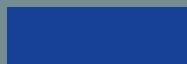
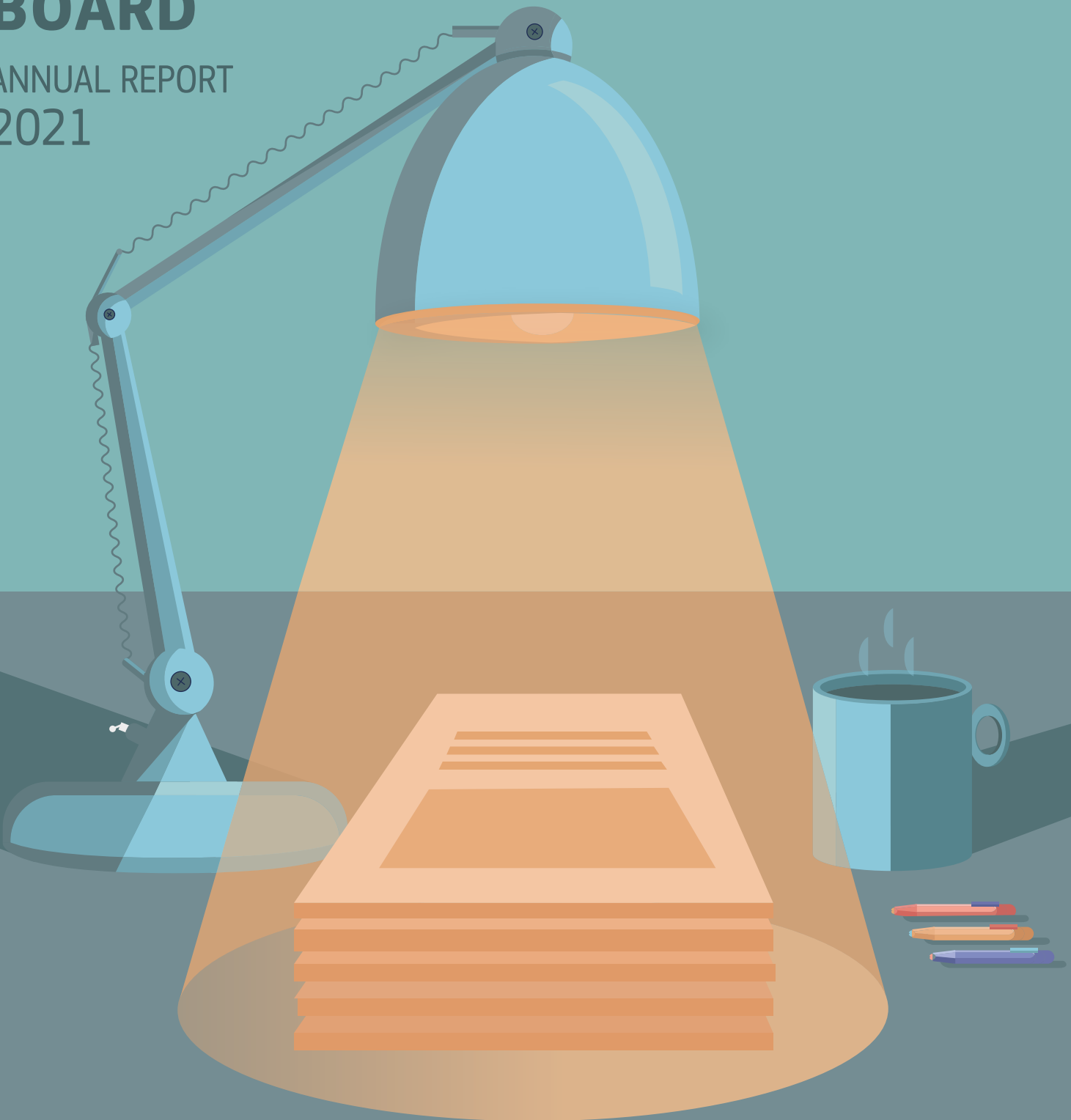




REGULATORY SCRUTINY BOARD

ANNUAL REPORT
2021



EUROPEAN COMMISSION

Regulatory Scrutiny Board

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Project Number: 2022.2495

Title: Regulatory Scrutiny Board Annual Report 2021

Linguistic version	Media/Volume	Catalogue number	ISBN	DOI
EN BOOK	PRINTED/Volume_01	KA-07-22-248-EN-C	978-92-76-52318-5	10.2792/262924
EN PDF	PDF/Volume_01	KA-07-22-248-EN-N	978-92-76-52317-8	10.2792/22024

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ANNUAL REPORT 2021
REGULATORY
SCRUTINY
BOARD

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FOREWORD BY THE CHAIR

This report covers the sixth year of operation of the Regulatory Scrutiny Board, which was the busiest ever for the Board. Despite working remotely throughout the year, the Board managed to scrutinise 98 impact assessments and evaluations ⁽¹⁾, an 81% increase on the workload of the previous year.

In our last annual report, we highlighted the importance of coherence between interlinked initiatives. The von der Leyen Commission has prioritised the twin transitions of the Green Deal and the Digital Agenda. In 2021, coherence remained a key issue as the Board scrutinised several interlinked initiatives under the Green Deal, stemming from the Climate Law, of which the Board scrutinised the impact assessment in 2020. Commission departments worked together effectively to share baselines, assumptions and models.

As well as its core function of assessing the quality of impact assessments and evaluations, the Board continued to provide advice to Commission departments in nearly 70 meetings at early stages of the preparations of their reports. The Board also provided advice to the Secretariat-General, as it reviewed the Commission's better regulation guidance. Despite the pandemic, the Board participated in the same number of outreach events as in 2020.

The recruitment process for the last external member of the Board was ongoing at the end of the year. I am grateful to the outgoing Chair Veronica Gaffey for all of her work. As ever, I would like to thank the Board secretariat for its dedicated support over the past year. They continued to cope with the challenges functioning effectively while working remotely.



Rytis Martikonis
Chair

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

CHAPTER 1

Activities of the Board

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

Within the Commission, in line with its mandate, the Board independently scrutinises the quality of all draft impact assessments and fitness checks, and a selection of evaluations. It reports on its activities to the President of the Commission and to the Vice-President for Inter-institutional Relations and Foresight.

The Board's mandate was renewed for the von der Leyen Commission by the adoption of a decision ⁽²⁾ reaffirming its internal role in supporting the implementation of the Commission's better regulation commitments including on 'one-in, one-out' and the integration of foresight into policy making that were announced in the new Commission communication on better regulation published in April 2021 ⁽³⁾. 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 provides independent quality control within the Commission

The Board cannot and does not question the political objectives presented in the impact assessments accompanying draft proposals, but considers 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⁾.

In fulfilling its mandate as an internal, independent and objective senior advisory group, the Board neither seeks nor takes instructions from any internal or external stakeholder or lobby group. It provides quality control and support for Commission evaluations and impact assessments at early stages of the legislative process. The Board does not decide on the political advisability of initiatives or on policy objectives: that role belongs to the College of Commissioners.

Figure 1 shows how the Board's internal quality control function within the Commission at the early stages of preparing legislation, to make sure Commission proposals are based on clearly defined problems, on the best available evidence, are proportionate and take into account the full range of stakeholder views. Through its opinions, it gives approval for work to progress to proposals that satisfy these criteria, unless the analytical work is deemed not to be up to standard. An initiative that the Board has found to be consistently lacking in adequate evidence requires a political decision by the Vice-President for Interinstitutional Relations and Foresight to proceed (for more details, see **Box 1**).

⁽²⁾ Decision of the President of the European Commission on an independent Regulatory Scrutiny Board, P(2020)2, Brussels 23.01.2020.

⁽³⁾ https://ec.europa.eu/info/sites/default/files/better_regulation_joining_forces_to_make_better_laws_en_0.pdf

⁽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

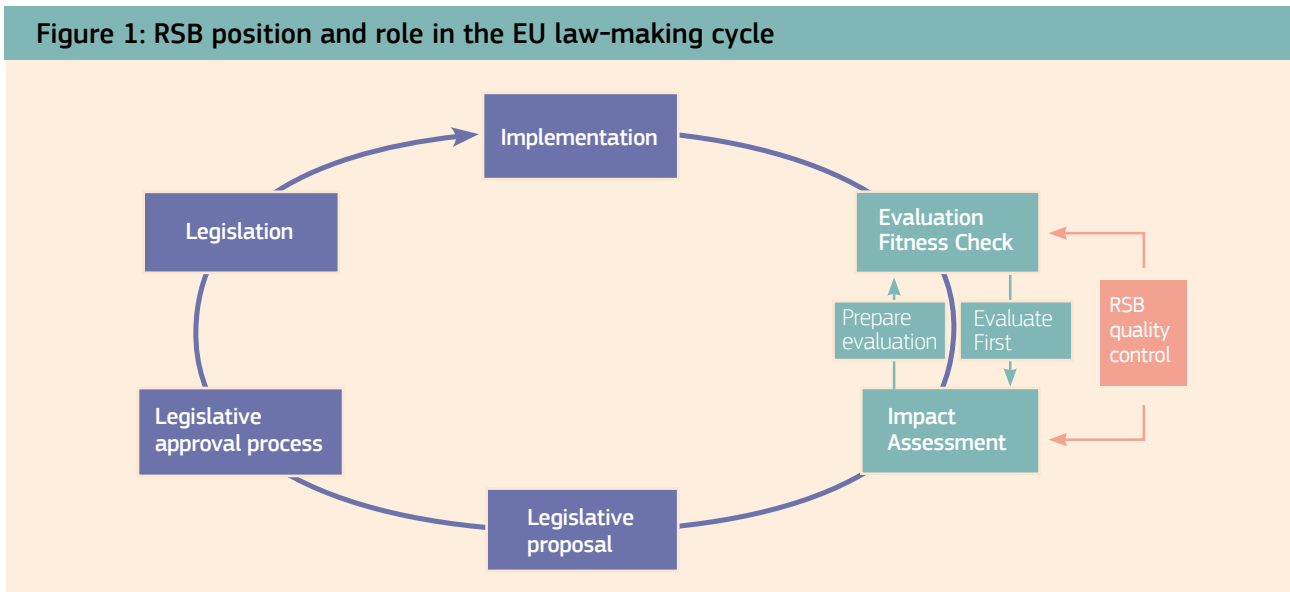
The Board's role is internal...

