



RSB

REGULATORY SCRUTINY BOARD

Annual Report 2022



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RSB

REGULATORY SCRUTINY BOARD

Annual Report 2022

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Foreword by the Chair



Rytis Martikonis
Chair

This report covers the seventh year of operation of the Regulatory Scrutiny Board, which continued the trend of the previous year with a high number of files to be scrutinised. The Board managed to scrutinise 70 impact assessments and 8 evaluations ⁽¹⁾, maintaining the workload of the previous year.

Building on the positive trend identified in last year's report the Board noticed in 2022 a further improvement in the overall quality of impact assessments and evaluations, with the second lowest rate of negative opinions for draft impact assessments ever observed by the Board. This demonstrates the continued commitment of the Commission services to produce high quality impact assessments and evaluations to inform political decision making effectively.

In our last annual report, we highlighted the importance of proportionality and coherence. This year we have a special feature on cost benefit analysis and on the implementation of 'one in, one out' approach. In 2022 the new requirements set out in the Better Regulation guidelines and toolbox became applicable to submitted reports. Our very first experience with the practical application of the new requirements and guidance tends to suggest that the new and strengthened tools help services to prepare balanced impact assessments, adequately balancing social, environmental and economic impacts in line with the overarching philosophy of the Commission integrated approach to impact assessments.

As in previous years, as well as performing its core function of assessing the quality of impact assessments and evaluations, the Board continued to provide advice to Commission departments at early stages of the preparations of their reports. Nearly 50 upstream meetings took place for 66 files during 2022.

The composition of the Board evolved further again in 2022, with two members leaving the Board (one internal, one external) and two joining (one external, one internal). Despite this, the Board remained under full strength and the decision was taken in December 2022 ⁽²⁾ to reinforce it with two extra members (one internal, one external) and to strengthen the Board's scrutiny on competitiveness. At the time of writing, the recruitment processes are underway to fill these posts. I am grateful to the outgoing Board members Bernard Naudts and to Antonio Nicita for all of their work. The Board wishes Bernard well in his retirement and Antonio well in his new role as a member of the Italian Senate. At the same time, I take this opportunity to welcome the Board's new members - Philippe Mengal and Elisabetta Siracusa.

As ever, I am grateful to the colleagues of Board secretariat for their dedicated support over the past year. They continued to function effectively despite the challenges of a sustained heavy workload.

⁽¹⁾ When this report refers to 'evaluation', this usually includes both (ex post) evaluations and fitness checks.

⁽²⁾ Decision of the President of the Commission P(2022)2 of 11.12.2022.

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Activities of the Board



Left to right: **Philippe Mengal**, Member of the Board; **Elisabetta Siracusa**, Member of the Board; **James Morrison**, (Director) Member of the Board; **Rytis Martikonis**, Chair of the Board; **Dr Dorota Denning**, Member of the Board; **Dr Michael Gremminger**, Member of 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. Within the Commission, in line with its mandate⁽³⁾, the Board scrutinises 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 Vice-President for Interinstitutional Relations and Foresight.

The Board provides independent quality control within the Commission

The Board is a quality control body governed by a mandate. It performs its task independently and prepares its opinions autonomously. It acts during the internal Commission phases preceding the preparation of 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.

In fulfilling its mandate as an internal, independent, and objective scrutiny body, the Board neither seeks nor takes instructions from any internal or external actor.

The Board's role is analytical

The work of the Board supports the implementation of the Commission's Better Regulation commitments, including on the 'one in, one out' approach and the integration of foresight into policy making. In its work, the Board also takes account of key principles such as 'do no significant harm', 'digital by default' and the UN Sustainable Development Goals (SDGs).

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 focuses on the quality of evidence, analysis and the logic of intervention. The Board assesses the files submitted to it objectively and solely on the basis set out in the Better Regulation guidelines and toolbox⁽⁴⁾.

⁽³⁾ Decisions C(2020)2 and C(2022)1.

⁽⁴⁾ SWD(2021) 305 final. https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox_en

The Board provides upstream advice

It provides independent quality control and support – via internal upstream meetings with Directorates General — for Commission evaluations and impact assessments at early stages preceding the Commission decision-making process.

Figure 1 shows how the Board’s internal quality control function fits within the Commission at the early stages preceding the preparation of legislation to make sure that the Commission proposals are based on clearly defined problems, on the best available evidence, are proportionate and take into account the full range of options and stakeholder views.

The Board issues opinions on draft reports

The Board issues different types of opinions on draft impact assessments and evaluations, with recommendations for improvements (for more details, see Box 2).

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 department 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, for evaluations the opinions are published together with the finalised evaluation.

BOX 1 : THE 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 department(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 on any likely weaknesses of the analysis, thereby allowing for adjustment of the problem definition, intervention logic, option structure and evidence gathering and methodology of the report prior to formal submission to the Board.

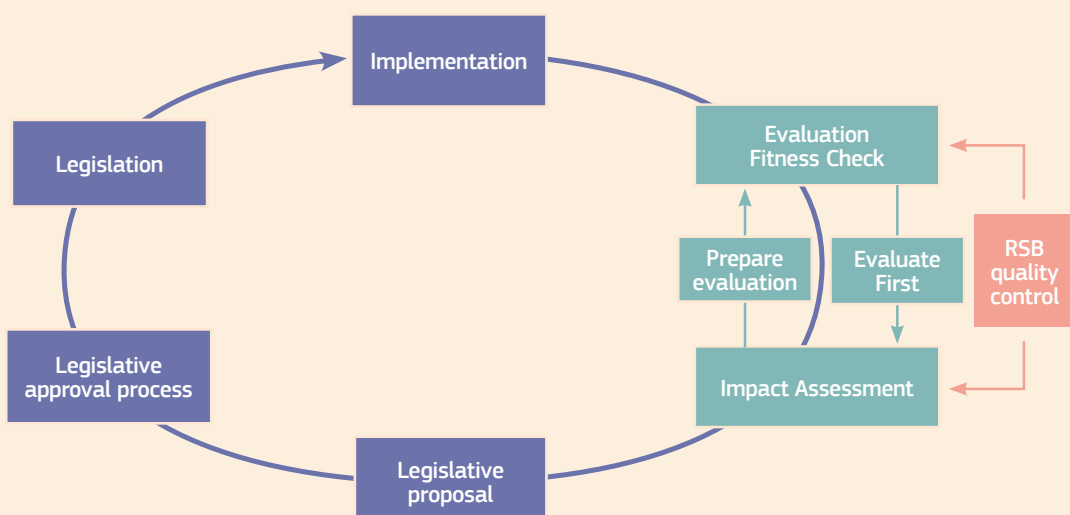
Once the Commission department has finalised its work on the draft impact assessment, it is formally submitted to the Board, normally four weeks before the Board meeting. All Board members read the full document and jointly produce a detailed impact assessment quality checklist (IAQC) using the criteria 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 departments three business days before the Board meeting. The department is invited to provide a written reply to the Board no later than the day before the Board meeting. Board members study any additional information provided in a written response to the checklist and take this into account in the questions they ask 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. There is also a possibility to have an upstream meeting, the Board produces an evaluation quality checklist (EQC), and after discussion in the Board meeting, the Board issues an opinion.

Board meetings are normally held on Wednesdays. The relevant departments are informed at the beginning of the 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 discussion among Board members to determine collectively the nature of the opinion to be issued. The opinion is normally submitted to the department on the following Friday.

During the full 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.

Figure 1: RSB role in the preparatory stages of the EU law-making cycle



BOX 3: TYPES OF RSB OPINION(S)

For impact assessments, there are three main types of Board's 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 and 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. In most cases, a resubmitted file will be sufficiently improved to address the Board's concerns and will be given a positive or positive with reservations second opinion.

In rare cases, the resubmitted text still contains fundamental deficiencies that have not been satisfactorily addressed. In these cases, the Board issues a **SECOND NEGATIVE OPINION ('DOUBLE NEGATIVE')**: The Board is still not satisfied with the way in which the revised draft impact assessment meets the standard set out in the Better Regulation guidelines and toolbox. The Vice-President for **Interinstitutional Relations and Foresight** then decides whether and in what form it may proceed.

For evaluations and fitness checks, there are only two types of Board's opinions: positive or negative. There is no obligation to resubmit a new version of the evaluation / fitness check to the Board after a negative opinion. This is because the Board does not scrutinise all evaluations, which could lead to unequal treatment. Nevertheless, when the Commission department judges that it can address the Board's remarks and improve the evaluation, it can submit a second version for a new opinion. So far, the Board has never given a second negative opinion on an evaluation.

1.1 How the Board performed in 2022

The Board's workload stabilised in 2022...

2022 was the third year of the von der Leyen Commission's mandate and the end of the emergency phase of the global COVID-19 pandemic, while a new emergency phase following the Russian war of aggression against Ukraine emerged. The increased flow of new initiatives that characterised 2021 was maintained with the remaining key legislative proposals designed to implement the broader strategic goals set out in the Political Guidelines of the President. Board staff turnover continued in 2022 and despite recruitment processes it remained below its full strength throughout 2022 increasing the workload on existing members. In December 2022, the President took the decision to reinforce the Board with an additional two members and to strengthen its scrutiny on competitiveness. The new members are expected to be recruited in 2023.

Back to the office... With the return to the office, in-person meetings resumed. However, all Board meetings, continued to be held online. For Board meetings, Commission departments were invited – if they wished – to submit written responses to the quality checklists issued by the Board. This facilitated discussions and Board deliberations. For more details on the Board’s working methods, see **Box 2**.

1.2 Sustained surge in scrutiny work

2022 saw 2021’s surge of scrutiny work largely maintained

2022 continued to be a busy year for the Regulatory Scrutiny Board, with 22 meetings and the third highest workload since 2016. This reflected the President’s ambitious agenda and the corresponding large volume of legislative proposals. The Board scrutinised 70 impact assessments (compared to 83 in 2021) and 8 major evaluations.

Table 1: Overview of Board regulatory scrutiny work by year, 2016-2022

Year	Meetings	Cases	Negative first opinions		Negative second opinions	
Impact assessments						
2016	22	60	25	42%	2	8%
2017	23	53	23	43%	1	4%
2018	27	76	21	28%	1	5%
2019	9	1	1	100%	0	0%
2020	23	41	19	46%	1	5%
2021	27	83	31	37%	4	13%
2022°	22	70	24	34%	0	0%
Evaluations*						
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%
° at the time of finalising the report, not all impact assessments with a first negative opinion had been resubmitted						
* resubmission of evaluations after a first negative opinion is optional						
⁺ in 2016, evaluations received opinions with comments, without mention ‘positive’ or ‘negative’						

... although fewer files received negative opinions...

The rate of negative opinions for initial submissions of impact assessments was 34%, which was an improvement on the 37% initial negative opinions in 2021. The initial negative opinion rate for evaluations was 0%, a significant improvement on the 27% rate in 2021, and well below the average between 2017 and 2020 of 40%.

Table 2 shows that one of the evaluations that were foreseen for scrutiny in 2022 was delivered on time, which is worse than previous years. However, seven of the scrutinised evaluations were delayed evaluations (7 out of 8), which indicates that some of the existing backlog was caught up.

	2017-2021 [°]	2022
Selected evaluations per year*	17	6
Evaluations presented on time	9	1
Delayed evaluations	8	5
Scrutinised evaluations per year	15	8
Evaluations presented on time	9	1
Delayed evaluations	6	7
[°] excluding evaluations that were removed from the list of selected evaluations [*] average per year		

1.2.1 Internal and external outreach

Outreach continued...

In 2022 Board members held over 20 meetings with stakeholders to explain the Board's role and took part in events on Better Regulation. The Annual Report for 2021 was presented at the Council Working Party in May. Board members had the opportunity to hold meetings with the European Parliament MEPS from different political groups ⁽⁵⁾.

The well-established practice of the Board holding 'upstream meetings' with the Commission departments to provide targeted advice at early stages of elaboration of the impact assessments and evaluations continued in 2022 with 50 meetings with Commission departments concerning overall for 66 different initiatives, consistent with 2021 (67 files) and 2020 (57 files), reflecting the steady flow of policy initiatives in the third year of the von der Leyen Commission.

