial financial market legislation to foster single supervision and market integration	●	●	Not needed
Digital Networks Act	●	●	Not needed
Revision of the State aid Guidelines for rail transport	ONGOING	ONGOING	Yes
Ecodesign requirements for printers and cartridges	ONGOING	ONGOING	Not needed
Legislative proposal on clean corporate fleets	●		Not needed
Review of the CO2 standards for light duty vehicles	●		No

Positive opinion ●
 Positive with reservations ●
 Negative opinion ●

2025 EVALUATIONS *adopted by 1 March 2026*

Title	First opinion	Second opinion
Evaluation of the Standardisation Regulation		
Mid-term evaluation of the European Maritime, Fisheries and Aquaculture Fund (EMFAF) 2021-2027	ONGOING	
Review of the Erasmus+		
Interim evaluation of Asylum, Migration and Integration Fund (AMIF) (2021/2027)		
Interim evaluation of Integrated Border Management Fund — Border Management and Visa Instrument (2021-2027)		
Interim evaluation of Integrated Security Fund (ISF) (2021/202)		
Consumer programme evaluation		
Fitness check on EU energy security, evaluating the EU's security of electricity and gas supply framework		
European Regional Development Fund and Cohesion Fund 2014-2020 – ex-post		
The Comprehensive evaluation of the European Commission's Humanitarian Aid (2017-2022)		
Interim evaluation of the European Defence Fund		
Evaluation of the implementation of the EU Drugs Strategy 2021-2025 and Action Plan		
Mid-term evaluation of the LIFE programme 2021-2027		
Fitness check of EU rules on trade in seal products		
Evaluation of Creative Europe		
Interim evaluation of the Public Sector Loan Facility (PSLF)		
Evaluation of the Unfair Trading Practices Directive		
Midterm evaluation on the Digital Europe Programme		
Fitness Check on market access in inland waterway transport		
National Emission reduction Commitments Directive (NEC) Directive (2016/2284/EU)		
Evaluation of the Nitrates from agriculture polluting waters	ONGOING	
Evaluation of the legislative framework for tobacco control	ONGOING	

Positive opinion 
 Positive with reservations 
 Negative opinion 

As explained in 'Box 4 MFF proposals' the Board exceptionally decided to issue 'Opinions without qualification' for the MFF impact assessments submitted to the Board listed below. All files have been adopted by the Commission.

National and Regional Partnership Plans
European Competitiveness fund
Global Europe instrument
Cross-border education and training, solidarity, youth, media, culture and creative sectors, values, and civil society
Civil protection, preparedness, and response to crises
Single market and cooperation between national authorities
Performance framework

ANNEX 2

Acronyms

AI	Artificial Intelligence
BRG	Better Regulation Guidelines
BRT	Better Regulation Tool
EQC	Evaluation Quality Checklist
ESTAT	European Statistical Office
EV	Evaluation
FC	Fitness Check
IA	Impact Assessment
IAQC	Impact Assessment Quality Checklist
ISC	Interservice Consultation
JRC	Joint Research Centre
MFF	Multi-annual Financial Framework (2028-2034)
MIDAS	Modelling Inventory and Knowledge Management System
RSB	Regulatory Scrutiny Board
SMART	Specific, Measurable, Achievable, Relevant and Time-bound
THEARI	Theoretical, Empirical, Applicable and Replicable Impact

ANNEX 3

Glossary

Better Regulation

“Better Regulation” means designing EU policies and laws so that they achieve their objectives at minimum cost. It is a way of working to ensure that political decisions are prepared in an open and transparent manner, informed by the best available evidence and backed by the comprehensive involvement of stakeholders. better regulation covers the whole policy cycle, from policy design and preparation, to adoption, implementation (transposition, complementary non-regulatory actions), application (including enforcement), evaluation and revision (1)

More information on better regulation is available at https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how_en

Consultation

Consultation describes a process of gathering feedback, comments, evidence or other input on a particular measure from outside the Commission. There are various forms of consultation, including internet-based public consultation open to a broad audience and targeted consultation with the most concerned stakeholders.

Do No Significant Harm

No measure (i.e., no reform and no investment) should lead to significant harm to any of the six environmental objectives within the meaning of Article 17 of the framework to facilitate sustainable investment (the EU Taxonomy Regulation): (1) climate change mitigation; (2) climate change adaptation; (3) sustainable use & protection of water & marine resources; (4) circular economy; (5) pollution prevention & control and; (6) protection and restoration of biodiversity & ecosystems.

Evaluation

An evaluation is an evidence-based judgement of the extent to which an existing policy, programme or legislation is effective, efficient, relevant given the current needs, coherent internally and with other EU interventions and has achieved EU added value. In the Commission, the evaluation report is the Staff Working Document prepared by Commission departments. These reports are often based on underlying studies carried out by external consultants. The Regulatory Scrutiny Board examines major evaluations.

Fitness check

A Fitness check is an evaluation of the effectiveness, efficiency, coherence, relevance and EU added value of a number of related EU measures in a policy area or business sector. It identifies excessive burdens, inconsistencies and obsolete or ineffective measures and helps to identify the cumulative impact of legislation. The Regulatory Scrutiny Board checks the quality of all Fitness check reports.