During the Commission's internal policy-definition 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.

...its opinions are published only with the final impact assessment

Once a legislative proposal has been approved by the College of Commissioners, there is full transparency on the Board's assessments and all its [relevant] opinions are published with the final impact assessment. Similarly, for evaluations the opinions are published together with the finalised evaluation.

Figure 1: RSB position and role in the EU law-making cycle



BOX 1: TYPES OF OPINION

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

POSITIVE:

The Board is satisfied that the 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 Board is largely satisfied with the impact assessment 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 file must be amended to take account of the Board's comments set out in the opinion. Only then can the file proceed.

NEGATIVE:

The Board is not satisfied with the impact assessment, which falls short of the standards set out in the better regulation guidelines and toolbox. The file requires substantial revision. A first negative opinion implies that the file may not proceed and 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 revised impact assessment because it still contains serious deficiencies. The file may not proceed without a decision by the Vice President for Inter-institutional Relations and Foresight as to whether and in what form it may proceed. There are in practice three broad possibilities:

- The political level can decide that the failure to write a satisfactory impact assessment shows that there is no convincing reason to proceed with the initiative. The initiative is *abandoned* under its current form and could be reconsidered in future.
- When the impact assessment process has shown that there is no convincing reason for particular parts of the initiative, the political level can decide to *revise or drop these parts*. No new impact assessment is made and the proposal is adopted in its revised or reduced form. In 2021, this happened with the impact assessment on the proposal for a revision of the Energy Performance of Buildings Directive.
- When there are more widespread but fixable problems in the second impact assessment, the political level can *exceptionally ask the Board to scrutinise a third version* of the impact assessment. When this version receives a positive or positive with reservations third opinion, it can proceed normally in the Commission's decision-making process. In 2021, this happened with the impact assessment on the proposal on strengthening the principle of equal pay between men and women through pay transparency, which received two negative opinions in 2020.
- For initiatives allowed to proceed, the process and reasons for adjustments made following the Board's opinion are explained in the Explanatory Memorandum published with the proposals.

For evaluations, there are only two types of Board opinions: positive or negative. There is no obligation to re-submit a new version of the evaluation to the Board after a negative opinion. This is because in many cases the collection of evidence and evaluative analysis is done by external consultants. Once the draft evaluation is finalised and submitted to the Board, it is often no longer feasible to amend or complement this work. In addition, the Board does not scrutinise all evaluations, which could lead to unequal treatment. Still, 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 2021

The Board's workload continued to increase in 2021...

2021 marked both the second full year of the von der Leyen Commission's mandate but also the second year of the global COVID-19 pandemic. Despite the pandemic and remote and new ways of working that it gave rise to, the flow of new initiatives saw a marked increase on the previous year with key legislative proposals designed to implement the broader strategic goals set out in the Political Guidelines and first year of the Commission's mandate. This, coupled with Board staff turnover, resulted in sustained and unprecedented pressure on the Board throughout the year.

...with some new faces...

Board members are appointed for three years, with a possibility of an extension of term by one year. In 2021, one internal and two external Board members were appointed. By the end of the year, only one external slot remained unfilled (although the publication of the post and the procedure to fill it were underway). This brought the Board back to a numeric level not seen since 2019, helping to spread the workload.

...when remote working became the new normal.

Due to the COVID-19 pandemic, the Board continued to work virtually all year, with just a few occasions when Board members met physically in the second half of the year. All Board meetings, upstream meetings and outreach events took place on line. For Board meetings, Commission departments were invited – if they wished – to submit written responses to the quality checklists issued by the Board. This facilitated virtual discussions and Board deliberations. For more details on the Board's working methods, see **Box 2**.

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 normally provides a copy of the 'Call for evidence', which sets out the problem, proposed options and main expected impacts, as well as the roadmap for the public consultation and any studies. The meeting is an opportunity for the department to outline their proposal and proposed approach and to seek the informal, upstream advice from the Board on any likely weaknesses of the initiative, thereby allowing for adjustment of the problem definition, intervention logic, option structure and evidence gathering and methodology of the proposal prior to formal submission to the Board.

Once the Commission department has finalised 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 toolbox identifying any weaknesses, inconsistencies or lack of clarity in the report. This is sent to the relevant departments on the Friday of the week 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.

Board meetings are 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 and any 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 normally issues to the department on the following Friday.

The process is fully similar 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.

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.

BOX 3: THE RSB PERFORMANCE MONITORING SYSTEM

In 2017, the Board introduced a detailed performance monitoring system. It covers the Board's activities, the quality of the scrutinised reports, and the content of the Board's opinions. All tables and figures in this report are based on this monitoring system. Based on 3 years of experience, the Board further refined the collected statistics in 2020. The main changes were explained in detail in Annex 2 of the 2020 Annual Report:

On the basis of these statistics, the Board assessed its work against three key performance indicators (KPIs):

- **KPI 1** - The number of impact assessments and evaluations scrutinised.
- **KPI 2** - On-time delivery of RSB opinions.
- **KPI 3** - Qualitative improvements of reports, following contacts with the Board.

1.2 Big surge in scrutiny work

2021 saw a big surge 2021 was the busiest year ever in the six years of operation of the Regulatory Scrutiny Board (see Table 1), a trend that looks set to continue given the Commission’s ambitious agenda and corresponding large volume of legislative proposals. The Board scrutinised 83 impact assessments (compared to 41 in 2020) and 15 major evaluations, including two fitness checks, (compared to 13 in 2020), amounting overall to an increase of 81%

TABLE 1: Overview of Board regulatory scrutiny work by year, 2016-2021

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%
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%
° 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 ‘negative2						

Although a smaller share of files received negative opinions...

The rate of negative opinions for initial submissions of impact assessments was 37%, which was an improvement on the 46% initial negative opinions in 2020. The initial negative opinion rate for evaluations was 20%, a further improvement on the 31% rate in 2020, and below the average between 2017 and 2019 of 40%.

...four files received double negative opinions

In the early part of 2021, the Board scrutinised four resubmissions from 2020, giving four positive opinions – two positive and two positive with reservations. Exceptionally, it scrutinised a third version of one impact assessment and issued a positive opinion ⁽⁵⁾. Of the 31 impact assessments that received an initial negative opinion in 2021, 16 received a second opinion during the year. Fourteen of these received a positive opinion (4) or positive opinion with reservations (10). The Board issued two double negative opinions in 2021 and a further two on 2021 files in January 2022. These double negative opinions were in principle final. The responsible Commission departments were advised to seek political guidance on whether and under which conditions the initiatives might proceed further.

Coherence emerged as a key theme

A number of key trends and themes emerged for the Board during the year with the increased number of impact assessments. The focus on key initiatives such as the twin climate and digital transitions highlighted the need for coherence between often overlapping initiatives from different Commission departments. For some packages – notably ‘Fit for 55’ – a common baseline and methodology was adopted, thereby greatly improving coherence. This practice was not however universal with initiatives on sustainability later in the year and those linked to the ‘Fit for 55’ package unfortunately not being coordinated in the same way. Coherence is further discussed in **Section 2.1**.

One of the three evaluations that received an initial negative opinion was resubmitted taking account of the Board’s comments and was subsequently given a positive opinion. **Table 2** shows that around half (7 out of 13) of the evaluations that were foreseen for scrutiny in 2021 were delivered on time, which is similar to previous years. However, a bigger proportion of the scrutinised evaluations were delayed evaluations (8 out of 15), which indicates that some of the existing backlog was caught up.

TABLE 2: Evaluation scrutiny, 2021 vs 2017-2020

	2017-2020*	2021
Selected evaluations	18	13
Evaluations presented on time	9	7
Delayed evaluations	9	6
Scrutinised evaluations	15	15
Evaluations presented on time	10	7
Delayed evaluations	5	8
* average per year		

⁽⁵⁾ "Strengthening the principle of equal pay between men and women through pay transparency."

1.3 Advice on better regulation policy and guidelines

The Board provided methodological advice on a range of issues

The Board continued to provide methodological and procedural advice to the Commission's Secretariat-General throughout the year.

