

Better Regulation for Better Health consultation project – recommendations

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Executive summary

The Better Regulation for Better Health project has organised a consultation activity to identify barriers and enablers of civil society participation, particularly in terms of consultation activities (i.e., surveys, workshops, events, feedback processes). Elements such as capacity, access to funding and the setting and design of the avenues and/or platforms for participation can be enablers as much as barriers to civil society participation.

The consultation project ran from March to June 2024 and was disseminated to health civil society organisations among EPHA's networks, in particular the EU4Health Civil Society Alliance and the Food Policy Coalition. The consultation was meant for organisations that had experience with at least one consultation related to public health, but not necessarily a consultation led by DG SANTE.

In total, 29 representatives from civil society organisations took part in the survey, including 26 representatives from non-governmental organisations (NGOs) and 3 representatives from professional associations. Among the respondents, 20 were representatives of organisations established at the EU/European level, while 3 worked on the global level and 6 on the national one. Overall, the organisations' areas of work include a wide range of public health issues, ranging from non-communicable diseases, cancer, disease-focused organisations, to environmental prevention, primary health care, social rights, healthcare workforce, mental health, harm reduction, patient advocacy and public health in general. The results of the study were anonymised and summarised by consultation type.

This document presents both the quantitative and qualitative results of the survey, culminating in 10 key recommendations, articulated in three key priorities, for improved avenues involving civil society in policy-making:

Improve design and planning to make it more accessible

1. Improve the written feedback designs: improve questionnaires' design, make them more user-friendly, and allow for more in-depth feedback. Provide more information in advance on the specific topic/piece of legislation, to support the preparation of feedback.
2. Improve planning: Adapt the timelines taking into consideration the needs of respondents, including those of networks/consortia. Make the consultations long enough to secure the legitimacy of the processes.
3. Improve the design of events: foresee input gathering in smaller group discussions and consider in person events for more meaningful participation of civil society in decision-making processes. Improve the opportunities for exchange in online/hybrid events, that are more inclusive.

Make the processes more meaningful, inclusive and diverse

4. Foresee more meaningful participation: move away from the tick-box exercise model/framework, and, specifically, envisage stronger citizen involvement in policy-making processes.

5. Ensure more balance, inclusivity and diversity in feedback and representation in events between private and public interest stakeholders and provide possibilities to be heard equally. This involves creating more opportunities to meet with civil society, or at least a balanced number of meetings. Provide greater diversity and transparency in the selection of participants, by focusing on underrepresented groups.
6. Improve participation: strengthen the visibility and accessibility of the process, make it more user-friendly, particularly for marginalised, vulnerable groups and smaller organisations. Provide resources to support the involvement of civil society in regular meetings and activities, particularly for smaller organisations from outside of Brussels.
7. Allocate more time for interaction: Secure sufficient time for civil society views in every conference. Ensure the participation of groups most affected by decisions discussed in the events.

Increase transparency to build trust

8. Enhance transparency: Strengthen transparency of the consultation process, including by providing information on how stakeholder input will be used and ensuring that feedback is acted upon in a timely manner. Ensure that the Transparency Register publishes further details about the European Commission's bilateral meetings.
9. Integrate feedback loops: Communicate back to the stakeholders on how their input was considered. Allow participants to understand the impact of their input, to learn from the decision-making process, and to refine their future contributions making them more effective, increasing the confidence in the process.
10. Build trust: by implementing the recommendations above, especially on transparency and feedback loops, to enhance trust.