⁽⁵⁾ A detailed list of all meetings of Board members in 2022 is available on-line: https://commission.europa.eu/system/files/2022-12/RSB%20-%20Meetings%20of%20Board%20Members%202022%20-Version%20published%20on%20Europa%20December%202022_0.pdf

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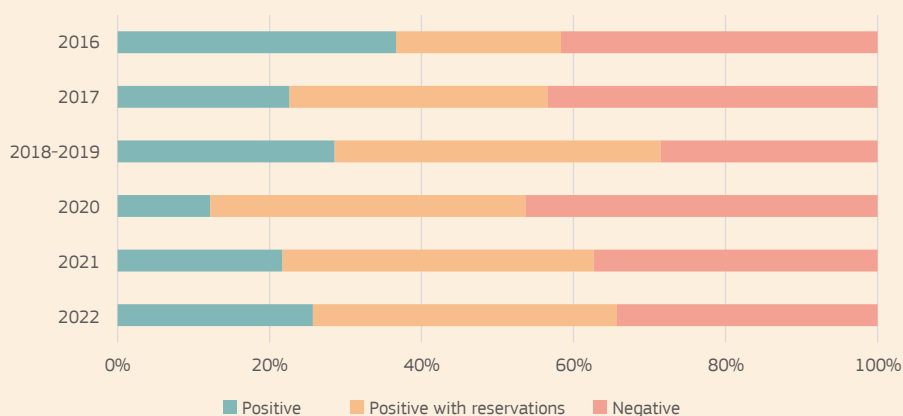
Trends and challenges in impact assessments and evaluations

2.1 Impact assessments: trends and challenges

The overall quality of impact assessments has further improved...

Building on the positive trend noticed last year, the Board observed in 2022 a further improvement of the scrutinised draft impact assessments. The percentage of ‘positive’ and ‘positive with reservations’ opinions on draft impact assessments rose and the percentage of ‘negative opinions’ dropped in 2022 in relation to 2021 and 2020. The percentage of negative opinions on first submissions (34%) was the second lowest since the establishment of the Board (see Figure 2).

Figure 2: Quality of draft impact assessments at first submission, 2022 vs 2016-2021 ⁽⁶⁾



...bringing greater predictability to policy development

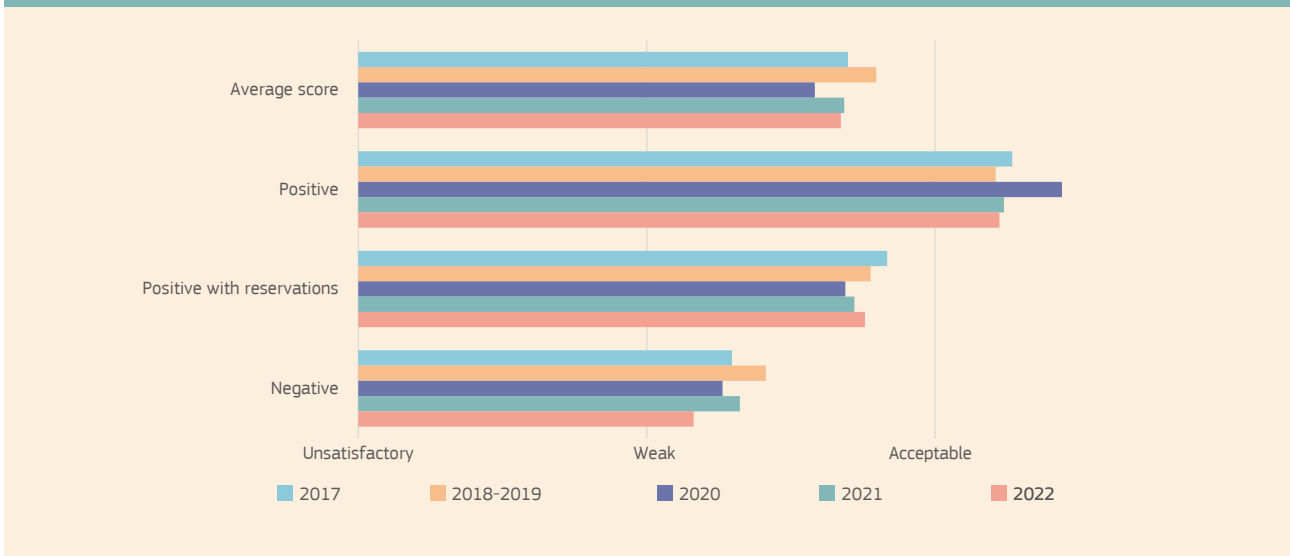
The observed improvement of acceptable overall quality in first submissions of draft impact assessments coincides with the Board’s general observation that there seems to be a positive relationship between the time and resources available to prepare an impact assessment, the effectiveness of the parallel inter-departmental coordination process and the quality outcome of the scrutinised draft impact assessment.

While this overall quality improvement trend is laudable, the development of the multi-criteria based ‘average quality score’ ⁽⁷⁾ indicators of initial submissions allows a slightly more differentiated picture of the quality observed. The average quality scores varied in a different manner depending on the opinion type of the draft impact assessment. On average, there was no significant change of the quality of initial draft impact assessment compared to last year (see Figure 3). Regarding the ‘positive’ and the ‘negative’ opinions, the quality has dropped for both in relation to the previous years, with a more significant effect for negative opinions. However, regarding the ‘positive with reservations’ opinion type, the average quality score has slightly increased and is almost as high as in 2018.

⁽⁶⁾ Note: 2018 and 2019 figures are indicated together due to the low cases in 2019, see table 1 above.

⁽⁷⁾ The ‘average quality score is calculated by taking the sum of each score per variable and dividing it with the number of variables (13), so that each variable has the same weight. The above scores refer to first submission opinions. The RSB quality indicators and elements are set out in more detail in annex 2. The 13 quality variables are the same as presented in Figure 4.

Figure 3: Average quality scores overall and by type of opinion



The analysis of impacts was the weakest part...

Assessment of impacts was the weakest element of all first submission impact assessments in 2022 (see criteria 8 in Figure 4). Draft impact assessments that received a negative opinion in absolute terms had the lowest quality markings.

As it can also be seen from Figure 5 most of the concerns raised in the Board's opinions relate to economic, social, societal, competitiveness and environmental impacts whereas the assessment of impacts on the EU budget, fraud or fundamental rights raised overall fewer concerns.

Deficiencies in the draft impact assessments were often caused by omission of certain impacts in the analysis, lack of or reliance on single sources of evidence, unbalanced inclusion of stakeholder feedback, lack of depth and rigor of impact analysis as well as lack of acknowledgement of uncertainties.

“Given the limitations of the evidence base and stakeholders’ feedback, the report should explain better the uncertainties of the impact analysis. In particular, it should account for the uncertainties of the key assumptions that drive the cost and benefit estimates by undertaking the sensitivity analysis. It should explain how the estimates are sensitive to alternative modelling assumptions.”⁽⁸⁾

RSB opinion on the draft impact assessment on the protection of from risks related to exposure to asbestos at work

The Board acknowledges 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.

⁽⁸⁾ RSB opinion on the draft impact assessment on the protection of workers from risks related to exposure to asbestos at work.

Figure 4: Quality of impact assessments at first submission by quality component, 2022



Problem definition, options and their comparison are other areas with frequent shortcomings

A low-quality score for the analysis of impacts often correlates with weaknesses in the problem definition, the design and the comparison of options. These elements, which are critical for building a clear and coherent *intervention logic*, received the lowest quality markings next to the assessment of impacts. Taken together they can explain to a large extent why certain draft impact assessments received overall a negative opinion by the Board.

Regarding the *problem definition and use of evaluation*, 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. They also did not sufficiently demonstrate the regulatory gap to be tackled. Even the best performing draft impact assessments just came close to an acceptable quality mark.

A good problem definition should also build on a clear presentation of the *policy context*, including the links to existing legislation and planned initiatives (i.e. policy coherence)⁽⁹⁾, and a clear identification of the issues that fall within the problem scope. While draft impact assessments that received a positive opinion usually had no issues with this, it remained a serious challenge for those that received a positive with reservation or negative opinion.

No significant improvement could be observed with respect to the *definition of options*. It remained one of the weakest elements of all first submission draft impact assessments in 2022 (see criteria item 7 in figure 4). The Board continued to observe often that the range of credible options considered was too limited, option designs were biased towards a preferred option, did not bring out clearly the available political choices or did not sufficiently anticipate combinations of options that were likely to emerge in the decisions making process.

The *baseline* (see criteria item 6 in figure 4 below) was often not sufficiently dynamic, being anchored too much in the past while not paying enough attention to the expected impacts from parallel or recently adopted initiatives, (disruptive) innovation and evolutionary market developments. More positively, the Board noticed in a significant number of cases the integration of foresight analysis when presenting the expected evolution of the problem and future-proofing options⁽¹⁰⁾.

A balanced *comparison of options* in terms of effectiveness, efficiency and coherence – informing transparently about all costs and benefits and the available trade-offs – is essential to allow fully informed decision-making on the best way forward. Many draft impact assessments, mainly those that received a negative opinion on first submission, did not yet meet this quality standard. The Board noticed often analytical inconsistency between the results of the impact and cost benefit analysis and the scoring of options. It noticed insufficient justification in cases where the preferred option was not selected based on the highest net benefits or best benefit cost ratio or support by key stakeholders.

On a positive note, the draft impact assessments that got a positive opinion continued to receive an ‘acceptable’ quality score for the comparison of options.

Presentation, objectives and subsidiarity were the best parts

In line with the findings of previous years, *presentation, objectives and subsidiarity and EU value added* remained overall the elements of draft impact assessments that received the highest quality scores, though with some variations and remaining potential for further improvement.

⁽⁹⁾ See also the special feature on coherence in the RSB Annual Report 2021 (pages 13-14).

⁽¹⁰⁾ The Board found that in 18 impact assessments scrutinised foresight elements were adequately considered. See also Figure 8. The Commission has made the greater use of foresight one of its key Better Regulation priorities. The Board already provided a special feature on integrating foresight and future proofing in its Annual Report 2020 (pages 31-33).

Regarding *subsidiarity and EU added value* of draft impact assessments with a positive opinion (and to some extent also for positive opinions with reservations) often had a very favourable quality score while those with a negative opinion performed clearly below acceptable quality norms. This strong variation probably can be explained by the different types of proposals scrutinised, with (targeted) revisions of long existing legislation often facing fewer challenges in respecting with the subsidiarity principle than proposals establishing new areas for EU action.

Presentation, which means readability and clarity of the draft impact assessment, was the element that received overall the highest quality score, with all ‘positive’ and ‘positive with reservations’ opinions having clearly an acceptable quality score. Preparing readable and clear impact assessment reports is not always an easy task given the often very technical and scientific nature of many initiatives and the challenge to translate this into an easily readable and accessible report for non-expert readers. The Board aimed to ensure that the length of the main reports generally respects the 40 pages length limit set in the Commission’s Better Regulation guidelines.

Monitoring, evaluation and consultation with further improvement potential

Effective *monitoring* arrangements clearly linked to operational objectives and credible indicators are essential to measure progress and ultimately, the success of an initiative. Clear *evaluation* commitments and timeliness help to ensure whether the proposal is delivering on the objectives in an effective and efficient manner, whether it adds EU value and whether timely improvement measures should be envisaged. While monitoring and evaluation were overall not the greatest quality challenge area for draft impact assessments the Board continued to observe in 2022 that draft impact assessments often just envisage the minimum requirements and did not yet fully make use of available best practices as for instance advocated in the Better Regulation toolbox. This is a missed improvement potential which makes effective progress monitoring, future evaluations, and timely corrective action more challenging and potentially also more costly.