The main focus of the advice was on the further development of the better regulation agenda, notably the revised better regulation guidelines and toolbox and the development and integration of the 'one in, one out' (OIOO) approach as well as trying to get greater clarity on the inclusion of the UN Sustainable Development Goals and on the 'Do No Significant Harm' principle.

On the OIOO approach, the Board provided advice on the main trade-offs of the different scopes of the OIOO approach, on the flexibility of the system and on a regular reporting. It also advised on the methodological issues and the integration of the rule into the impact assessment template. The Board stressed the importance of a transparent and robust methodology underpinning the OIOO approach.

1.4 Internal and External outreach

Despite the pandemic, outreach continued

The Board organised a virtual annual conference on 6 May to discuss its 2020 Annual Report with 168 participants from the European Commission, other institutions and from 20 EU Member States, the UK and Norway. Despite the pandemic, the Board participated in 33 virtual and physical outreach events over the year with external bodies, more or less the same as in 2020.

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 resulted in 67 meetings with Commission departments, up from 59 in 2020 and 20 in 2019, reflecting the increase in policy initiatives in the second full year of the von der Leyen Commission.

CHAPTER 2

Impact assessments and evaluations: trends and challenges

2.1 Special feature: Coherence

Ensuring policy coherence is a key objective of better regulation

Ensuring coherence between EU policy objectives, policy initiatives and instruments is one of the fundamental objectives of the Commission's better regulation agenda. Coherence is one of the key performance standards against which alternative policy options are assessed along with effectiveness, efficiency, proportionality and EU value added.

Coherence is essential in maximising intra- and inter-instrument synergies and minimising regulatory overlaps and inconsistencies. Checking internal coherence means looking at how the various components of the same EU intervention operate together to achieve its objectives. Similar issues can arise externally at different levels, between interventions within the same policy field or in areas that may have to work together.

The Board is a key actor in checking coherence

The Board plays an important role in ensuring policy coherence through its scrutiny practice, both in upstream support meetings and in particular when scrutinising the quality of impact assessments, evaluations and fitness checks. The RSB is particularly well placed to do this as it looks at all impact assessments and can flag coherence issues at an early stage of the policy development process.

Interlinked policy packages raised particular coherence challenges

Scrutinising coherence is particularly critical for interlinked packages of initiatives or comprehensive fitness check evaluations. During 2021, the Board looked into the impact assessments of a number of policy packages of closely related initiatives. The most prominent one was the 'Fit for 55' climate policy package adopted on 14 July 2021 as a follow-up to the Climate Target Plan and the Climate Law adopted in 2020. This package of initiatives was informed by nine individual but interrelated impact assessments ⁽⁶⁾. The Board scrutinised these impact assessments almost in parallel and put a particular emphasis on checking the internal and external coherence of

TABLE 3: Coherence in RSB scrutiny, 2021

Coherence mentioned in RSB opinions and quality checklists on impact assessments				
	Positive	Positive with Reservations	Negative	Total
Quality Checklists	12	26	26	64
Opinions	7	23	20	50

⁽⁶⁾ Effort Sharing Regulation, updating the EU Emissions Trading System, Revision of the EU Emissions Trading System Directive concerning aviation, CO2 emission standards for cars and vans, Land use, land use change and forestry, Energy Efficiency Directive, Renewable Energy Directive, ReFuelEU Aviation, FuelEU Maritime

the package. In its scrutiny, the Board formulated a number of recommendations common across the impact assessments with a view to ensure coherence within and across these closely interrelated and connected impact assessments. The Board recommended, for example, that the impact assessment report(s) should:

- clearly define the scope of the initiative and specify how it aligns with the greenhouse gases reduction targets of the Climate Law, and how it follows or differs from the Climate Target Plan modelling scenarios,
- explain how the other 'Fit for 55' initiatives may affect the scope, choices or impacts of this initiative,
- clarify in the baseline that all 'Fit for 55' initiatives are considered as one package, despite possible timing differences and as a result, all initiatives share a common baseline scenario,
- explain the reasons and advantages of having a common baseline,
- be clear on complementarities and key trade-offs between the (preferred) options of the initiatives,
- anticipate that in the legislative process, positions may deviate from the Climate Target Plan's preferred scenarios, ambitions and policy mix, and include, therefore, the most relevant alternative options or ambition levels supported by stakeholders.

Some examples of the coherence oriented Board's recommendations are presented in the **Box 4**.

BOX 4: EXAMPLES OF THE BOARD'S RECOMMENDATIONS REGARDING COHERENCE OF THE 'FIT FOR 55' PACKAGE ⁽⁷⁾

- The report should clearly define the scope of the initiative. It should specify how it aligns with the greenhouse gas reduction targets of the Climate Law, and how it follows or differs from the CTP modelling scenarios. On this basis, the report should make clear what are the open policy choices that this impact assessment aims to inform. The report should explain how the other 'Fit for 55' initiatives may affect the scope, choices or impacts of this initiative.
- The methodological section, including methods, key assumptions, and baseline, should be harmonised as much as possible across all 'Fit for 55' initiatives. Key methodological elements and assumptions should be included concisely in the main report under the baseline section and the introduction to the options. The report should refer explicitly to uncertainties linked to the modelling. Where relevant, the methodological presentation should be adapted to this specific initiative.

Another policy area where the Board paid particular attention to coherence issues concerned sustainability related initiatives ⁽⁸⁾.

⁽⁷⁾ See for example the Board opinions on the revisions of the Energy Efficiency Directive and the Renewable Energy Directive.

⁽⁸⁾ Empowering Consumers for the Green Transition, Substantiation of Green Claims, Sustainable Corporate Governance, Sustainable Products Initiative, Review of the Construction Products Regulation, Marketing Standards framework for Fishery and Aquaculture Products.

2.2 Special feature: Proportionality

The Board considers if the initiative and the analysis are proportionate

In the Commission's better regulation agenda, proportionality has two dimensions.

The **principle of proportionality** is to ensure that the EU acts in a way that does not go beyond what is needed to address the problem at hand ⁽⁹⁾. Proportionality is one of the key performance standards against which alternative policy options are assessed in an impact assessment along with effectiveness, efficiency, coherence and EU value added.

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.

The Board looks at the proportionality concept in both its meanings.

Proportionality principle

The Board flagged that the proportionality of the preferred option should be assessed in light of...

Respecting the proportionality principle is about ensuring that the policy response corresponds to the size and nature of the identified problems and achieves its objectives at the lowest possible cost.

In its scrutiny, the Board often recommended that the proportionality of the preferred option should be assessed in light of the scale of the problem and the expected costs and benefits.

...the scale of the problem, including for SMEs...

The Board noted that some reports did not present coherent arguments for the scope of the initiatives, for example, the inclusion or exclusion of certain activities or sectors. In cases of initiatives with a broad scope, it asked for better justification of why this approach (sometimes the broadest possible scope) was preferable to a narrower scope; and for further assessment, whether a narrower scope would likely to deliver similar benefits in a more efficient manner. The Board emphasised that the inclusion of SMEs in scope of the initiatives required a more critical proportionality reflection. In those cases, it recommended that the reports should explain why more targeted approaches, including exempting SMEs (or at least micro enterprises), were not considered.

⁽⁹⁾ 'The content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties.' (Article 5 TEU)

...and the expected costs and benefits

The Board emphasised that the reports should sufficiently take into account proportionality considerations in comparison of options. It often asked for a better justification of the preferred option, in particular where it contained measures with low or negative net benefits, where it had a lower benefit-to-cost ratio compared to other options and where there was significant uncertainty that the expected benefits would actually materialize.

Proportionate analysis

The Board observed that the impact analysis was often underdeveloped...

The proportionate level of the analysis in impact assessments is about ensuring that the depth and scope of the overall analysis corresponds to the significance of the expected impacts. Other factors such as the magnitude and complexity of the problem and the risk of significant unintended consequences should also be taken into account. The level of analysis is also linked with the type of the initiative.

The Board noted that the impact analysis in some reports was underdeveloped, with certain significant impacts not sufficiently assessed. It frequently asked for further analysis of the impacts on consumers, competitiveness, innovation, Member States and SMEs. It often asked for further quantification, in particular of the administrative costs and savings.

...but on rare occasions, it was over and above what was expected

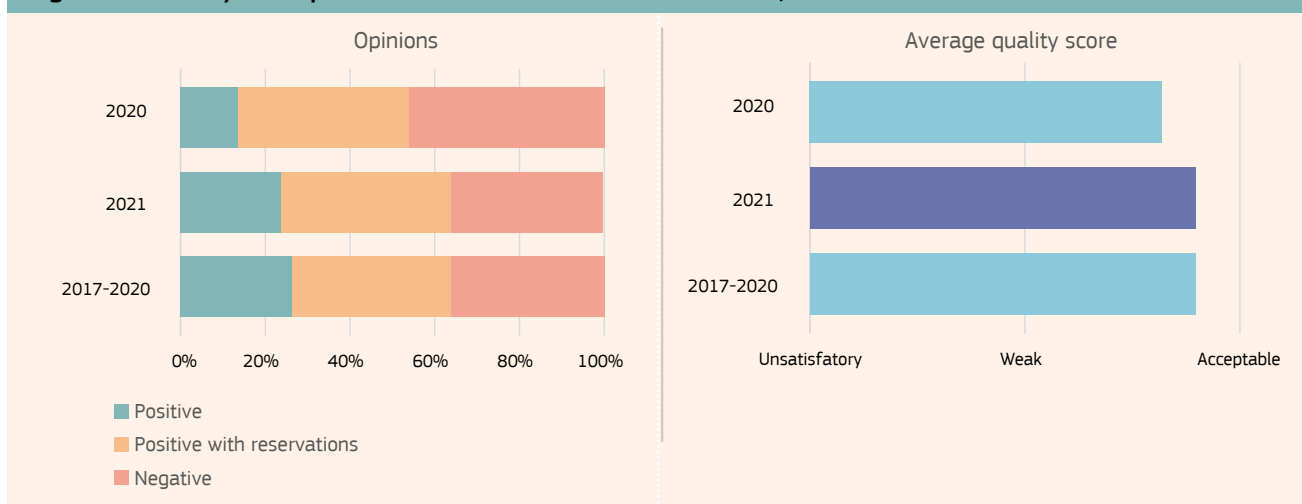
On rare occasions, however, the Board noticed that the level of analysis was over and above what could have been expected for a non-binding proposal and a proposal with low expected impacts.