Impact

In an impact assessment process, the term impact describes all the changes which are expected to happen due to the implementation and application of a given policy option/intervention. Such impacts may occur over different timescales, affect different actors and be relevant at different scales (local, regional, national and EU). In an evaluation context, impact refers to the changes associated with a particular intervention which occur over the longer term.

Impact assessment

Impact assessment is an aid to policy-making. It collects evidence on the problem, assesses if future legislative or non-legislative EU action is justified and how such action can be best designed to achieve the desired policy objectives. In the Commission, the lead department prepares impact assessment reports, which need to be submitted to the Regulatory Scrutiny Board for quality check. A positive opinion from the Board is in principle required in order to launch the interservice consultation for the related initiative.

Implementation

Implementation describes the process of making sure that the provisions of EU legislation can fully enter into application. For EU Directives, this is done via transposition of its requirements into national law, for other EU interventions such as Regulations or Decisions other measures may be necessary (e.g. in the case of Regulations, aligning other legislation that is not directly touched upon but affected indirectly by the Regulation with the definitions and requirement of the Regulation). Whilst EU legislation must be transposed correctly it must also be applied appropriately to deliver the desired policy objectives.

Initiative

An initiative is a policy proposal prepared by the European Commission to address a specific problem or societal need. An impact assessment assesses options to inform the policy content of the initiative.

Interservice consultation

Before the Commission takes its decisions, all relevant Commission departments are consulted on the draft legislative or non-legislative documents via “interservice consultations”.

Intervention logic

The intervention logic is the logical link between the problem that needs to be tackled (or the objective that needs to be pursued), the underlying drivers of the problem, and the available policy options (or the EU actions actually taken) to address the problem or achieve the objective. This intervention logic is used in both prospective impact assessments and retrospective evaluations.

One in, One Out (OIOO)

The Commission has committed to the one in, one out approach (OIOO). This means offsetting new administrative burdens resulting from the Commission’s proposals by reducing existing burdens, ideally in the same policy area. The Commission Communication ‘Better regulation: Joining forces to make better laws’, COM(2021)219 of 29 April 2021, sets out the main principles of the approach.

REFIT

REFIT is the European Commission’s Regulatory Fitness and Performance programme. Under REFIT, action is taken to make EU law simpler, lighter, more efficient and less costly, thus contributing to a clear, stable, least burdensome and most predictable regulatory framework supporting growth and jobs.

ANNEX 4

Examples of digital observational data

EXAMPLES OF OBSERVATIONAL DATA	DESCRIPTION	OBSERVED ADVANTAGES	POINTS OF ATTENTION
Administrative data in digital form	<ul style="list-style-type: none"> ■ Created as part of the routine operation of institutions, organisations, and public authorities (e.g. in tax collection, health systems, benefit administration, or school registers). ■ They are not collected specifically for research or evaluation purposes, but records are necessary for the operation of public services. 	<ul style="list-style-type: none"> ■ Availability and often full population coverage at micro level (individuals, firms, etc.). ■ May be used to derive indicators such as the number of registrations, service use, or the occurrence of events. ■ Valuable insights may be generated with various types of administrative data linked together (linked data). 	<ul style="list-style-type: none"> ■ Must be processed into an analytically usable form. ■ Potential data protection and security issues must be taken care of (e.g. by setting up procedures such as anonymization of data, safe environments (on-site safe data rooms), secure remote access, data spaces or cooperation with researchers internal to the institution holding the data).
Digital traces	<ul style="list-style-type: none"> ■ Arise passively when digital technologies are used. ■ Include logs, transaction records, or geolocation data. Typical examples are credit card transactions (location, amount, type of vendor), data from social networks (posts, interactions, network ties), mobile telecommunications data (call records, GPS tracks), and others. 	<ul style="list-style-type: none"> ■ Include large data volumes and high temporal granularity. 	<ul style="list-style-type: none"> ■ Method of data collection and indicator construction depends on the specific data source. ■ Need for (extensive) data cleaning. ■ They may not always be freely available as certain data are owned by private entities. ■ In non-anonymised form may be highly sensitive, requires compliance with data protection rules.
Data obtained from sensors and remote sensing	<ul style="list-style-type: none"> ■ Data produced through physical devices used for automatic collection of objective measurements. Examples include environmental sensors (air quality, temperature, humidity), GPS units for tracking movements, remote sensing devices (satellite imagery, LiDAR), or biometric sensors (heart rate, fingerprints). 	<ul style="list-style-type: none"> ■ Include large data volumes and high temporal granularity. 	<ul style="list-style-type: none"> ■ Need for extensive data cleaning and processing. ■ They may not be freely available as certain data are owned by private entities. ■ They may be sensitive.
Data obtained from the analysis of documents in digital form	<ul style="list-style-type: none"> ■ Documents directly reflecting a phenomenon may provide both qualitative evidence and quantitative observational data through the extracting information (e.g. words, references, logical structures). 	<ul style="list-style-type: none"> ■ Low-cost approach. ■ Detailed information may be obtained . 	<ul style="list-style-type: none"> ■ The documents most suitable to obtain such data are documents with a consistent structure, such as legislative texts (e.g. extracting obligations) or Court decisions (e.g. judgments). ■ Certain documents (e.g. complaints, clients' qualitative feedback) may not be easily available and accessible. ■ Extraction involves certain modern techniques and it may not be easy to verify the result data.