“The section on future monitoring and evaluation should be further developed. It should define operational objectives and identify core monitoring indicators for the specific policy objectives against which progress will be evaluated. It should be more specific about what kind of information to look for and define indicators to monitor outcomes.”⁽¹¹⁾

RSB opinion on the draft impact assessment on fighting organised crime

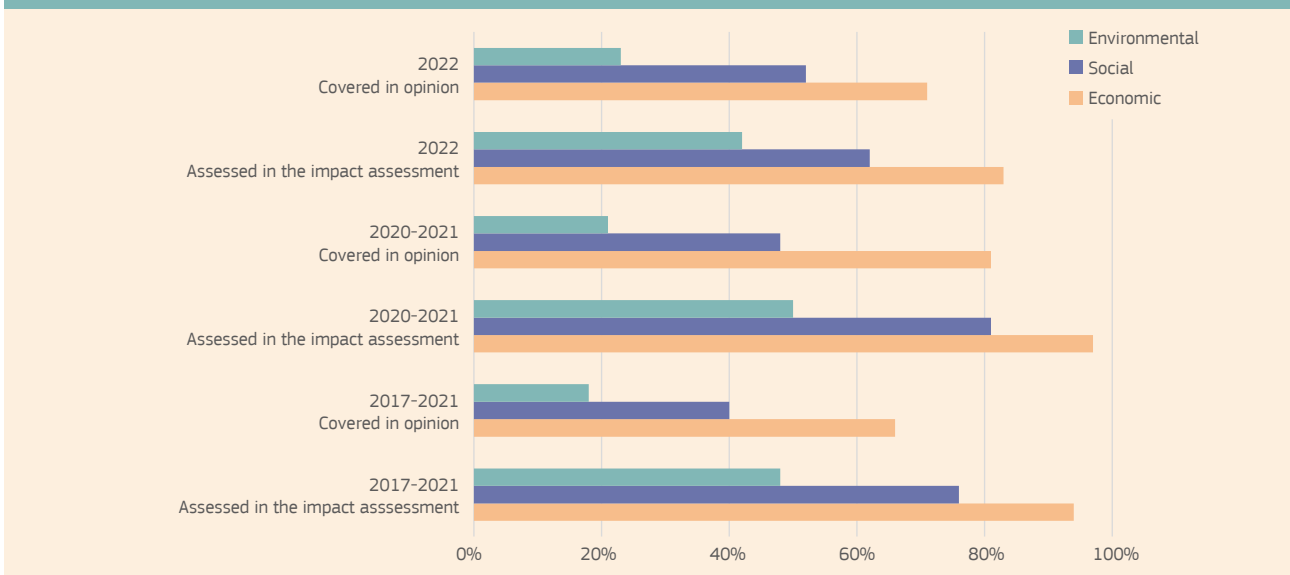
⁽¹¹⁾ RSB opinion on the draft Impact assessment on fighting organised crime.

In line with the results from previous years *consultation* is another element with clear potential for improvement. In particular, draft impact assessments receiving an initial negative opinion often had major deficiencies, such as not sufficiently presenting the often contradictory views of different stakeholder categories in a sufficiently transparent, granular and balanced manner. This often includes not paying sufficient attention to the non-representativeness of the stakeholder feedback received or the overall lack of views of some affected actors, including more vulnerable groups.

More environmental and social impacts covered in Board's opinions

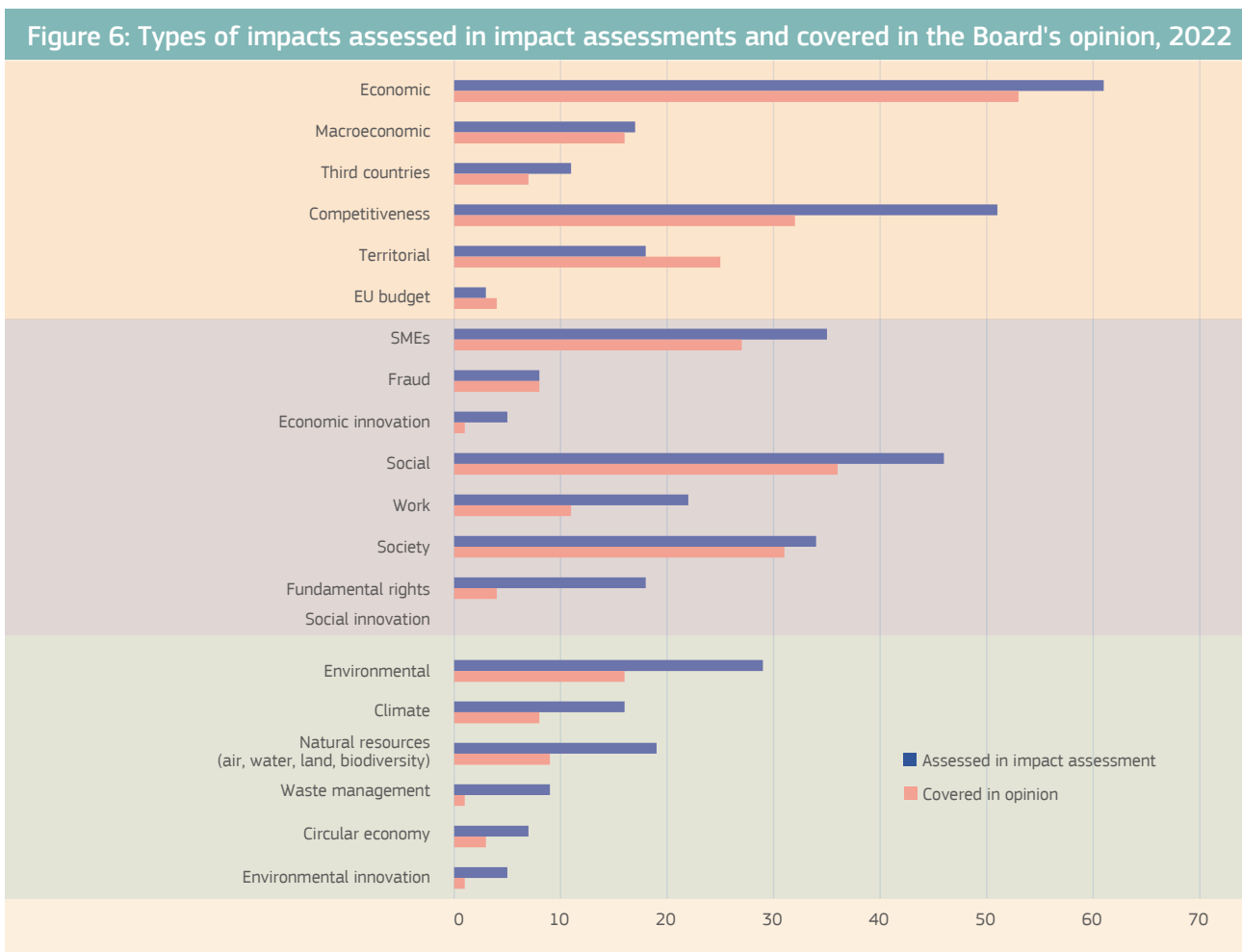
In 2022, economic impacts, which included cost and benefit estimates of all types of measures, continued to represent the most frequent category of impacts assessed in draft reports, followed by social and environmental impacts. While this was broadly in line with the pattern observed in the previous years, the Board issued in 2022 more recommendations with respect to environmental and, in particular, social impacts (when compared to the 2017-2021 average), to ensure sufficiently balanced implementation of the Commission's integrated impact assessment approach as stipulated in its Better Regulation guidelines and toolbox.

Figure 5: Types of impacts assessed in impact assessments and concerns raised in the Board's opinion, 2022 vs 2020-2021



Not all impacts were assessed to the same extent

Regarding specific impacts, Figure 6 outlines in more detail the impact statistics for 2022 (based on the 1st submission of draft impact assessments). It shows that almost all types of impacts were assessed and addressed by Board's opinions. Next to economic and social impacts, impacts on society and competitiveness as well as on SMEs and territorial impacts featured most prominently in the Board's opinions. When comparing the coverage of impact types in draft impact assessments with those in the Board's opinions, territorial impacts and the impacts on the EU budget were the most 'missing' type of impacts. The Board will continue to scrutinise whether different regional and other distributional impacts are assessed in impact assessments as appropriate and where relevant.



Competitiveness and SME impacts

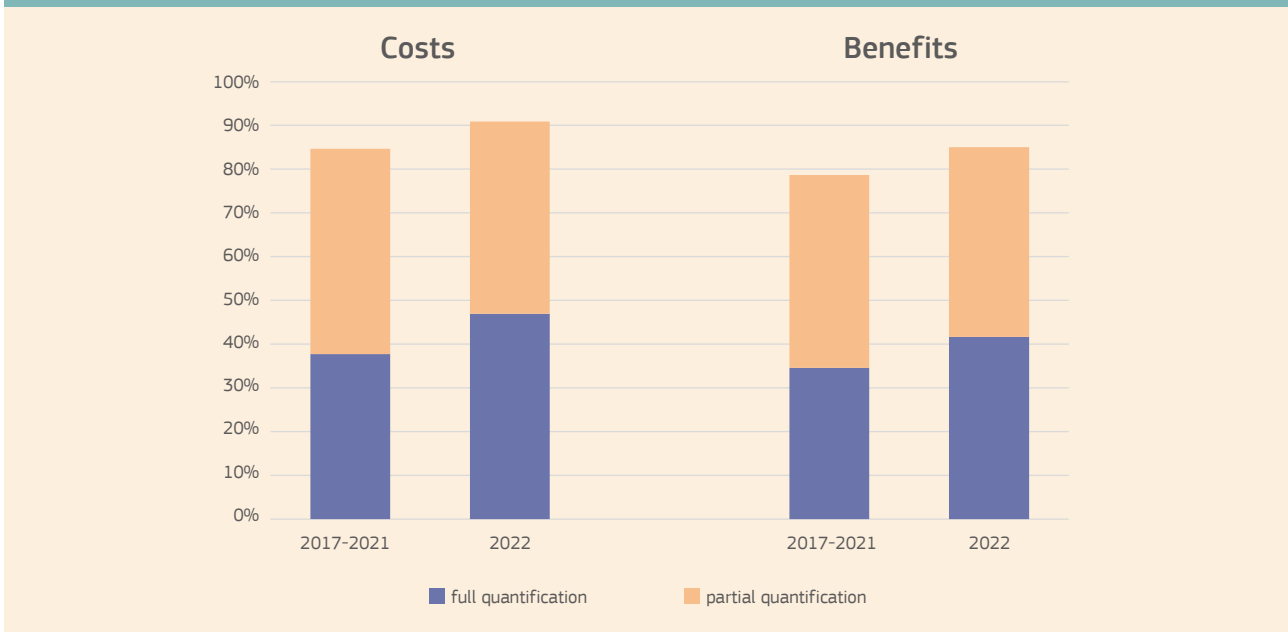
In 2022, the analysis of competitiveness issues was the second most frequently assessed impact category in submitted draft impact assessments. It also featured among the most frequently made recommendations in Board's opinions. Recommendations on competitiveness are often linked to or made together with more specific recommendations, such as on innovation, jobs and skills, investment, or the Single Market. Often a particular focus is given to the competitiveness of SMEs and the proper application of the SME test.

In line with the Commission’s renewed focus on a growth enhancing regulatory framework as part of its competitiveness strategy⁽¹²⁾ and the strengthened mandate of the Board⁽¹³⁾ the assessment of competitiveness impacts will continue to feature in the scrutiny work of the Board, including the correct application of the new ‘competitiveness check’.

Further progress on quantification

The proportion of draft impact assessments with quantified analysis on costs and benefits (both fully and partially) further increased during 2022 in relation to the previous five years’ average with respect to both benefits and costs.

Figure 7: Trends in quantification of costs and benefits in draft impact assessments, 2022 vs 2017-2021⁽¹⁴⁾



Scrutinising new Better Regulation requirements

The Better Regulation Communication of April 2021 introduced several new requirements that Commission impact assessments must comply with and that are subject to quality scrutiny of the Board. These requirements concern the ‘one in, one out’ approach, the mainstreaming of the Sustainable Development Goals, ‘climate consistency check’, the integration of strategic foresight analysis, the application of the ‘do no significant harm’ and the ‘digital by default’ principles and are covered for the first time in this year’s Board report.

⁽¹²⁾ https://commission.europa.eu/document/download/af444130-5a3e-44f2-bea6-5b9ddcb46012_en?filename=Communication_Long-term-competitiveness.pdf

⁽¹³⁾ Decision of the President of the Commission P(2022)2 of 11.12.2022.

⁽¹⁴⁾ Percentages include only cases where quantification was judged to be required on proportionality grounds.

The corresponding performance statistics in Table 3 indicate the scope for improvement regarding these new aspects in the 2022 first submission impact assessments, with sufficient analysis on the 'digital by default' principle being the best performer. 'One in, one out' and the 'climate consistency check' were, in a majority of cases, not sufficiently considered in the first submissions. A sufficient quantification of costs for the 'one in, one out' approach at first submission was the most difficult aspect out of the new Better Regulation requirements – despite the improvement made in the overall quantification of costs and benefits as reported earlier (see also Figure 7). In its opinions the Board often underlined the need to quantify, to the extent possible and proportionate, the costs and cost savings that are relevant for the 'one in, one out' approach and that the estimates should be clearly and consistently presented in the main report and annexes (see also special feature on this).

