

Better Regulation's "how to" - Consultation exercises

Consultation in the Better Regulation agenda

Regulation for Better Health project, 2025).

Stakeholder consultation is a core pillar of the Better Regulation agenda. Including stakeholder inputs in the policy-making process supports the agenda's goal of delivering evidence-based policies. This "how to" guide presents three pathways of contributing to policy-making. It provides an introduction to each pathway, step-by-step guidance, and links to key portals and websites on which to find information on the consultation processes. More detailed information on how consultation is organised, and through which formats, is provided in the section "Instruments for civil society and stakeholder participation in the Better Regulation" of the Better Regulation for Better Health civil society toolkit (Better

1. Call for evidence

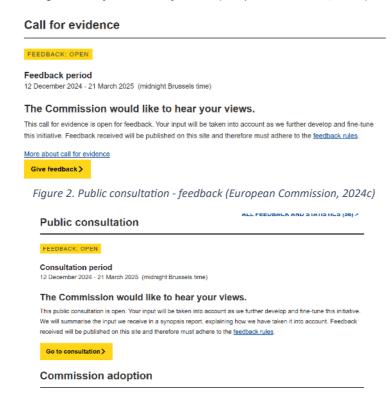
The call for evidence is an exercise that is launched for evaluations and impact assessments. Its main element is a survey, called the open public consultation (OPC), that should remain open to the public for a minimum of 12 weeks. The call for evidence combines and replaces previous exercises where separate feedback could be provided on roadmaps and inception impact assessments, at the beginning of the process for new legislative proposals (Better Regulation for Better Health project, 2025).

Other elements of the call for evidence include the possibility to provide feedback on the consultation strategy itself, i.e., how the impact assessment or evaluation study plans to involve stakeholders, gather their inputs, and how can stakeholders overall take part in the process. Consultation strategies are required and guided by the Better Regulation toolbox, and set out the Commission's plans for the OPC and various other consultation activities, such as conferences, focus groups, targeted surveys and workshops. It is foreseen that such strategies are open for feedback, allowing stakeholders to shape the later points of engagement available (Better Regulation for Better Health project, 2025).

To take part in the call for evidence, stakeholders need to register through EU Login, and provide their input on the given proposal through the <u>Have Your Say Portal</u> (European Commission, 2024a). The Portal's research tool allows to filter for the calls for evidence, open and upcoming, as available <u>here</u> (European Commission, 2024b).

As an example, in December 2024, the Commission published a call for evidence and OPC on the targeted evaluation of EU rules on medical devices and in vitro diagnostics (European Commission, 2024c). The initiative is first presented. Then the possibility to share feedback on the call for evidence is made available, through the button "provide feedback". The inputs provided are available publicly, on the same page. The OPC is then presented, as shown in the figures below. The page also provides a timeline of the process, allowing stakeholders to follow it.

Figure 1. Call for evidence - feedback (European Commission, 2024c)

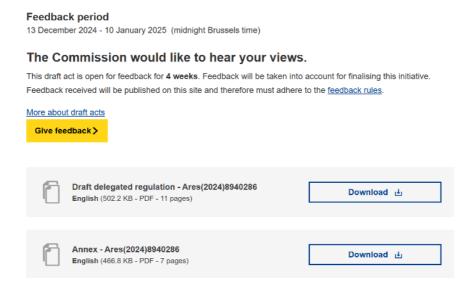


2. Other feedback pathways

Feedback on legislative drafts and delegated/implementing acts is a pathway of engagement less commonly utilised by civil society, but it offers a crucial benefit over OPC input, in that it is usually unstructured. Feedback is entered into a "free text" box, rather than being based on a questionnaire or survey, giving greater freedom to convey information. For these exercises, the Commission is required to report on how feedback is accounted for via the comitology register (Better Regulation for Better Health project, 2025).

Feedback on draft delegated acts, implementing acts, and measures subject to regulatory procedure with scrutiny, is also organised via the Have Your Say portal, and is usually open for four weeks. They can be found through the search engine, with the filter "draft act", as shown here (European Commission, 2024d). To provide feedback, it is necessary to login through the EU Login. This page is shown in the figure below, with the example of the EU emissions trading system (ETS) – update of Registry Regulation following ETS revision/Fit For 55 (European Commission, 2024e).