2.3 Trends: impact assessments

The quality of impact assessments improved...

The observed quality of the scrutinised impact assessments improved markedly compared to 2020, returning to a level that is similar to the average of preceding years (**Figure 2**). The share of the negative opinions in the first submissions declined from 46% in 2020 to 37% in 2021, while the initial positive opinions increased from 12% to 22%. The share of the first opinions with reservations remained constant at 41%. However, because of the high number of impact assessments in 2021 (see **Section 1.2**), the absolute number of negative opinions (31) was higher than ever before.

Figure 2: Quality of impact assessments at first submission, 2021 vs 2020 and 2017-2020



... possibly as a result of less time pressure

The return to a more 'normal' impact assessment quality seems largely the result of declining time pressure on their preparation. While there were ambitious political deadlines to deliver the first initiatives of the von der Leyen Commission in 2020, most initiatives in 2021 had more time to prepare the analysis for the impact assessment.

Options were the weakest part

The definition of the options was the weakest element for all impact assessments in 2021 (**Figure 3**). Even impact assessments that received a positive opinion had, on average, less than acceptable options. For impact assessments with a negative opinion, the definition of options was particularly weak, with many receiving an unsatisfactory score. Often, the set of options was not complete and overly focussing on the predetermined (political) choice. The presented options often failed to integrate the main policy choices that needed to be made based on the impact assessment. In its Annual Report 2020, the Board suggested alternative approaches to defining a more complete set of options, which were included in the revised better regulation toolbox at the end of 2021.

Impact assessments with negative opinions had wider problems

Next to the options definition, the weaknesses in impact assessments with negative opinions were mostly found in (i) the problem definition and evaluation, (ii) the analysis of impacts, and (iii) the comparison of options and proportionality. These weaknesses often occurred in initiatives that had drawn their primary impetus from political commitments and target setting. The resulting impact assessments often lacked convincing evidence to demonstrate the existence and size of the problem. For the same reasons, they were also not able to demonstrate that the options can make a difference, leading to an unconvincing choice of preferred option.

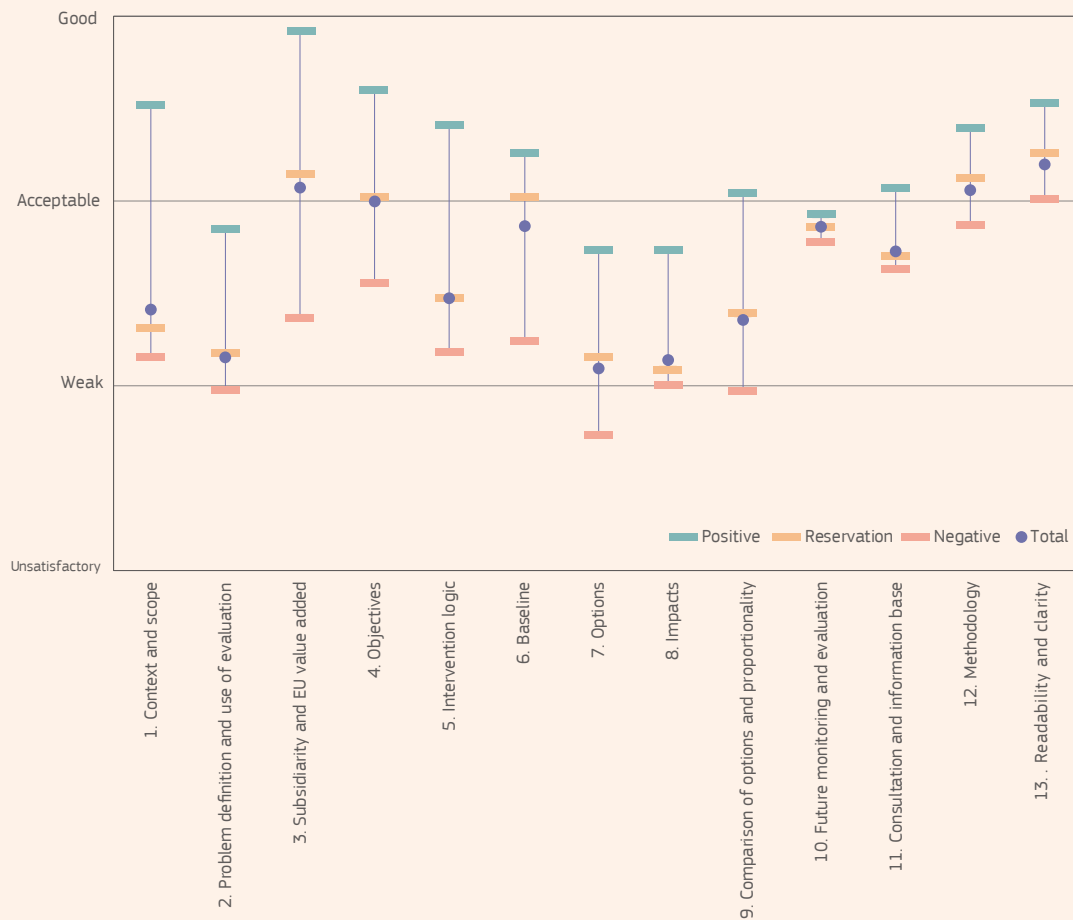
Consultation results were often not used well

Despite the close-to-acceptable score for consultation and information base (**Figure 3**), the Board made critical remarks on this quality component in almost 60% of its first opinions, particularly for positive opinions with reservations and negative opinions. These remarks usually did not put into question the comprehensiveness of the consultation activities, but mainly concerned the insufficient use of the results of the consultation in the impact assessment. Stakeholders' views were obtained, but insufficiently reflected in, for example, the problem definition or the discussion of the impacts. Too often, the consultation outcomes were wrongly used as if they were the result of a representative survey. The consultation results should mainly be used to identify what different stakeholder groups think about the issue at hand. Accordingly, the impact assessment should clearly present these different views, including the diverging ones. In particular, the discussion and design of the options should include those options that were raised or favoured by relevant stakeholder groups and are likely to emerge in the political discussions of the legislators.

Readability of reports improved

The readability and clarity of the impact assessments improved compared to previous years, in particular for impact assessments that received an initial negative opinion. In the early part of the year, the Board noted an increasing length of impact assessments, with hundreds of pages and many annexes. As this reduces readability and their usefulness for supporting policymaking, the Board insisted to limit the length of the main report to 50 pages. This forced departments to focus more on the narrative of the impact assessments and to find an appropriate balance between the key information in the main report and the details in the annexes.

Figure 3: Quality of impact assessments at first submission by quality component, 2021



Methodology, and EU value added were often good

As in previous years, the methodological approach and the analysis of subsidiarity and EU value added remained satisfactory, except for impact assessments that received an initial negative opinion. They usually identified appropriate methodologies to assess the expected impacts of the different options. Most impact assessments were also successful in demonstrating the need for the EU to act and in showing the EU value added.