This implementation challenge was to be expected given that the new elements became mandatory standards only as of as 1st January 2022, following also the publication of the updated Better Regulation guidelines and toolbox in November 2021. Past experience showed that fully mainstreaming new requirements into the policy preparation practices of the services usually took some time, partly because new requirements were not sufficiently anticipated or reflected in preparatory studies or data collection exercises. Improvements should be achieved more easily regarding 'climate law consistency' and 'digital by default' while the other elements may require more analytical efforts.

Regarding the use of 'strategic foresight' the Board observed greater use of foresight tools in the preparation of impact assessments and evaluations compared to the previous year. Foresight analysis, for instance, helped to describe the expected problem evolution under the dynamic baseline scenario, and the relevance assessment in evaluations.

Overall, there is a need to further improve the compliance with the new impact assessment requirements. The Board will continue to pay special attention to their proper implementation. It will engage with the Secretariat-General on how to further improve the quality of these new elements. It will also more systematically raise the need to fully respect the new Better Regulation compliance standards in its upstream support meetings with the respective responsible Commission departments.

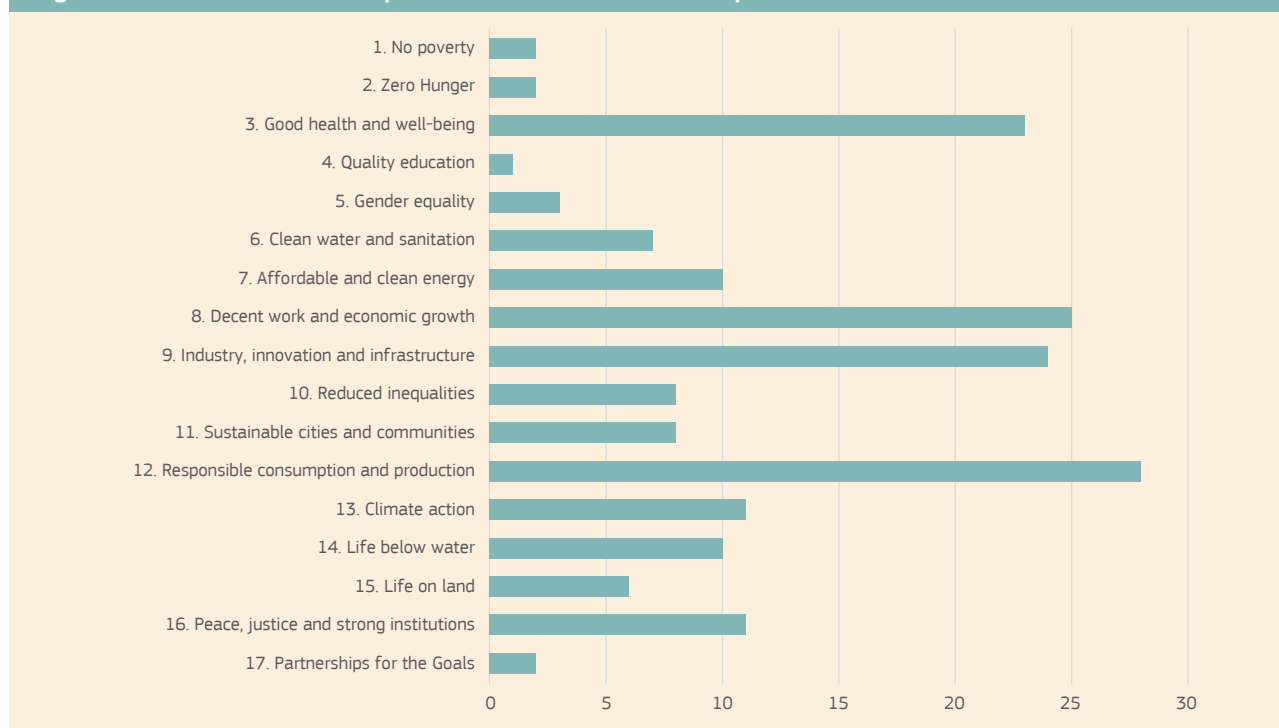
Table 3: Assessment of new requirements in impact assessments 2022

First submission	Total IAs	Yes	No	Not relevant	% yes out of relevant
Sufficient quantification of costs for 'one in, one out'	70	23	32	15	42%
Sufficiently assesses consistency with the European Climate Law	70	21	16	33	57%
Sufficiently analyses the 'do no significant harm' principle	70	25	10	35	71%
Sufficiently analyses the 'digital by default' principle	70	29	6	35	83%
Foresight elements adequately considered	70	18	21	31	46%

Links to Sustainable Development Goals

The Better Regulation Communication of 2021 made also a commitment to identify relevant UN Sustainable Development Goals (SDGs) for each Commission initiative and to include links to the SDGs throughout impact assessments and evaluations. The SDGs have been identified in impact assessments for the first time in 2022 (see Figure 8). While Commission proposals prepared in 2022 covered all SDGs, they were mostly related to the following four: responsible consumption and production (SDG 12), decent work and economic growth (SDG 8), industry, innovation, and infrastructure (SDG 9) and good health and well-being (SDG 3).

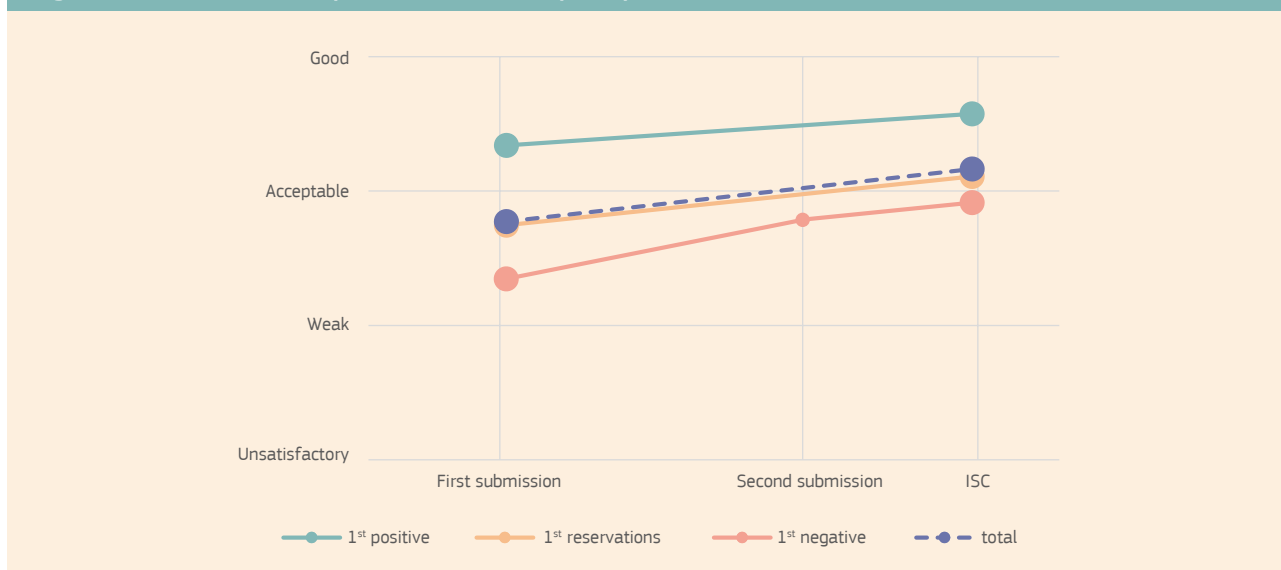
Figure 8: Sustainable Development Goals identified in impact assessments in 2022



The Board's scrutiny overall improved quality of impact assessments

Figure 9 shows that all impact assessments with a positive or positive with reservations opinion had an acceptable quality level⁽¹⁵⁾ at the end of the interservice consultation stage, before reaching the College for decision-making. The greatest improvement continued to take place between the first and second submission of draft impact assessments that received an initial negative opinion. All these indications taken together confirm that the scrutiny of the Board plays an instrumental role in ensuring the quality of Commission impact assessments.

Figure 9: Evolution of impact assessment quality 2022



2.2 Evaluations: trends and challenges

Fewer evaluations scrutinized but many back-to-back evaluations

In 2022, the Board scrutinised significantly fewer (8) self-standing evaluation reports than in the preceding three years. This might be explained on the one hand by the fact that the number of new proposals and the need for preceding evaluations often decreases in the final years of a Commission mandate. On the other hand, there was a significant number of evaluations, which were annexed to and scrutinised as part of the corresponding impact assessments (so-called ‘back-to-back’ evaluations), and thus did not receive a separate Board's opinion.⁽¹⁶⁾ Yet the Board's opinion on such draft impact assessments also covered the quality of the evaluation and how its findings contributed to the problem analysis. While the increased use of back-to-back evaluations allows analytical synergies and still allows the Commission to comply with the ‘evaluate first’ principle (see figure 10) and to respect political delivery commitments, this can come also with several shortcomings.

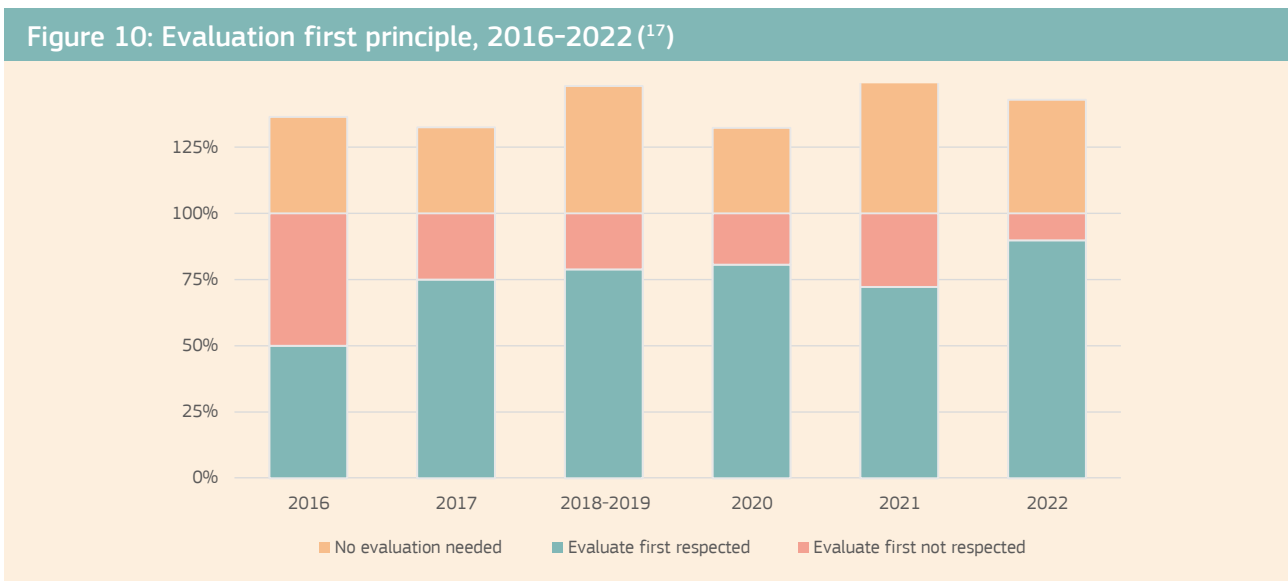
⁽¹⁵⁾ The overall quality score represents an average score, which is calculated by taking the sum of each score per variable and divide it with the number of variables (13).

⁽¹⁶⁾ Evaluations and impact assessments are usually conducted sequentially so that the results of the evaluation can be fully used in the subsequent impact assessment.

Highest compliance rate ever observed for the ‘evaluate first’ principle

The Board observed in 2022 overall a significant increase in initiatives complying with the ‘evaluate first’ principle, following the decrease noticed in the year 2021 when compared to the average of 2017-2020 (see Figure 10). In fact, 2022 saw with almost 90% the highest compliance rate ever observed (not counting the ‘no evaluation needed’) since the introduction of the ‘evaluate first’ principle. This is also a strong indication that evaluations have been further mainstreamed into the policy development process and culture of the Commission. It is now key that this momentum is used to further reduce the remaining 10% evaluation gap and to further improve the quality of evaluations.

Figure 10: Evaluation first principle, 2016-2022 ⁽¹⁷⁾



Further quality improvement of evaluations

All opinions on standalone evaluation reports were positive this year (see Figure 11). This is a further improvement compared to the already positive 2021 outcomes (with 80% positive opinions) and clearly represents the best result achieved since the Board started to issue positive or negative opinions in 2017. Also, the average quality score indicator for evaluations further improved (see Figure 11) and reached in 2022 for the first time a quality score of fully “acceptable”. Nevertheless, these results need to be interpreted with the necessary caution, given the quite small sample of evaluations covered, which is not robust enough to allow any proper trend estimation. Finally, making progress towards moving from an overall ‘acceptable’ score to an overall good average score will require substantial further efforts and investments.