Figure 3. Feedback on draft acts (European Commission, 2024e)

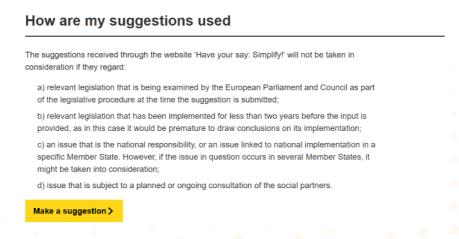


3. Feedback on existing law

A third pathway permits feedback on any existing EU law, via the Have Your Say: Simplify! portal (European Commission, 2024f). This portal feeds into the Fit for Future high-level expert group (Fit for Future Platform). It corresponds to the objective of the Better Regulation agenda to simplify EU regulations. The goal is to allow citizens to identify existing EU laws that are burdensome or problematic. Its relevance for civil society is not immediately apparent, and it can be seen as a tool that is more advantageous for economic and commercial actors. However, the Platform's scope is broader than burden reduction, as it also looks at making laws more efficient and fit for future, while supporting the fulfilment of EU policy objectives. Therefore, there is potential for civil society to use the tool as a way to bring attention on legislation that fails to achieve health objectives, or imposes a burden on specific groups, for instance (Better Regulation for Better Health project, 2025).

To take part in this consultation process, it is necessary to log in through EU Login to the Have Your Say: Simplify! portal. The portal then allows for suggestions to be shared through a form (see the figure below). It is also possible to consult suggestions made previously, in the "recent suggestions" section.

Figure 4. Have Your Say: Simplify! (European Commission, 2024f)



Accessing key documents

Impact assessments, when finalised, are published on the European Commission website, in the publications, and/or on the webpage of the proposal or revision. For instance, the impact assessment on the European Health Data Space was published alongside the new Regulation and is now available on the Commission website (European Commission, 2022). Another example, where the impact assessment is not published yet as the process is delayed, is the revision of the Food Information to Consumers regulation, where the webpage mentions the exercise and provides access to the consultation results (European Commission, 2020). Finally, the Regulatory Scrutiny Board's opinions on the impact assessments are published on the Board's website (European Commission, 2024g) for opinions on evaluations and fitness checks. For impact assessments, the opinion is also presented within the annexes of the assessment report / staff working document.

Additional sources and steps

The main Have Your Say portal provides an email-alert system. This is available by clicking on the subscribe button on the homepage, which then provides a list of topics of interest to select for the alerts. This process requires logging in/registering to the portal.

Step 1. Step 2. Log in / Register to contribute Subscribe In order to contribute you'll need to register or login using Subscribe to stay up to date on topics and initiatives that your existing social media account interest you. Subscribe Log in Register Step 3. My account details Subscriptions Be notified about changes to initiatives from the following topics: Agriculture and rural development Banking and financial services Borders and security Climate action Budget Business and industry Competition Culture and media Economy, finance and the euro Digital economy and society Education and training Employment and social affairs Energy Environment EU enlargement European neighbourhood policy Food safety Foreign affairs and security policy Fraud prevention Home affairs Humanitarian aid and civil protection Institutional affairs Maritime affairs and fisheries International partnerships Justice and fundamental rights Migration and asylum Public health Regional policy Research and innovation Single market Sport ☐ Statistics Taxation Trade Transport Youth

Figure 5. Setting alerts on the Have Your Say Portal (European Commission, 2024a)

<u>For further reading, or information gathering, the website of the European Ombudsman gathers key sources and opinions, such as the one referred to in the brief on the Food Information to Consumers (see European Ombudsman, 2024).</u>

Sources

- Better Regulation for Better Health project (2025). Civil society toolkit. "Instruments for civil society and stakeholder participation in the Better Regulation". Available at: https://epha.org/better-regulation-for-better-health-toolkit
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- European Commission (2024b). Have Your Say Search Calls for evidence. Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives en?frontEndStage=PLANNING WORKFLOW
- European Commission (2024c). EU rules on medical devices and in vitro diagnostics targeted evaluation. Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14155-EU-rules-on-medical-devices-and-in-vitro-diagnostics-targeted-evaluation_en
- European Commission (2024d). Have Your Say Search Draft acts. Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives en?frontEndStage=ISC WORKFLOW
- <u>European Commission (2024e)</u>. EU emissions trading system (ETS) update of Registry Regulation following ETS revision/Fit For 55. <u>Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14371-EU-emissions-trading-system-ETS-update-of-Registry-Regulation-following-ETS-revision-Fit-For-55 en
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- European Commission (2024f). Have Your Say: Simplify! Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say-simplify en
- <u>European Commission (2024g). Regulatory Scrutiny Board opinions on evaluations and fitness checks.</u> Available at: https://commission.europa.eu/law/law-making-process/regulatory-scrutiny-board/regulatory-scrutiny-board-opinions-evaluations-and-fitness-checks en
- European Ombudsman (2024). The European Commission's refusal to give public access to documents concerning an impact assessment on the revision of the Food Information to Consumers Regulation. https://www.ombudsman.europa.eu/en/case/en/65397

Further readings

• European Ombudsman (2024). Available at: https://www.ombudsman.europa.eu/en/home