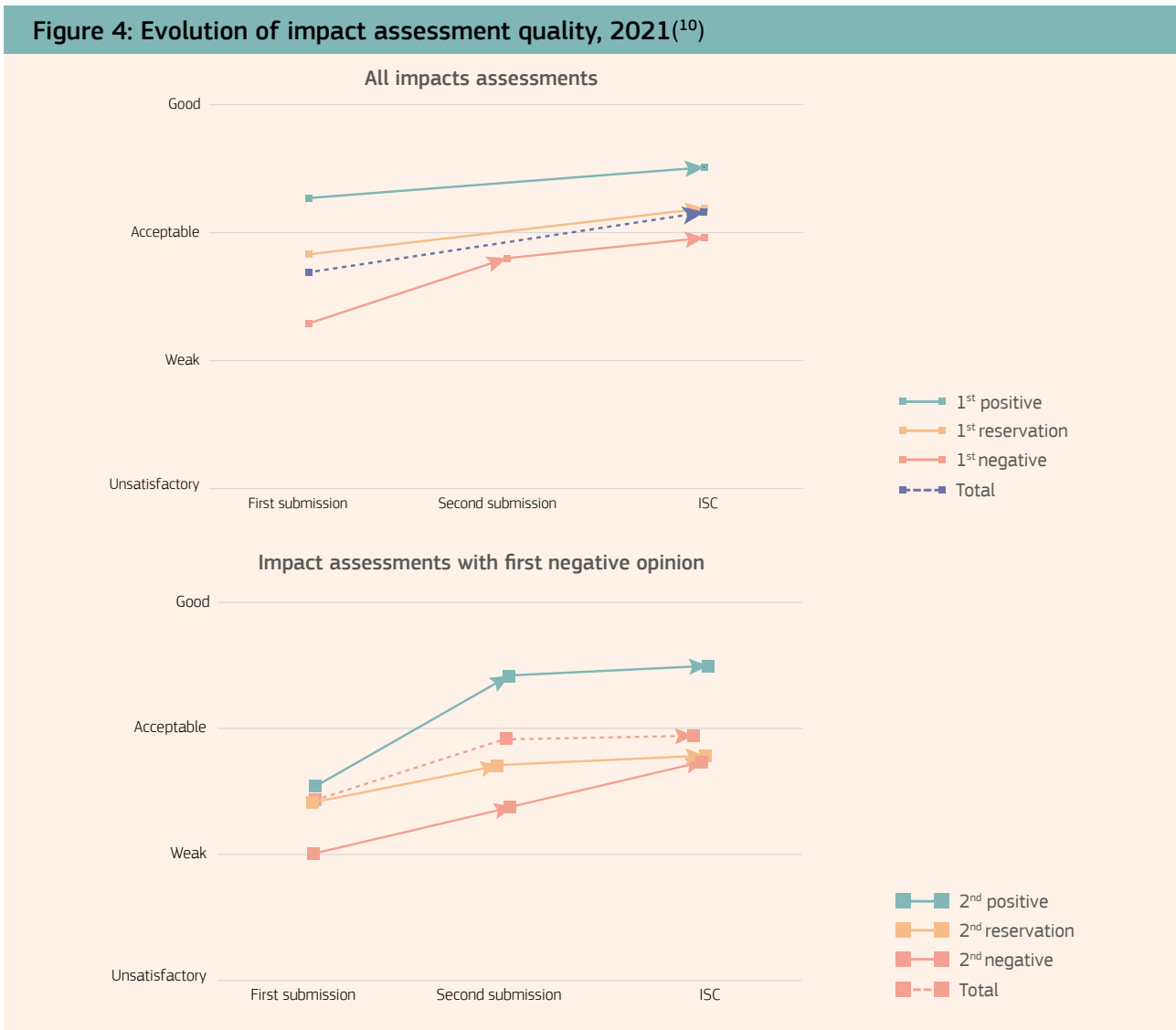
Scrutiny continued to improve quality

The Board’s scrutiny continued to improve the quality of the final impact assessments (KPI 3). The average quality of all impact assessments improved to acceptable levels after the Board’s opinion(s) (Figure 4, top graph). Impact assessments that had a more than acceptable quality at first submission received a positive opinion. Despite their acceptable initial quality, they still tended to integrate the Board’s recommendations to improve the quality of the final impact assessment. Impact assessments with a somewhat less than acceptable initial quality received a positive opinion with reservations. Afterwards, they also sufficiently incorporated the Board’s recommendations to improve the quality to an acceptable level. The weakest impact assessments received a first negative opinion. On average, their quality improved significantly by the second submission, although their final quality remained somewhat below acceptable levels.

The quality of second submissions was mixed

The bottom graph of **Figure 4** zooms in on the impact assessments that received a first negative opinion. It shows that impact assessments that managed to improve their quality considerably by the second submission received a second positive opinion. The incorporation of the Board's recommendations has clearly made the quality of these impact assessments more than acceptable. Other impact assessments that had about the same insufficient initial quality improved much less by the time of the second submission and received a positive opinion with reservations. This opinion was clearly not a sufficient motivation for the responsible department to introduce the necessary further improvements to bring the quality of the final impact assessment to an acceptable level. Finally, a limited number of impact assessments had an overall weak quality at the time of their first submission. While the departments managed to improve the quality of these report significantly in the second submission, the progress was insufficient and they received a second negative opinion. As a result, further efforts were made to improve the quality of the final impacts assessment, but it remained below acceptable.

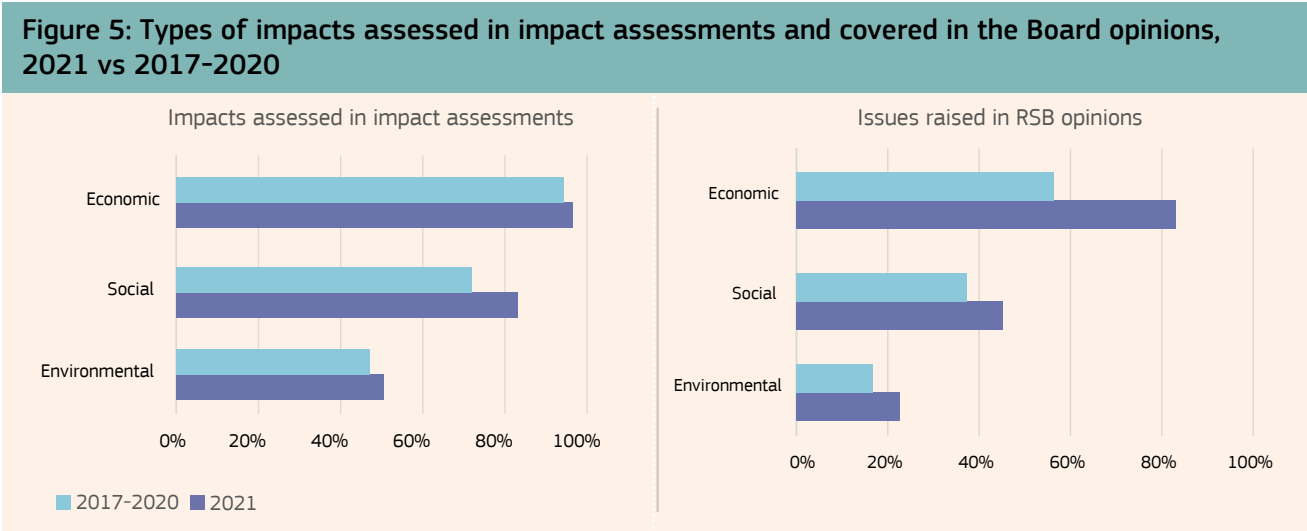
Figure 4: Evolution of impact assessment quality, 2021⁽¹⁰⁾



⁽¹⁰⁾ Figure 4 shows all cases where the interservice consultation (ISC) was finalised in 2021. It concerns 60 impact assessments, of which 15 received a positive opinion, 27 a positive with reservations and 18 a negative opinion. Of these 18 impact assessments with a first negative opinion, 6 received a second positive opinion, 10 a second positive opinion with reservations and 2 a second negative opinion.

Impact assessments continued to cover economic, social and environmental impacts...

The Commission’s better regulation guidelines require that impact assessments ‘are based on an integrated approach that addresses impacts across the environmental, social and economic pillars of sustainable development and so contribute to the mainstreaming of sustainability in policymaking’ ⁽¹¹⁾. They should analyse all relevant impacts in a proportionate way (see **Section 2.2**). While the Green Deal has resulted in a high number of green initiatives, the left graph in **Figure 5** shows, that the number of impact assessments covering environmental issues only marginally increased in 2021; given the overall high number of impact assessments, the share covering environmental impacts did not increase. This also indicates that even before the Green Deal, the Commission was paying due attention to environmental impacts. The analysis of social impacts, on the other hand, did increase in 2021 compared with previous years.



⁽¹¹⁾ European Commission, Better regulation guidelines, SWD(2017)350, p. 8

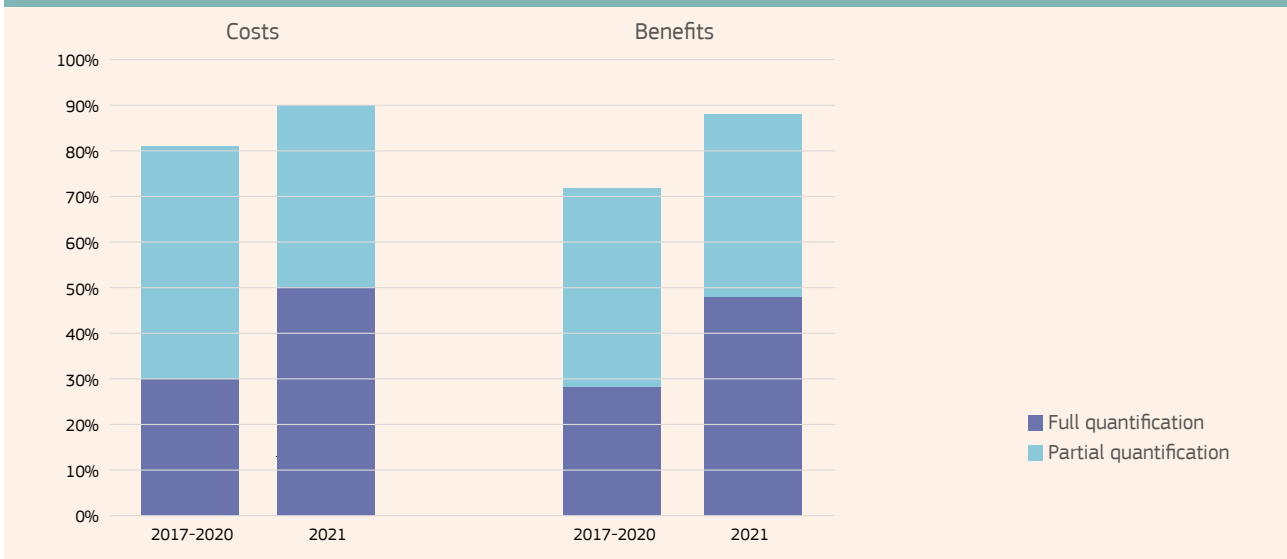
**... although opinions
flagged more issues with
impact analysis**

In 2021, the Board issued more recommendations on all types of impacts. These recommendations can concern the quality of the analysis or the lack of sufficient analysis of certain impacts. Among the economic impacts, the Board most often raised issues on the competitiveness analysis because costs and benefits of the initiative were not appropriately or insufficiently assessed or evidence-based. A lack of analysis of the impacts on Member States or groups of Member States was also often raised. In almost a quarter of the impact assessments, the Board found that the analysis on SMEs was not sufficiently developed. On the social impacts, the Board mainly noted weaknesses in the analysis of the impacts on the organisation of the public sector in Member States or at the EU level. In addition, it raised issues on the analysis of employment impacts. The remarks on environmental impacts concerned about equally climate impacts and impacts on natural resources (air, land, water, biodiversity).