⁽¹⁷⁾ No evaluation is needed when the impact assessment concerns a new initiative in an area where the EU was not previously active.

Figure 11: Share of positive opinions for evaluations, 2017-2022

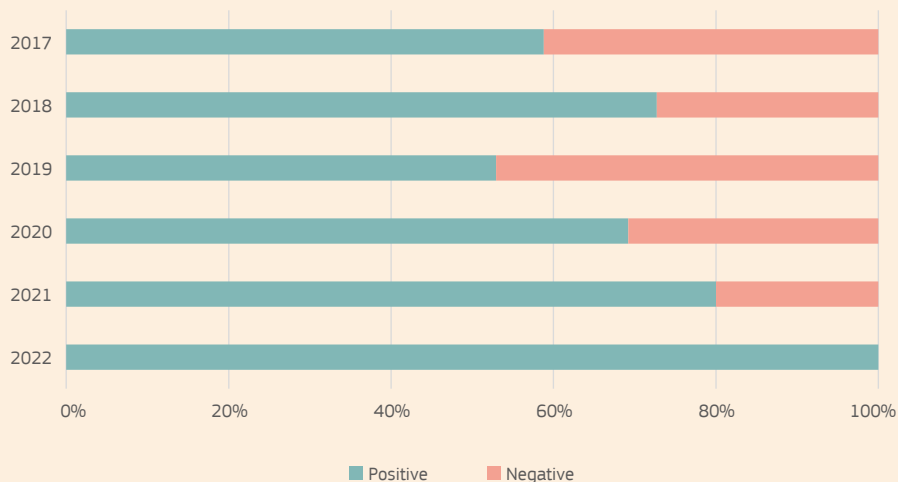
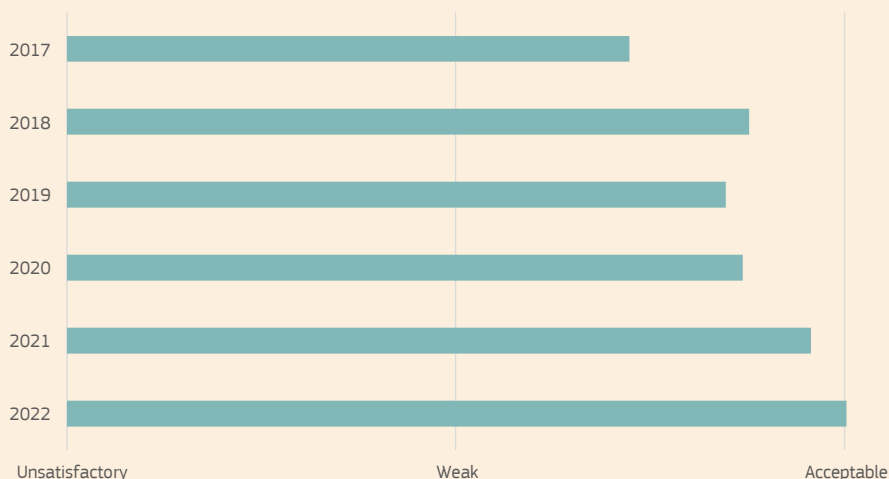


Figure 12: Average quality score of evaluations, 2017-2022



As indicated above there are situations where the evaluation and the impact assessment is carried out as a single process, in a so-called ‘back-to-back’ manner ⁽¹⁸⁾. In 2022, 12 out of the 70 impact assessments scrutinised included a ‘back-to-back’ evaluation. As it can be seen from Table 4 in most cases the evaluation was adequate and properly used in the impact assessment. However, there is scope for further improvement of the quality and use of back-to-back evaluations.

⁽¹⁸⁾ See Tool#50 of the Better Regulation Toolbox.

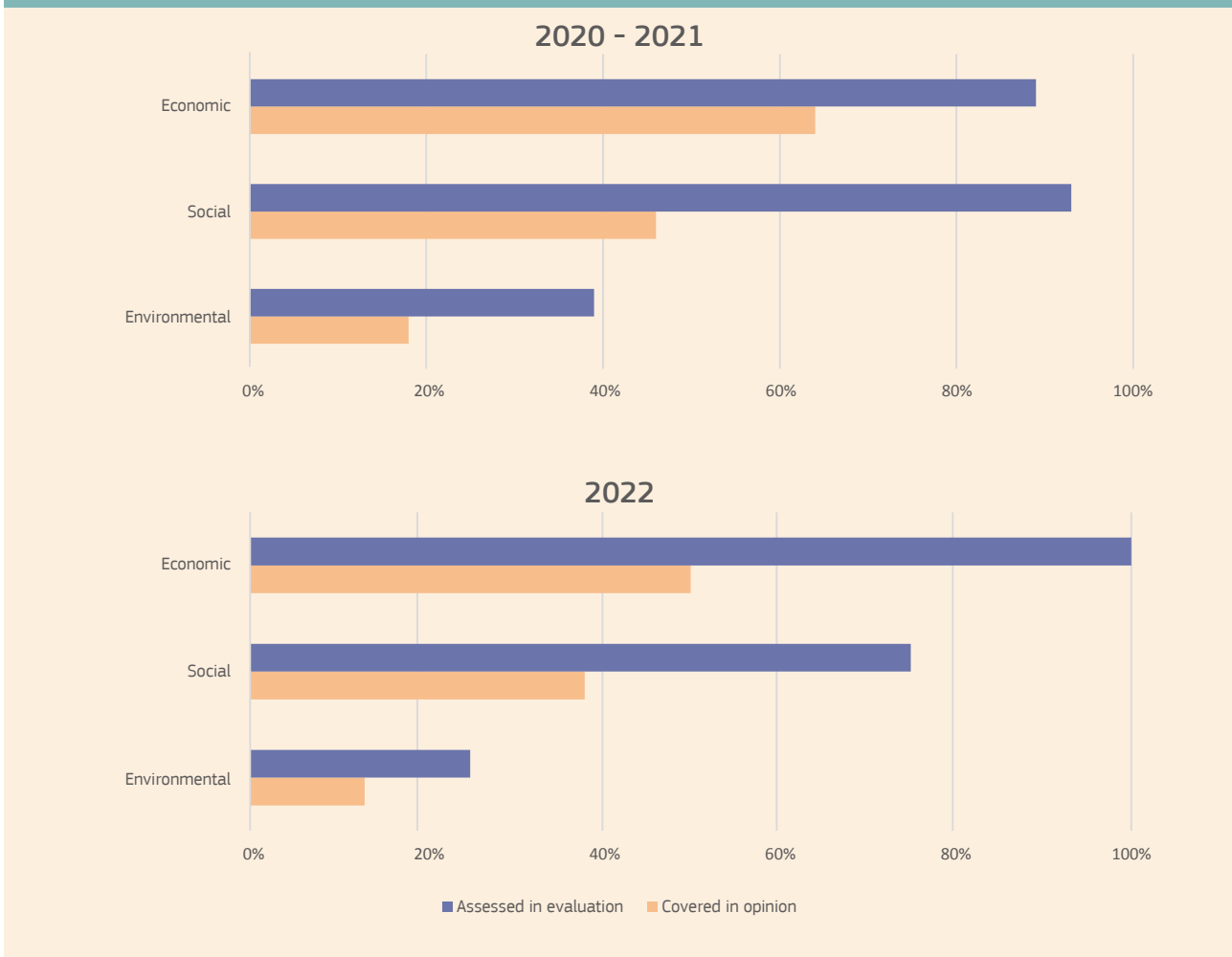
Table 4: Quality and use of 'back-to-back' evaluations in 2022

Back-to-back evaluations	Total IAs	yes	no	% yes
Adequate evaluation (1 st submission)	12	9	3	75%
Evaluation results properly used in impact assessment (1 st submission)	12	6	6	50%

Types of impacts analysed in evaluations and fitness checks

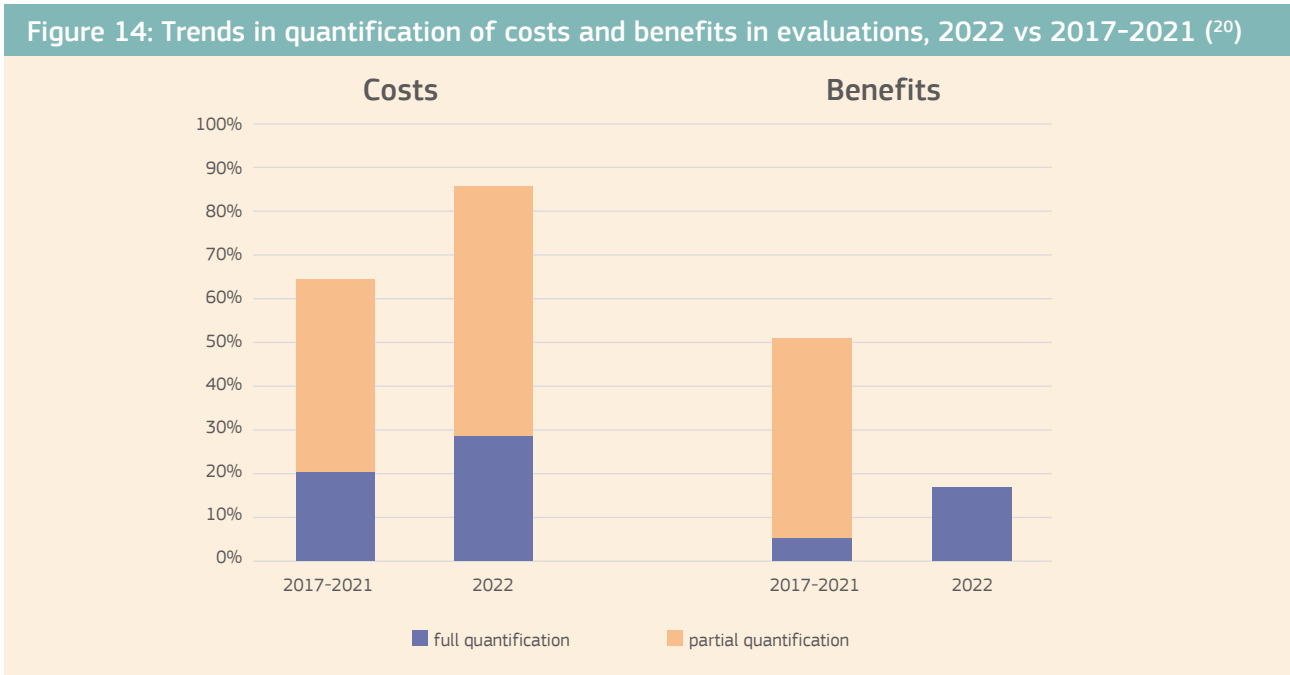
The analysis of economic impacts prevailed in the 2022 evaluations submitted to the Board, featuring in all of them, followed by social impacts considered in three quarters of cases and environmental impacts in one quarter. No significant deviation from the 2020-2021 trend could be observed regarding the overall distribution of social, environmental and economic impacts covered in the Board's opinions. Regarding impacts covered in Boards opinions overall fewer impacts were covered, probably reflecting the overall better quality of the limited number of evaluations scrutinized (see Figure 13).

Figure 13: Types of impacts assessed in evaluations and covered in the Board's opinion, 2022 vs 2020-2021



Further progress on quantification

The quantified analysis of costs and benefits has been more systematic in 2022 than in the previous years (see Figure 14) as the share of evaluations with fully quantified analysis has risen from 20% to almost 30% in relation to costs, and from 5% to almost 20% regarding benefits. Partial quantification of costs was present in over 50% of evaluations scrutinised by the Board, compared to 43% on average in the previous years ⁽¹⁹⁾.



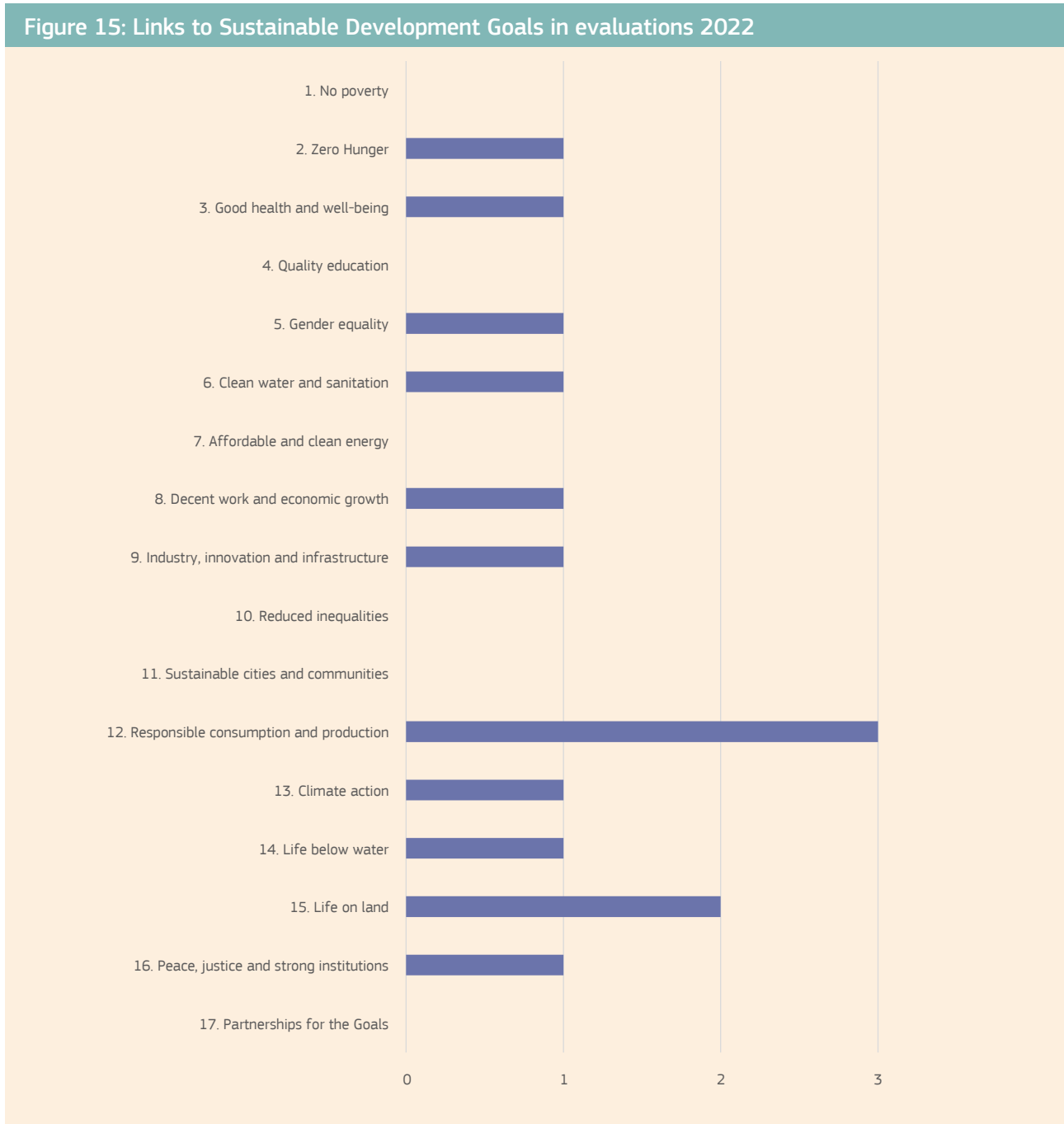
⁽¹⁹⁾ Please note that Figure 4 reflects the fact that there no evaluations with partial quantification of benefits were observed for 2022.

⁽²⁰⁾ Percentages include only cases where quantification was judged to be required on proportionality grounds.

Sustainable Development Goals

The Sustainable Development Goals identified as relevant across the draft evaluations covered in 11 out of 17 areas. Only two SDGs (SDG 12 – Responsible consumption and production, and SDG 15 – Life on land) were relevant in more than one evaluation (see Figure 15), but again the relative small sample of evaluation covered is recalled.

Figure 15: Links to Sustainable Development Goals in evaluations 2022



3

Special features

3.1 The 'one in, one out' approach in the RSB Scrutiny 2022

The 'one in, one out' approach is part of the Board's comprehensive scrutiny

The Better Regulation Communication of 2021 introduced several new requirements that Commission impact assessments have to comply with and that are subject to quality scrutiny of the Board. The 'one in, one out' approach is one of them.

The Board scrutinised the 'one in, one out' approach as part of its comprehensive scrutiny of the quality of evidence and analysis presented in impact assessments. In particular, the Board:

- Looked at whether all costs and benefits in scope of the approach were identified, for both stakeholder groups in scope – citizens and businesses;
- Considered whether the identified costs and benefits in scope of the approach were quantified to the extent possible and proportionate;
- Looked at whether the analytical approach for the cost benefit analysis was appropriate — the use of the Standard Cost Model for administrative costs and benefits;
- Considered the robustness and validity of the assumptions and data used in the analysis;
- Considered whether the analysis reflected the associated risks and uncertainties in the evidence and key assumptions used;
- When the costs and benefits in scope of the approach were not quantified, looked at whether this was reasonably justified, and that the costs and benefits were described in qualitative terms;
- Looked at whether the costs and benefits in scope of the approach were presented clearly both in the main report and the dedicated table in the annex (the obligatory 'one in, one out' section in the main report and the summary tables in annex 3).

A sufficient quantification of costs for the 'one in, one out' approach was the most difficult aspect out of the new Better Regulation requirements

A sufficient quantification of costs for the 'one in, one out' approach was the most difficult aspect out of the new Better Regulation requirements; 42 % of the reports relevant to the 'one in, one out' approach provided sufficient quantification (Table 3).

The Board observed that some reports did not indicate clearly what costs and benefits were to be considered within the scope of the 'one in, one out' approach at first submission. The Board recommended that the reports should present the costs and benefits with sufficient granularity so that it was clear which ones were in scope of the 'one in, one out' approach.

“The report should better distinguish between the overall estimates and the specific ones required for the One In, One Out approach. The One In, One Out estimates should be revised to make sure that only costs and cost savings considered within the scope of One In, One Out are included.”⁽²¹⁾

RSB opinion on the draft impact assessment on the recognition of parenthood between Member States

The Board often asked for clarifications of the assessments of costs and benefits in the ‘one in, one out’ approach.

- *When the costs and benefits were quantified*, the Board frequently asked what exact costs and savings were included in quantification for ‘one in, one out’ purposes and how the estimates were calculated. The Board recommended that the reports should be clear about the methodologies, the underlying assumptions and the data sources and clearly outline the metrics used.
- The Board often recommended that the reports should better distinguish between the overall estimates and the specific ones required for the approach. In some cases, the ‘one in, one out’ estimates should be revised to make sure that only costs and cost savings considered within the scope were included.
- In some cases, the Board simply asked that the figures should be recalculated to eliminate the mistakes and that consistency of the figures should be ensured throughout.
- *When the costs and benefits were not quantified*, the Board asked for quantification to the extent possible and proportionate, or justification and further explanation on why it was concluded that the preferred option would not entail significant costs and/or benefits in scope of the ‘one in, one out’ approach.

The Board formulated a number of recommendations with a view to ensure transparency of the ‘one in, one out’ analysis in impact assessments. It recommended that the reports should show comprehensive overviews of the administrative and adjustment costs and savings for businesses and citizens to allow assessments of their magnitude for the purpose of ‘one in, one out’. It also emphasised that the estimates presented in the main reports and in the annexes should always be clear, comprehensive and aligned.

3.2 Cost benefit analysis in the RSB Scrutiny 2022

The Board scrutinises the application of cost benefit analysis

Cost benefit analysis is one of the methodologies for analysing impacts in impact assessments and evaluations. In cost benefit analysis all relevant and significant costs and benefits are valued in monetary terms (unless it is not proportionate or possible to do so). In practice, cost benefit analysis often contains a mix of quantitative and qualitative elements. It is an assessment methodology that allows the comparative analysis of all types of impacts be it social, environmental or economic.

The Board in its opinions commented both on the application of cost benefit analysis (the identification and monetisation of costs and benefits as well as the robustness and transparency of the analysis) and the use of the results from cost benefit analysis in the comparison of options and the justification of the choice

⁽²¹⁾ RSB opinion on the draft impact assessment on the Regulation on the recognition of parenthood between Member States.

of the preferred option. This also included reviewing cost and cost saving estimates for the 'one in, one out' approach.

Out of 78 files scrutinised by the Board in 2022, almost 90% had a remark on cost benefit analysis. The Board mentioned the shortcomings related to cost benefit analysis in all but one negative options ⁽²²⁾.

The cost benefit analysis was often incomplete

The Board often recommended that the reports should identify all relevant costs and benefits for each policy option. It also often recommended that the reports should make sure that the analysis covered all relevant stakeholders and was clear on how different stakeholder types were impacted. The Board also recommended that the reports should sufficiently assess the associated risks including the risk that the estimated benefits may not fully materialise, the risk that costs might be underestimated and the risk of unintended consequences.

The Board emphasised that the reports should better distinguish between the different categories of costs and benefits (e.g. adjustment and administrative, one-off and recurring, direct and indirect).

The Board noted that some reports did not present the complete cost benefit analysis with certain significant impacts not sufficiently identified and assessed. It also noted a lack of sufficient monetisation without clear justification. Although the proportion of impact assessments with quantified analysis on costs and benefits increased during 2022 in relation to the previous five year's average, less than half of the reports included full quantification of costs and benefits. In its scrutiny, the Board emphasised that all impact assessments should include proportionate analysis – the scope and depth of the analysis should be proportionate to the nature and magnitude of the expected impacts and the type of initiative. It often recommended that the reports should make efforts to further quantify and monetise the expected significant costs and benefits. This particularly included further monetisation of social and environmental benefits as well administrative costs/savings. If some costs and benefits were considered negligible, the reports should demonstrate that. Where quantification and/or monetisation was not possible, the reports should explain why and provide well integrated qualitative analysis. The Board emphasised that, in particular, this should be done when the reports concluded that the benefits outweighed the costs without full monetisation or adequate quantification of benefits.

“The report needs to strengthen its narrative significantly and the argumentation in support of the proportionality of the preferred set of measures, in particular on storm water overflows and urban runoff. It should make an effort to further quantify the expected, most significant, benefits. Where this is not possible, the report should explain why and provide qualitative analysis to support the conclusion that the benefits outweigh the costs. It should provide more convincing arguments to show how the intervention is expected to bring about the non-monetised benefits and the extent to which this will happen.” ⁽²³⁾

RSB opinion on the draft impact assessment on the Revision of the Urban Wastewater Treatment Directive

⁽²²⁾ 1st submission. Based on the internal analysis of the Board's opinions.

⁽²³⁾ RSB opinion on the draft impact assessment on the Revision of the Urban Wastewater Treatment Directive.

The cost benefit analysis lacked clarity on the main conclusions

The Board noted that the reports often did not provide clear overviews of the different types of costs and benefits (monetised and non-monetised), net benefits, net present value, benefit cost ratios as well as distributional impacts on stakeholders. The reports often did not sufficiently and consistently use the results of the cost benefit analysis in comparisons of options and the justifications of the choices and proportionality of the preferred options.

The Board recommended that the reports should improve the presentation of the impacts so that they were structured in such a way that allowed clear identification of impacts for each policy option, measure and stakeholder group affected and be explicit about the overall costs and benefits of all options bringing together all monetised and non-monetised impacts. The Board recommended that the reports should make greater use of the results of the cost benefit analysis in the comparisons of options to better explain the choices and proportionality of the preferred options.

“The report should better compare options (including sub-options) in terms of effectiveness, efficiency and coherence while bringing out more clearly the related costs and benefits. In particular, the efficiency analysis should bring out more clearly the expected costs and benefits and should include the estimates of costs and benefits, the net impact and the Benefit Cost Ratios per policy option and sub-option in the comparison table(s). On that basis, the report should further explain the choice and proportionality of the preferred option.” (24)

RSB opinion on the draft impact assessment on the European cyber resilience act

The robustness and limitations of cost benefit analysis were not clear

The Board recommended that the reports should better explain the underlying methodologies for the cost and benefit estimates. They should be clear on how the estimates were calculated and what the evidence base for them were and summarise in the main reports the key methodological aspects, assumptions, and limitations. The same metrics should be used to enable better comparison of impacts and the appraisal periods should be specified and consistently use in the analysis.