**Quantification increased
further**

The quantification of benefits and costs continued to increase in 2021 (Figure 6). Around 90% of all impact assessments included at least a partial quantification of benefits and costs, with around half of them being quantified fully.

Figure 6: Trends in quantification of costs and benefits in impact assessments, 2021 vs 2017-2020 ⁽¹²⁾



**The Board has taken
up the 'one in, one out'
aspect in its scrutiny**

The pilot phase of the OI00 approach was introduced in the second half of 2021. The Board scrutinised the impact assessments of initiatives in the pilot. It often asked for clearer distinction between different categories of costs and further quantification of the administrative costs and savings.

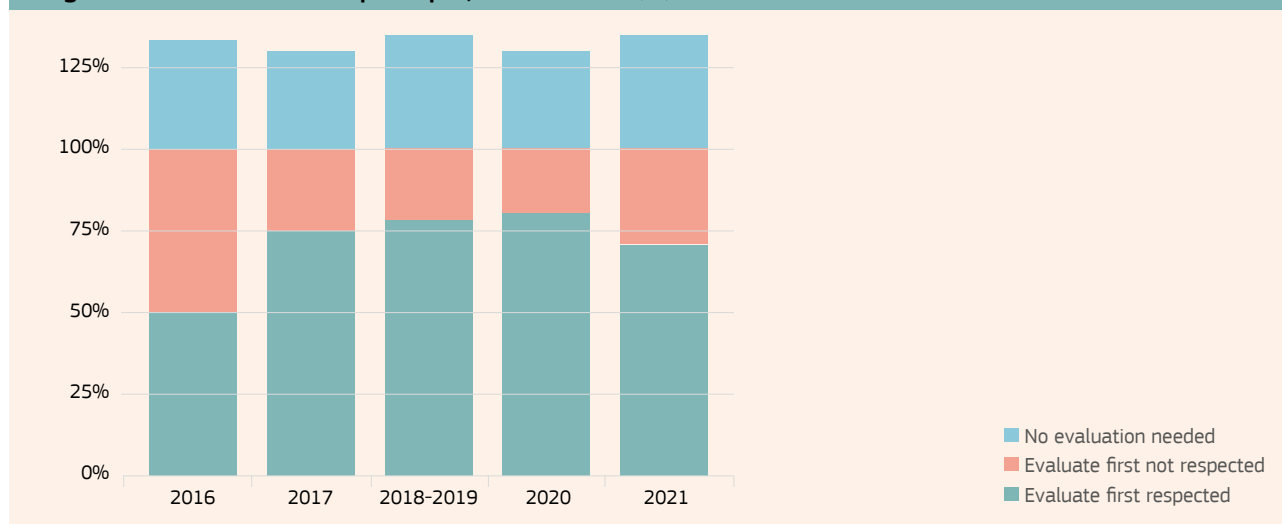
⁽¹²⁾ Percentages include only cases where quantification was judged to be required on proportionality grounds

2.4 Trends: Evaluations

'Evaluate first' principle was observed less

The Board observed that fewer impact assessments came with a fitness check or evaluation ⁽¹³⁾. Since 2016, the Commission requires that all impact assessments that aim to revise existing legislation should be preceded by an evaluation that assesses to what extent the current policy or programme is effective, efficient, coherent, adds value and remains relevant. After the introduction of this 'evaluate first' principle, the proportion of impact assessments that met the requirement increased gradually to 81% in 2020 (Figure 7). However, in 2021 it declined to 72%.

Figure 7: Evaluation first principle, 2016-2021 ⁽¹⁴⁾



Fewer evaluations were planned

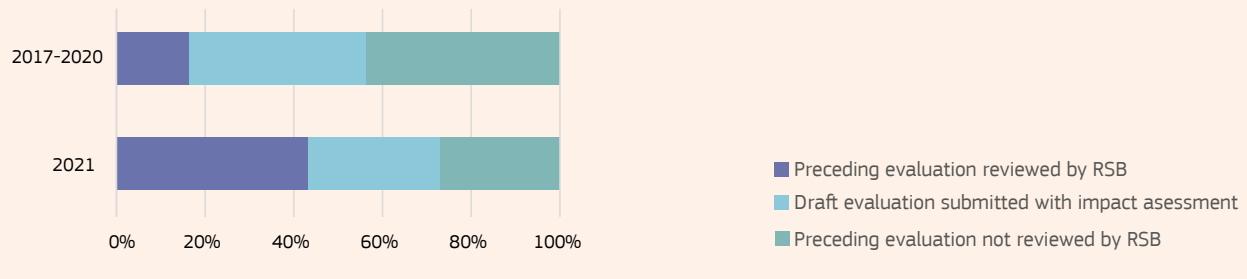
The Board also observed that fewer evaluations were being planned when it selected the main evaluations to scrutinise. As a result, in 2021 it had previously scrutinised ⁽¹⁵⁾ a much higher proportion of the evaluations that accompanied impact assessments than before (Figure 8).

⁽¹³⁾ As a fitness check is a specific type of evaluation, the remainder of this Section uses the term 'evaluations' for fitness checks and evaluations jointly.

⁽¹⁴⁾ No evaluation is needed when the impact assessment concerns a new initiative in an area where the EU was not previously active.

⁽¹⁵⁾ The Board scrutinises all fitness checks and the main evaluations. Each year, it makes a selection from the planned evaluations to identify the main evaluations

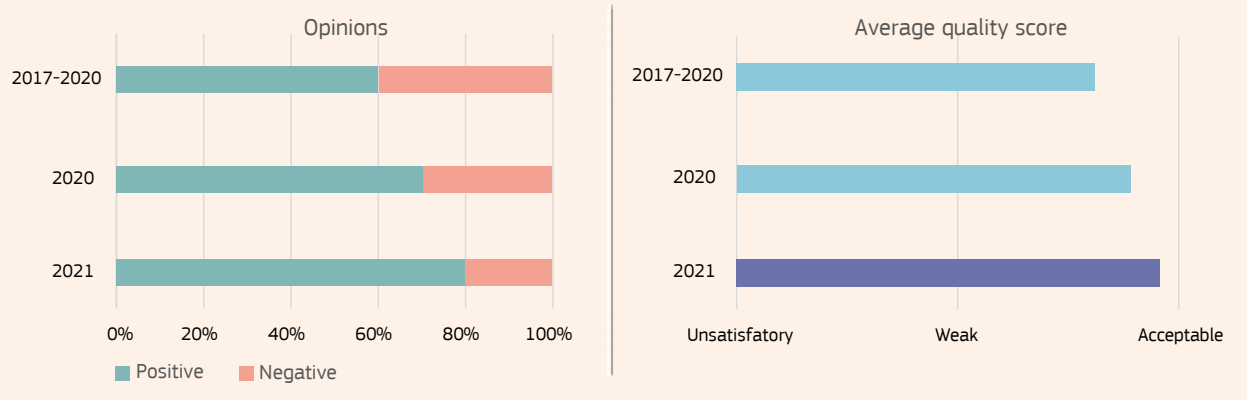
Figure 8: Evaluations seen by the Board, 2021 vs 2017-2020 ⁽¹⁶⁾



The quality of evaluations improved

The quality of the reviewed evaluations at first submission improved in 2021, with only 20% receiving a negative opinion. This confirmed the improvement that was already observed in 2020 (Figure 9). The quality score of all evaluations also further increased in 2021 to a close to acceptable average level. This would indicate that the increased focus on the quality of evaluations that was introduced in the better regulation strategy in 2016 and the Board’s evaluation scrutiny had the desired effects.