The Board paid particular attention to the modelling used to assess economic, social and environmental impacts. It noted that the reports were often not sufficiently clear on the methodological assumptions and parameters underpinning the models. It observed that the reports did not clearly present the risks and uncertainties associated with the assessed impacts. It often recommended that sensitivity analysis should be undertaken to understand how the uncertainties in model results could be attributed to the different sources of uncertainties in the model inputs. The Board recommended that the reports should be more explicit about the uncertainties influencing the conclusions of the analysis.

The Board aims to further strengthen the scrutiny of the analytical modelling in the coming year.

(24) RSB opinion on the draft impact assessment on the European cyber resilience act.

4

Conclusions and outlook



The year 2022 was another busy year for the board with a high number of reports scrutinised. Building on the positive trend already identified in last year's report, the Board noticed a further improvement in the overall quality scores of draft impact assessments and evaluations. While this trend is applaudable, continuous strong efforts and investments are needed from all actors involved to maintain or further accelerate this momentum.

There is scope to further improve the compliance with the new requirements set out in the revised Better Regulation guidelines and toolbox. The Board will therefore continue to pay special attention to their implementation. It will continue to support the Commission departments with its recommendations, so impact assessments are prepared that adequately assess social, environmental and economic impacts, in line with the overarching principle of the Commissions integrated approach to impact assessment.

The Board will continue to engage with the Secretariat-General on how to further improve the quality of these new requirements and will also more systematically raise the need to fully respect them in its upstream support meetings with Commission departments.

In line with the Commission's renewed focus on competitiveness and the strengthened mandate of the Board⁽²⁵⁾ the assessment of competitiveness impacts will continuously feature in the scrutiny work of the Board, including the correct application of the new 'competitiveness check'. The Board will specifically report on its first experience on this in a special feature in next year's annual report.

The Board also aims to further strengthen the scrutiny of the analytical modelling in the coming year. It will also streamline and make better use of its internal quality reporting and monitoring system.

As the Commission is moving closer towards the end of its mandate with the most important legislative initiatives already presented, evaluation work will become increasingly more prevalent. The Board will select the most important evaluations for its scrutiny, including by looking in particular at their continued relevance in view of the ongoing green and digital transitions as well as the new global economic and political challenges.

Following the lifting of remaining Covid-19 measures the Board, will further intensify its outreach activities, both internally and externally. Internally, we will reach out to the senior management teams of the Commission departments to share experiences and best practices. Externally, we will dialogue more systematically with representatives of the other players active in the European Better Regulation eco-system, including the co-legislators as well as other independent scrutiny bodies. Finally, the Board aims to conclude the recruitment process of the two additional Board members in line with the new decision of the President.

⁽²⁵⁾ Decision of the President of the Commission P(2022)2 of 11.12.2022.

The RSB team



From left: **James Morrison**, Member of the Board (Director); **Philippe Mengal**, Member of the Board; **Dr Dorota Denning**, Member of the Board, **Elisabetta Siracusa**, Member of the Board; **Claudia Di Dio**, Assistant; **Rytis Martikonis**, Chair of the Board, **Alix Van Acker**, Assistant; **Dr Michael Gremminger**, Member of the Board; **Antonina Cipollone**, Board Secretary; **Deirdre Hughes**, Assistant.

The RSB Secretariat



From left: **Christoffer Branzen**, **Andres Aristegui Cortijo**, **Joanna Leszczuk**, **Ulrik Mogensen**, **Alexandra Berketi**, **Manol Bengyuzov**, **Antonina Cipollone**, **Ioana Condurat**, **Joanna Berlinska**, **Pieter Bouwen**, **Mercedes de Miguel Cabeza**, **Serge Le Gal**, **Fabienne Corvers**, **Bernhard Winklehner**.

(Not on the picture: **Nikolaos Archontas**, **Ima Gomez Lopez**, **Julie Guermonprez**, **Yanis Koutsikidis**, **Alexandra Manole**, **Hans Moons**, **Michal Narozny**, **Nicolas Tokalatzidis**, **Serena Trentinaglia**).

The Board expresses its great appreciation and deep gratitude to its former members **Bernard Naudts** and **Antonio Nicita** who left in 2022.



Bernard Naudts
Member of the Board



Antonio Nicita,
Member of the Board

ANNEX 1

Impact assessments and
Evaluations 2022

IMPACT ASSESSMENTS

The Board's opinions are published with the impact assessment once adopted by the Commission.

(*) 2022 files whose relevant legal act has been adopted by 3 March 2023

Impact assessments reviewed in 2022	First opinion	Second opinion	'Evaluate first' principle
Proposal for a Regulation on fluorinated greenhouse gases	●	●	✓
Proposal for a strengthened EU governments' interoperability	●		✓
Ocean observation	Ongoing		
Review of the Directive on Consular protection in third countries	Ongoing		
Amendment of Council Regulation (EC) No. 2271/96 of 22 November 1996 protecting against the effects of the extra-territorial application of legislation adopted by a third country, and actions based thereon or resulting therefrom	Ongoing		
Short-term rentals initiative for a stronger tourism ecosystem	●	●	no evaluation needed
Revision of EU marketing standards for agricultural products	Ongoing		
Fighting organised crime – freezing and confiscating the proceeds of crime & strengthening the mandate of EU Asset Recovery Offices	●		✓
European statistics on population ESOP*	●		✓
Connectivity Infrastructure Act*	●		✓
Revision of the Urban Wastewater Treatment Directive	●	●	✓
Directive on an allowance to neutralize the tax-debt-equity bias	●		no evaluation needed
Firearms – review of export rules and import & transit	●		✓
Liability rules for Artificial Intelligence	●		no evaluation needed
Revision of the Product Liability Directive	●		✓
Protection of workers from risks related to exposure to asbestos at work	●		✓
Maritime Accident Investigation	Ongoing		
Ecodesign requirements for local space heaters	Ongoing		
Revision of Directive 94/62/EC on Packaging and Packaging Waste Directive to reinforce the essential requirements for packaging and assess the feasibility to establish EU level packaging waste prevention measures and targets	●	●	✓

Positive opinion ●
 Positive with reservations ●
 Negative opinion ●

Impact assessments reviewed in 2022	First opinion	Second opinion	'Evaluate first' principle
Revision of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45 EC	●		✓
Revision of the State aid framework for agriculture, forestry	●		✓
Proposal for a Regulation on fees charged by the European Medicines Agency (EMA)	●		✓
Initiative on instant payments in the EU	●	●	no evaluation needed
Regulatory measure on energy labelling requirements for household tumble dryers –Review of Regulation (EU) No 392/2012	Ongoing		
Revision of the State aid framework for fishery and aquaculture	●		✓
Regulation on the recognition of parenthood between Member States	●		no evaluation needed
European Media Freedom Act	●	●	no evaluation needed
Revision of lists of pollutants affecting surface and groundwaters	●		✓
VAT in the Digital Age	●		✓
Enhancing the convergence of Insolvency laws	●	●	no evaluation needed
Revision of ecodesign requirements for water pumps	Ongoing		
Revision of the EU legislation on medicines for children and rare diseases	Ongoing		
Single Market Emergency Instrument (SMEI)	●	●	no evaluation needed
Revision of the EU competition rules on horizontal agreements	Ongoing		
European cyber resilience act	●		no evaluation needed
Review of the listing rules applicable to companies issuing securities in the EU (Listing Act)	●		✓
Revision of the Council Directive 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco products	Ongoing		
Revision of the general pharmaceutical legislation	Ongoing		
Digitalisation of labels on Fertilising Products*	●		✓
Revision of the Ambient Air Quality Directives 2008/50/EC and 2004/107/EC	●		✓
Port State Control	Ongoing		

Positive opinion ●
 Positive with reservations ●
 Negative opinion ●

Impact assessments reviewed in 2022	First opinion	Second opinion	'Evaluate first' principle
Revision of Directive (EU) 2015/413 facilitating cross-border exchange of information on road-safety-related traffic offences*	●		✓
Revision of the Detergents Regulation	Ongoing		
Certification of carbon removals	●		✓
EMIR targeted review	●		✓
Revision of the CO ₂ emission standards for heavy-duty vehicles (Regulation (EU) 2019/1242)*	●	●	✗
Revision of the legislation on supplementary protection certificates	Ongoing		
Initiative to promote sustainability of consumer goods in the Sale of Goods Directive and through a new consumer right to repair	Ongoing		
Proposal for a Regulation of the European Parliament and of the Council on the obligation of carriers to communicate advance passenger data	●		✓
Regulation of the European Parliament and of the Council amending Regulation (EU) No 1169/2011 on the provision of food information to consumers	Ongoing		
Protection of workers health from risks related to exposure to lead and di-isocyanates*	●		✓
Proposal for a Directive amending Directive 2011/36/EU on preventing and combating trafficking in human beings and protecting its victims	●		✓
Upgrading digital company law	Ongoing		
Revision of the Union Customs Code	Ongoing		
Crisis Management and Deposit Insurance	Ongoing		
Revision of the Toy Safety Directive	Ongoing		
Revision of certain procedural aspects of EU merger control	Ongoing		
Revision of the Directive on driving licences*	●		✓
Revision of EU legislation on registration, evaluation, authorisation and restriction of chemicals	Ongoing		
Establishing the digital euro	Ongoing		
Measures to reduce the release of microplastics in the environment	Ongoing		
Revision of the Cosmetic Products Regulation (EC No 1223/2009) following the EU Chemicals Strategy for sustainability	Ongoing		
Proposal for a revision of Directive 2005/35/EC on ship-source pollution	Ongoing		
Amendment of the EU rules on victims' rights	Ongoing		

Positive opinion ●
 Positive with reservations ●
 Negative opinion ●

Impact assessments reviewed in 2022	First opinion	Second opinion	'Evaluate first' principle
Ecodesign and energy labelling requirements for water heaters and hot water storage tanks.		Ongoing	
Ecodesign and energy labelling requirements for space heaters (incl. combination heaters)		Ongoing	
Revision of the Mercury Regulation		Ongoing	
New EU system for the avoidance of double taxation and prevention of tax abuse in the field of withholding taxes (WHT) initiative', so-called FASTER (Fast-track Assured and Safer Tax Excess Refunds		Ongoing	
Environmental, social and governance (ESG) ratings and sustainability risks in credit ratings		Ongoing	
Driving and rest times for bus drivers		Ongoing	

Positive opinion ●
Positive with reservations ●
Negative opinion ●

EVALUATIONS

Evaluations reviewed in 2022	First opinion	Second opinion
Evaluation of the European Interoperability Framework (EIF)	●	
Mid-term evaluation of the implementation of the Union Customs Code.	●	
Meta-evaluation of Macro-Financial Assistance (MFA) programmes 2010-202	●	
Evaluation of Regulation (EC) No 1831/2003 on additives for use in animal nutrition	●	
Sewage Sludge Directive (Council Directive 86/278/EEC)	●	
Evaluation of the New Legislative Framework for EU legislation on industrial products	●	
Evaluation of the Directive 2011/36/EU on preventing and combating trafficking in human beings and protecting its victims	●	
Fitness check of the EU Animal Welfare legislation	●	

Positive opinion ●
Negative opinion ●

ANNEX 2

The updated RSB
monitoring system

In 2020, the Board presented its revised monitoring system (see RSB Report 2020, annex 2). It covers the Board's activities, the quality of the scrutinised reports, and the content of the opinions. It measures changes in quality by having statistics on first submissions of each report, possible second (or third) submissions, and on the version of the report that was submitted in interservice consultation.

The 2021 Better Regulation Communication introduced several new elements (integration of strategic foresight, introduction of the 'one in, one out' approach with an increased focus on the quantification of costs and benefits, mainstreaming of sustainable development goals, application of the 'do no significant harm' and 'digital by default' principles) and put more emphasis on green and digital aspects of the impact analysis in evaluations and impact assessments. Therefore in 2022, the RSB reporting, and monitoring system was updated to incorporate these new developments. While the overall structure of the system did not change, several new elements were added to the 'other indicator' section.

1. Quality components

For the quality scrutiny of impact assessments as well as evaluations and fitness checks respectively the Board uses two different sets of 13 quality components. Each quality component is scored on a five item scale covering 'very good, good, acceptable, weak and unsatisfactory'.