Figure 9: Quality of evaluations at first submission, 2021 vs 2020 and 2017-2019

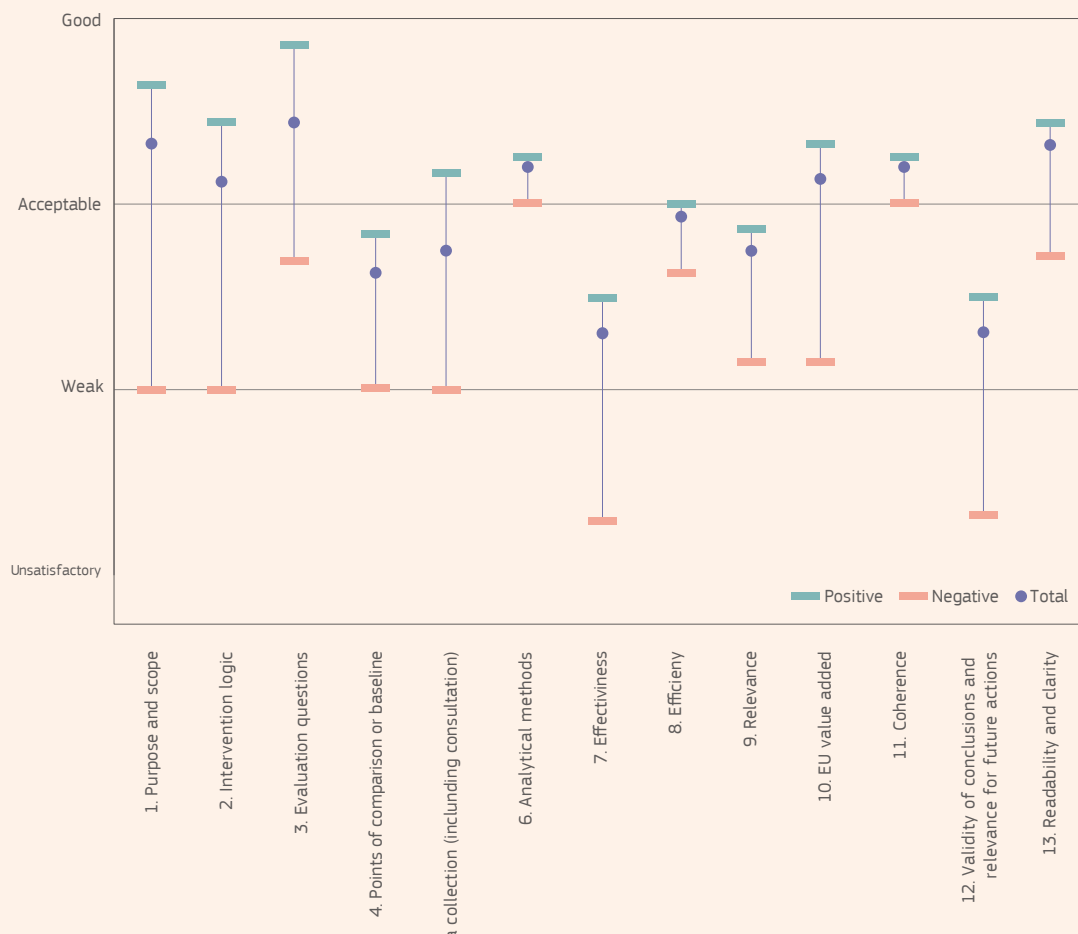


⁽¹⁶⁾ As a percentage of the impact assessments meeting the ‘evaluate first’ principle.

Evaluations with a negative opinion often had design problems

Figure 10 shows that the few evaluations that received an initial negative opinion in 2021 had a significantly lower quality on most quality components. They scored low on most design elements of the evaluation, such as the definition of the purpose and scope, the intervention logic (what was the initiative supposed to achieve and how), the definition of the points of comparison, and the data collection and consultation. As a result, the analysis of the effectiveness of the initiative and the usefulness and validity of the conclusions were very weak for these evaluations. Fixing these design flaws often was no longer possible at the time the draft evaluation was submitted for scrutiny to the Board, as the fieldwork and the collection of data had been completed at that time. More Commission departments, therefore, chose not to resubmit their evaluation to the Board after receiving a negative opinion. Of the seven evaluations that received a negative opinion in 2020 and 2021, only three were resubmitted and received a second positive opinion. The other four were either published together with the Board's negative opinion or were not published as a formal evaluation.

Figure 10: Quality of evaluations at first submission by quality component, 2021



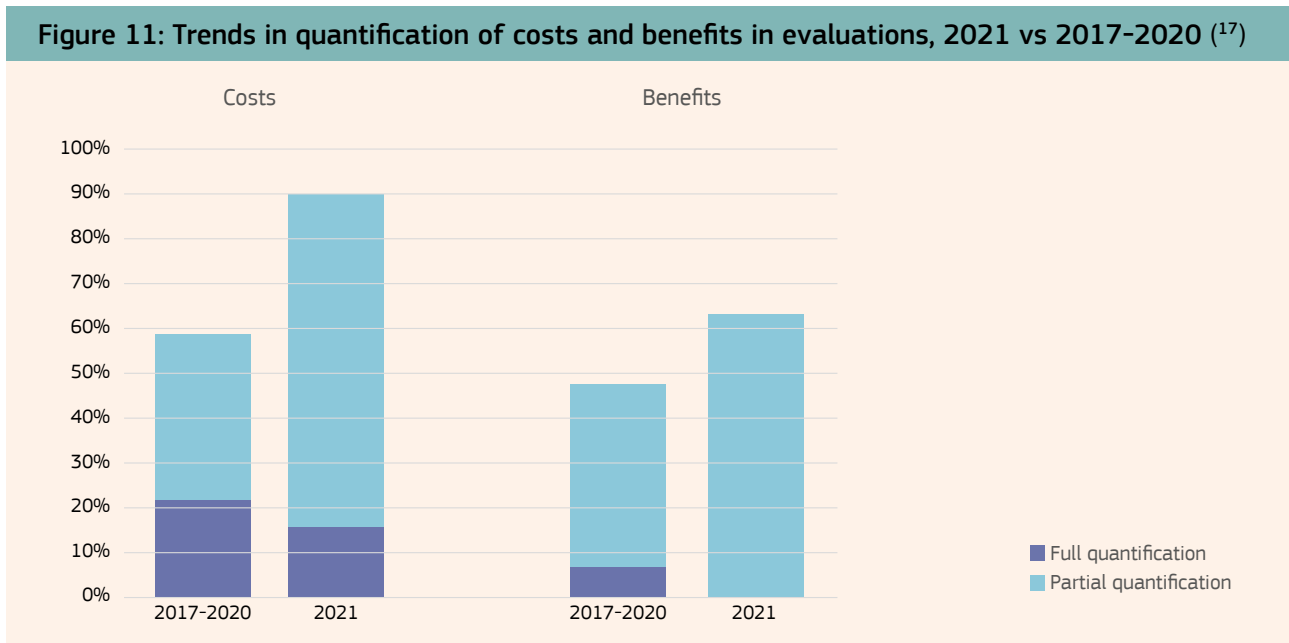
Evaluations with a positive opinion mostly performed well on all quality components

The evaluations that received a positive opinion, on the other hand, performed relatively well across all quality components. Elements of the evaluation design, such as the definition of the purpose and scope, the intervention logic and especially the definition of the evaluation questions, scored particularly well. Their weakest elements were again the effectiveness analysis and the usefulness of the conclusions for future actions.

Quantification increased, but remained partial

The overall quantification of costs and benefits in evaluations improved in 2021 (Figure 11). Costs were quantified in 85% of the cases, while benefits were quantified in close to 65% of the evaluations. However, the quantification tends to be partial. Full quantification remained rare in evaluations. All evaluations predominantly used qualitative tools in 2021, while only close to half of them also used quantitative tools.

Figure 11: Trends in quantification of costs and benefits in evaluations, 2021 vs 2017-2020 ⁽¹⁷⁾



⁽¹⁷⁾ Percentages include only cases where quantification was judged to be required on proportionality grounds.

CONCLUSIONS

RSB TEAM

Conclusions

Scrutiny of impact assessments and evaluations contributes to higher quality information to support decision making. In 2021, the Regulatory Scrutiny Board had a very busy year with the major flagship packages of the von der Leyen Commission. Planning for 2022 suggests that it will be an even busier year.

Chapter 2 of this report reflects the Boards' analysis of the quality of impact assessments and evaluations examined during 2021. The observed quality of the scrutinised impact assessments improved markedly compared to 2020, returning to a level that is similar to the average of preceding years. It was notable that the Board issued a lower proportion of negative opinions on first submitted impact assessments. This is remarkable given that departments produced the highest number of impact assessments and evaluations over the last six years and often faced tight deadlines and challenging delivery conditions. It also demonstrates their continued commitment to the Commission's Better Regulation agenda. The quality of the reviewed evaluations at first submission improved in 2021, with only 20% receiving a negative opinion.

A key challenge in 2021 was to ensure the proper analysis of proportionality. The other noteworthy aspect, which will continue in 2022, is the close interlinkage between related initiatives. Coherence needs to be considered carefully when assessing linked initiatives, such as in the green and digital transitions.

Outreach activities continued to be hampered by the COVID-19 pandemic and the shift to distance working. However, the Board managed to hold the greatest ever number of upstream meetings with Commission departments on future initiatives. As well as the intense work programme of scrutiny, the Board will continue its outreach work during 2022.

The Board remained below full membership in 2021 and this will hopefully be resolved in 2022 as recruitment procedures are finalised for the remaining external member. Board members remain strongly committed to fulfilling their role to provide independent scrutiny and advice to Commission departments with the aim of improving the quality of both impact assessments and evaluations, thereby helping to ensure the best informed policy choice for EU decision makers.