Quality components impact assessment	Quality components evaluations & fitness check
<ul style="list-style-type: none"> ■ Context and scope ■ Problem definition and use of evaluation ■ Subsidiarity and EU value added ■ Objectives ■ Intervention logic ■ Baseline ■ Options ■ Impacts ■ Comparison of options and proportionality ■ Future monitoring and evaluation ■ Consultation and information base ■ Methodology ■ Readability and clarity 	<ul style="list-style-type: none"> ■ Purpose and scope ■ Intervention logic ■ Evaluation questions ■ Point of comparison of options or baseline ■ Data collection (including consultation) ■ Analytical methods ■ Effectiveness ■ Efficiency ■ Relevance ■ EU value added ■ Coherence ■ Validity of conclusions and relevance for future actions ■ Readability and clarity

2. Impact criteria and indicators

When reporting impacts assessed in impact assessments, evaluations and fitness checks or mentioned in Board's opinions the Board uses the following criteria:

Economic impacts	
Macroeconomic	
Trade	Impact on third countries Foreign direct investment
Competitiveness	Internal market Sectors
Territorial impacts	Member states Regions
SMEs	
Fraud	
Economic innovation	

Social impacts and fundamental rights

Work	Employment Working conditions and job quality ⁽²⁶⁾ Health and safety Governance, participation, social dialogue ⁽²⁷⁾
Society	Income distribution, social inclusion, social security Good administration, public services and citizen's rights ⁽²⁸⁾ Public health ⁽²⁹⁾ Consumers' protection ⁽³⁰⁾ Education / culture
Fundamental rights: Human dignity ⁽³¹⁾	
Fundamental rights: Freedoms ⁽³²⁾	
Fundamental rights: Equality ⁽³³⁾	
Fundamental rights: Justice ⁽³⁴⁾	
Social innovation	
Climate	
Natural resources: air/water/land/biodiversity ⁽³⁵⁾	
Waste management	
Circular economy	
Environmental innovation	

Environmental impacts

- ⁽²⁶⁾ Including the following fundamental rights concerning solidarity: right of access to placement services; protection in the event of unjustified dismissal; fair and just working conditions; prohibition of child labour and protection of young people at work, family and professional life; social security and social assistance.
- ⁽²⁷⁾ Including the following fundamental rights concerning solidarity: workers' right to information and consultation within the undertaking; right of collective bargaining and action.
- ⁽²⁸⁾ Fundamental rights concerning citizen's rights: right to vote and to stand as a candidate at elections to the European Parliament; right to vote and to stand as a candidate at municipal elections; right to good administration; right of access to documents; Ombudsman; right to petition, freedom of movement and of residence, diplomatic and consular protection. Including the following fundamental right concerning solidarity: access to services of general economic interest.
- ⁽²⁹⁾ Including the following fundamental right concerning solidarity: health care.
- ⁽³⁰⁾ Including the following fundamental right concerning solidarity: consumer protection.
- ⁽³¹⁾ Human dignity; right to life; right to the integrity of the person; prohibition of torture and inhuman or degrading treatment or punishment; prohibition of slavery and forced labour.
- ⁽³²⁾ Right to liberty and security; respect for private and family life; protection of personal data; right to marry and right to found a family; freedom of thought, conscience and religion; freedom of expression and information; freedom of assembly and of association; right to education; freedom to choose an occupation and right to engage in work; freedom to conduct a business; right to property; right to asylum; protection in the event of removal, expulsion or extradition.
- ⁽³³⁾ Equality before the law; non-discrimination; cultural, religious, and linguistic diversity; equality between men and women; the rights of the child; the rights of the elderly; integration of persons with disabilities.
- ⁽³⁴⁾ Right to an effective remedy and to a fair trial; presumption of innocence and right of defence; principles of legality and proportionality of criminal offences and penalties; right not to be tried or punished twice in criminal proceedings for the same criminal offence.
- ⁽³⁵⁾ Including the following fundamental right concerning solidarity: environmental protection.

3. Quantification

The structure of the statistics is the same for costs and benefits, and for impact assessments and evaluations. It distinguishes between direct and indirect costs and benefits, and between one-off and recurrent costs and benefits. Furthermore, it records whether costs are distinguished by affected group (citizens/consumers, business, and administrations). There is also a summary assessment of the degree of quantification of costs and benefits. The details are presented in the table below:

Indicator	Possible values	IA/Eval
Benefits/costs identification	<input type="checkbox"/> Identified	IA
	<input type="checkbox"/> Not identified	Eval
	<input type="checkbox"/> Cannot be identified reasonably	
If benefits/costs identified		
■ One-off/recurrent benefits/costs	<input type="checkbox"/> Distinguished	IA
	<input type="checkbox"/> Not distinguished	Eval
	<input type="checkbox"/> Cannot be distinguished reasonably	
■ Direct benefits/costs	<input type="checkbox"/> Quantified	IA
	<input type="checkbox"/> Not quantified	Eval
	<input type="checkbox"/> Cannot be quantified reasonably	
■ Indirect benefits/costs	<input type="checkbox"/> Quantified	IA
	<input type="checkbox"/> Not quantified	Eval
	<input type="checkbox"/> Cannot be quantified reasonably	
■ Benefits/costs quantification	<input type="checkbox"/> Quantified	
	<input type="checkbox"/> Partially quantified	IA
	<input type="checkbox"/> Not quantified	Eval
	<input type="checkbox"/> Cannot be quantified reasonably	

4. Other indicators

The new Better Regulation Communication introduced several new elements and puts more emphasis on green and digital aspects of the impact analysis in evaluations and impact assessments. The RSB reporting and monitoring system was updated to incorporate the following elements in the other indicators section:

- Sustainable development goals
- Foresight
- Climate consistency check
- ‘Do no significant harm’ principle
- ‘Digital by default’ principle
- ‘One in, one out’ principle’

The table below presents all the other indicators used by the RSB in 2022, including the new ones added:

Indicator	Possible values	IA/Eval
Evaluate first principle	<input type="checkbox"/> Respected <input type="checkbox"/> No prior evaluation <input type="checkbox"/> No evaluation needed	IA Eval
If evaluate first principle respected		
Evaluation scrutiny	<input type="checkbox"/> Preceding evaluation reviewed by RSB <input type="checkbox"/> Draft evaluation submitted with IA <input type="checkbox"/> Preceding evaluation not reviewed by RSB	IA Eval
If evaluation reviewed by RSB or submitted with impact assessment		
Adequate evaluation	<input type="checkbox"/> Yes <input type="checkbox"/> No	IA Eval
If adequate evaluation		
Evaluation results properly used in IA	<input type="checkbox"/> Yes <input type="checkbox"/> No	IA Eval
Scope	<input type="checkbox"/> Sufficiently defined <input type="checkbox"/> Partially defined <input type="checkbox"/> Not defined	Eval
Baseline included	<input type="checkbox"/> Yes <input type="checkbox"/> No	
If baseline included		
Baseline quantification	<input type="checkbox"/> Sufficiently quantified <input type="checkbox"/> Not sufficiently quantified <input type="checkbox"/> There is no need to quantify	IA Eval
Baseline sufficiently reflects future developments	<input type="checkbox"/> Yes <input type="checkbox"/> No	IA Eval
Baseline or points of comparison appropriately defined	<input type="checkbox"/> Yes <input type="checkbox"/> No	Eval
Intervention logic appropriately describes how intervention was expected to work	<input type="checkbox"/> Yes <input type="checkbox"/> No	Eval
Intervention logic is used appropriately	<input type="checkbox"/> Yes <input type="checkbox"/> No	Eval
Simplification objective included	<input type="checkbox"/> Yes <input type="checkbox"/> No	IA
Sufficient analysis on simplification	<input type="checkbox"/> Yes <input type="checkbox"/> No	IA Eval
Self/co-regulation option considered	<input type="checkbox"/> Yes <input type="checkbox"/> No	IA
Lighter regime for SMEs considered	<input type="checkbox"/> Yes <input type="checkbox"/> No	IA
Appropriate range of options considered	<input type="checkbox"/> Yes <input type="checkbox"/> No	IA

Most relevant sustainable development goals identified	<input type="checkbox"/> 01 - No poverty <input type="checkbox"/> 02 - Zero hunger <input type="checkbox"/> 03 - Good health and well-being <input type="checkbox"/> 04 - Quality education <input type="checkbox"/> 05 - Gender equality <input type="checkbox"/> 06 - Clean water and sanitation <input type="checkbox"/> 07 - Affordable and clean energy <input type="checkbox"/> 08 - Decent work and economic growth <input type="checkbox"/> 09 - Industry, innovation, infrastructure <input type="checkbox"/> 10 - Reduced inequalities <input type="checkbox"/> 11 - Sustainable cities and communities <input type="checkbox"/> 12 - Responsible consumption, production <input type="checkbox"/> 13 - Climate action <input type="checkbox"/> 14 - Life below water <input type="checkbox"/> 15 - Life on land <input type="checkbox"/> 16 - Peace, justice and strong institution <input type="checkbox"/> 17 - Partnerships for the Goals	IA Eval
Implementation and enforcement requirements of options considered	<input type="checkbox"/> Yes <input type="checkbox"/> No	IA
Sufficient analysis on digital by default principle	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not relevant	IA Eval
Sufficient analysis on do not significant harm principle	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not relevant	IA Eval
Sufficient assessment of consistency with the European Climate Law	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not relevant	IA Eval
Sufficient quantification of costs for one in, one out	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not relevant	IA Eval
Foresight analysis adequately considered	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not relevant	IA Eval
Preferred option identified	<input type="checkbox"/> Yes <input type="checkbox"/> No	IA
Types of impacts as in original impact assessment	<input type="checkbox"/> Defined as in original IA <input type="checkbox"/> Not defined as in original IA <input type="checkbox"/> No original IA was made	Eval
Impacts analysed against the predicted impacts of the original impact assessment	<input type="checkbox"/> Yes <input type="checkbox"/> No	Eval
Evidence base	<input type="checkbox"/> Adequate <input type="checkbox"/> Partial <input type="checkbox"/> Not adequate	Eval
External study/ies used	<input type="checkbox"/> Yes <input type="checkbox"/> No	Eval
Public consultation	<input type="checkbox"/> Yes <input type="checkbox"/> No	IA Eval
Targeted consultation	<input type="checkbox"/> Yes <input type="checkbox"/> No	IA Eval
Summary of all consultation results appropriately presented in Annex 2	<input type="checkbox"/> Yes <input type="checkbox"/> No	IA Eval

Stakeholders' views appropriately collected	<input type="checkbox"/> Yes <input type="checkbox"/> No	IA Eval
Stakeholders' views appropriately analysed	<input type="checkbox"/> Yes <input type="checkbox"/> No	IA Eval
Stakeholders' views appropriately reported in staff working document	<input type="checkbox"/> Yes <input type="checkbox"/> No	IA Eval
Quantitative tools used	<input type="checkbox"/> Yes <input type="checkbox"/> No	IA Eval
Predominantly qualitative tools used	<input type="checkbox"/> Yes <input type="checkbox"/> No	IA Eval
Readability statistics for executive summary	<input type="checkbox"/> Percentage of passive sentences <input type="checkbox"/> Flesch Reading Ease indicator <input type="checkbox"/> Flesch-Kincaid Grade Level indicator	IA Eval

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 revision³⁶

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 / Fitness check report

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.

A Fitness check report is prepared by the lead department. 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.

⁽³⁶⁾ More information on Better Regulation Harmonisation is available at https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how_en

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. IMPLEMENTING ACTS Primary responsibility for implementing EU law lies with EU countries. However, in areas where uniform conditions for implementation are needed (taxation, agriculture, internal market, health and food safety, etc.), the Commission (or exceptionally the Council) adopts an implementing act.

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 burdens resulting from the Commission’s proposals by reducing existing burdens in the same policy area. The Better Regulation Communication of 29 April 2021, *COM 2021 219 Final* sets out the main principles of the approach³⁷

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.

Stakeholder

Stakeholder is any individual or entity impacted, addressed or otherwise concerned by an EU measure.

Stakeholder Consultation

Stakeholder consultation is a formal process of collecting input and views from citizens and stakeholders on new initiatives or evaluations/fitness checks, based on specific questions and/or consultation background documents or Commission documents launching a consultation process or Green Papers. When consulting, the Commission proactively seeks evidence (facts, views, opinions) on a specific issue.

Transposition

Transposition describes the process of incorporating the rights and obligations set out in an EU Directive into national legislation, thereby giving legal force to the provisions of the Directive. The Commission may take action if a Member State fails to transpose EU legislation and/or to communicate to the Commission what measures it has taken. In case of no or partial transposition, the Commission can open formal infringement proceedings and eventually refer the Member State to the European Court of Justice.

⁽³⁷⁾ COM(2021) 210 Final https://ec.europa.eu/info/sites/default/files/better_regulation_joining_forces_to_make_better_laws_en_0.pdf