RSB Team



Starting from the left: **Bernard Naudts**, Member of the Board; **Antonio Nicita**, Member of the Board; **Dorota Denning**, Member of the Board; **Deirdre Hughes**, Assistant; **Claudia Di Dio**, Assistant; **Rytis Martikonis**, Chair; **Alix Van Acker**, Assistant; **Michael Gremminger**, Member of the Board; **Antonina Cipollone**, Board Secretary; **James Morrison**, Member of the Board.

The Board expresses its great appreciation and deep gratitude to its former members and assistants who left in 2021 and 2022.



Veronica Gaffey
Chair



Andreas Kopp
Member of the
Board



Mona Bjorklund
Member of the
Board



Corinne Tailly
Assistant


































ANNEX




Impact assessments and Evaluations 2021

IMPACT ASSESSMENTS

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

(*) 2021 files where resubmission and second opinion issued in first quarter of 2022

Impact assessments reviewed in 2021	First opinion	Second opinion	'Evaluate first' principle
ReFuelEU Aviation - Sustainable Aviation Fuels			no evaluation needed
FuelEU Maritime (Green European Maritime Space)			no evaluation needed
Revision of the General Product Safety Directive – Refit initiative			
Revision of the Machinery Directive			
Empowering consumers for the green transition	Ongoing		
Revision of the Consumer Credit Directive			
Establishment of an EU Green Bond Standard			no evaluation needed
Intra-EU Investment protection and facilitation framework	Ongoing		
Addressing distortions caused by foreign subsidies			no evaluation needed
Update of concentration limit values of persistent organic pollutants in waste			no evaluation needed
Proposal for a revision of Directive 2003/96/EC restructuring the Community framework for the taxation of energy products and electricity			
European Digital Identity			
Schengen evaluation and monitoring mechanism			
Review of Regulation (EC) No 1013/2006 on Shipments of Waste			
Generalised Scheme of Preferences Regulation applying as of 2024			
Updating Member State emissions reduction targets (Effort Sharing Regulation) in line with the 2030 climate target plan			
Updating the EU Emissions Trading System			
Revision of the EU Emission Trading System Directive concerning aviation			

Positive opinion 
 Positive with reservations 
 Negative opinion 

Revision of the CO2 emission standards for cars and van	●		✗
Land use, land use change and forestry – review of EU rules	●		✗
Revision of the Energy Efficiency Directive	●	●	✓
Revision of the Renewable Energy Directive (EU) 2018/2001	●	●	✗
Proposal for a Carbon Border Adjustment mechanism (CBAM)	●		no evaluation needed
Review of measures on taking up and pursuit of the insurance and reinsurance business (Solvency II)	●		✓
Accession to the Judgments Convention	●		no evaluation needed
Minimising the risk of deforestation and forest degradation associated with products placed on the EU market	●	●	✓
Sustainable corporate governance (*)	●	●	no evaluation needed
Revision of Alternative Fuels Infrastructure Directive	●		✓
Amendment of the Schengen Borders Code	●		✗
Digital levy	Ongoing		
European fishery statistics	Ongoing		
Common chargers for mobile phones and similar devices	●		no evaluation needed
Regulation on detection, removal and reporting of child sexual abuse online, and establishing the EU centre to prevent and counter child sexual abuse	Ongoing		
Revision of the EU geographical indications (GI) systems in agricultural products and foodstuffs, wines and spirit drinks	Ongoing		
Ozone layer protection – revision of EU rules	Ongoing		
Euro 7/VII	Ongoing		
European Long term investment funds (ELTIF) review	●		✓
Markets in Financial Instruments Regulation/Directive (MiFID/R) Review	●	●	✗
Protecting biodiversity: nature restoration targets	Ongoing		

Positive opinion ●
 Positive with reservations ●
 Negative opinion ●

Alternative Investment Fund Managers – review of EU rules	●		✓
Strengthening the automated data exchange under the Prüm framework	Ongoing		
EU single access point for financial and non-financial information publicly disclosed by companies (EFTG/ESAP)	●		✓
Review of the Construction Products Regulation	Ongoing		
Revision of Regulation on Union guidelines for the development of the trans-European transport network (TEN-T)	●		✓
Proposal for a legislative act on methane leakage in the energy sector	●	●	no evaluation needed
Substantiation of green claims using product / environmental claims based on environmental footprint methods	Ongoing		
Revision of the Energy Performance of Buildings Directive	●	●	✗
Revision of EU rules on Gas	●		✓
Sustainable Products Initiative	Ongoing		
Digitalisation of visa procedures	Ongoing		
Revision of Regulation 1141/2014 on the statute and funding of European political parties and European political foundations ('EUPP Revision')	●		✗
Revision of the Intelligent Transport Systems Directive	●		✓
Digitalisation of cross border judicial cooperation	●		no evaluation needed
Law enforcement cooperation code	●		✗
Instrument to deter and counteract coercive actions by third countries	●		no evaluation needed
Transparency of political advertising	●		no evaluation needed
Revising the Environmental Crime Directive	●		✓
Supporting broad and inclusive participation of mobile EU citizens in Europe and in the elections to the European Parliament	●		✗
Individual Learning Accounts – A possibility to empower individuals to undertake training	●		no evaluation needed
Preventing and combatting gender-based violence (*)	●	●	✗
Revision of the Energy and Environmental Aid Guidelines (EEAG) (*)	●		✓

Positive opinion ●
 Positive with reservations ●
 Negative opinion ●

EU Legislative initiative to fight the use of shell entities and arrangements for tax purposes	●		no evaluation needed
Single permit for third-country nationals to reside and work in the EU	Ongoing		
Rights of third-country nationals who are long-term residents in the EU	Ongoing		
Improving the working conditions of platform workers	●		no evaluation needed
Collective bargaining agreements for self-employed	Ongoing		
Data Act (*)	●	●	no evaluation needed
Central security depositories – review	Ongoing		
Strengthening existing rules and expanding exchange of information framework in the field of taxation (DAC8)	Ongoing		
EU Space-based secure connectivity (*)	●	●	no evaluation needed
Review of Designs Directive	Ongoing		
Digital health data and services – the European health data space	Ongoing		
EU farm and food products – review of policy on promotion inside and outside the EU	Ongoing		
Sustainable use of pesticides – revision of the EU rules	Ongoing		
Revision of the Vertical Guidelines and Revision of the Vertical Block Exemption Regulation	Ongoing		
Revision of the Industrial Emissions Directive (IED) and the European Pollutant Release and Transfer Register Regulation (EPTR)	Ongoing		
Road circulation requirements for mobile machinery	Ongoing		
Revision of the Distance Marketing of Consumer Financial Services Directive	Ongoing		
Revision of the Union legislation on blood, tissues and cells	Ongoing		
Review of the marketing standards framework for fishery and aquaculture products	Ongoing		
Uniform rounding rules for cash payments, Legislative initiative on uniform rounding rules	Ongoing		
Geographical indication protection at EU level for non-agricultural products	Ongoing		
Ecodesign/Energy labelling of smartphones and tablets	Ongoing		

Positive opinion ●
 Positive with reservations ●
 Negative opinion ●

EVALUATIONS

Evaluations reviewed in 2021	First opinion	Second opinion
Evaluation of procedural and jurisdictional aspects of EU Merger Control?	●	
European network of employment services (EURES)	●	●
Evaluation of the eIDAS Regulation	●	
Report on the Application and Evaluation of the Postal Services Directive	●	
EU Timber Regulation and Forest Law Enforcement, Governance and Trade	●	
Evaluation of the Commission notice on market definition in EU competition law	●	
Mid-term evaluation of JASPERS	●	not resubmitted but finalised
Evaluation of the impact of the common agricultural policy on natural resources	●	
Evaluation of Geographical Indications and Traditional Specialities Guaranteed protected in the EU	●	
Evaluation of Biodiversity	Ongoing	
Evaluation of CAP general objective on balanced territorial development	●	
Directive (EU) 2017/541 on combatting terrorism	●	
Fitness check of the EU legislation on violence against women and domestic violence	●	not resubmitted but finalised
Food contact materials evaluation	Ongoing	
Evaluation of the Directive establishing an infrastructure for spatial information (INSPIRE)	Ongoing	

Positive opinion ●
Negative opinion ●

GLOSSARY

Better Regulation	‘Better Regulation’ means designing EU policies and laws so that they achieve their objectives at minimum cost. It is a way of working to ensure that political decisions are prepared in an open and transparent manner, informed by the best available evidence and backed by the comprehensive involvement of stakeholders. Better regulation covers the whole policy cycle, from policy design and preparation, to adoption, implementation (transposition, complementary non-regulatory actions), application (including enforcement), evaluation and revision. ⁽¹⁸⁾
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	<p>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.</p> <p>A Fitness check report is prepared by the lead department. The Regulatory Scrutiny Board checks the quality of all Fitness check reports.</p>

⁽¹⁸⁾ More information on Better Regulation is available at https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how_en

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.
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 approach ⁽¹⁹⁾ .
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.

⁽¹⁹⁾ COM(2021) 210 Final better_regulation_joining_forces_to_make_better_laws_en_0.pdf (europa.eu)