About the project

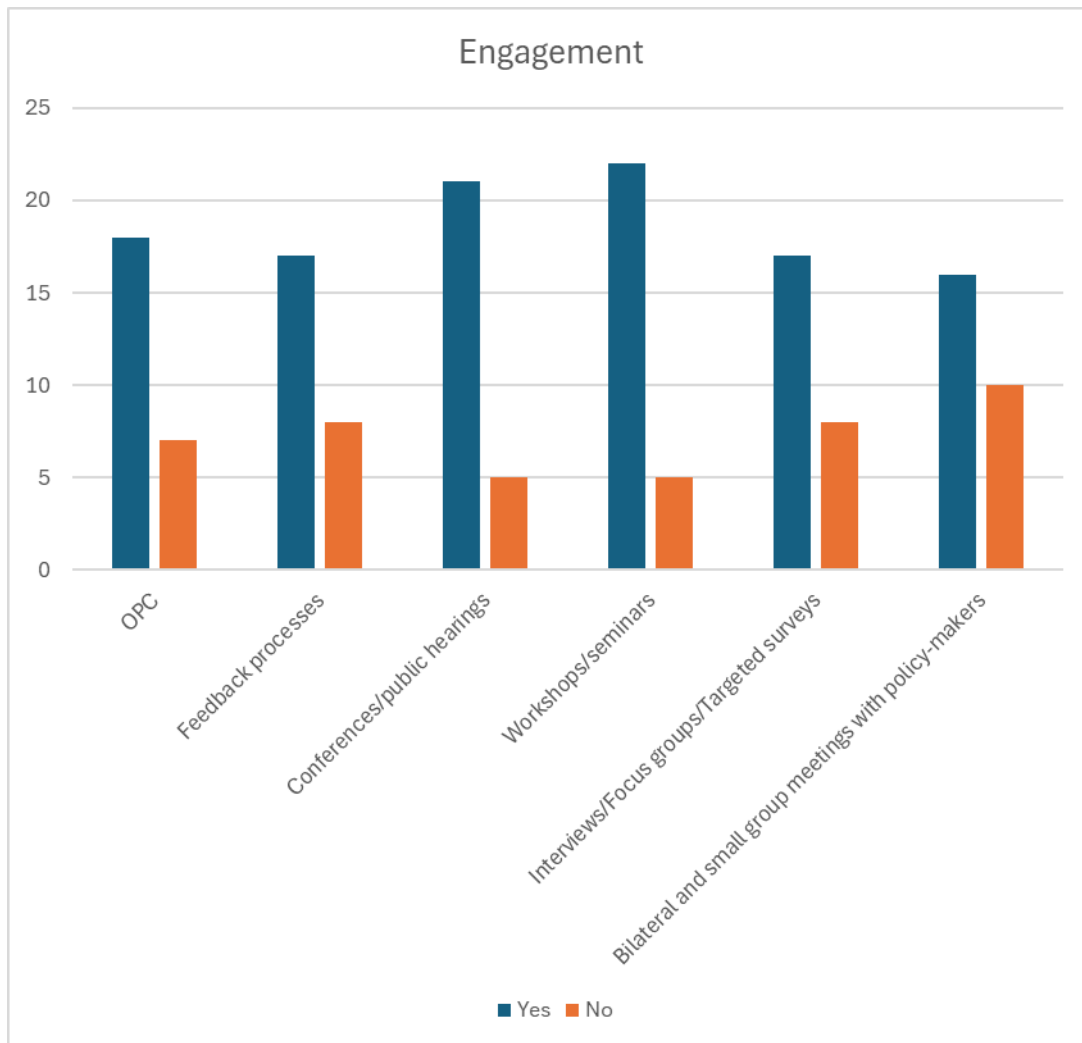
The Better Regulation for Better Health (BRBH) project is a multi-disciplinary study of how the European Union's Better Regulation agenda affects its health policies and governance. It is funded by UK Research & Innovation (UKRI) as part of a Future Leaders Fellowship, held by the project's principal investigator, Dr Eleanor Brooks. The project runs from 2021 to 2025 and is hosted within the Global Health Policy Unit at the University of Edinburgh's School of Social and Political Science. The survey was conceived and designed by the BRBH team at University of Edinburgh; the analysis presented in this report was conducted by the European Public Health Alliance.

Quantitative analysis

The survey included questions on whether the respondents had engaged with the different existing avenues for participation, and if so, at which frequency.

Overall, most of the respondents have engaged with the ways of engagement studied in the survey (Open Public Consultation, feedback processes, conferences and public hearings, workshops and seminars, interviews/focus groups and targeted surveys, and meetings with policy-makers), as demonstrated in the figure below.

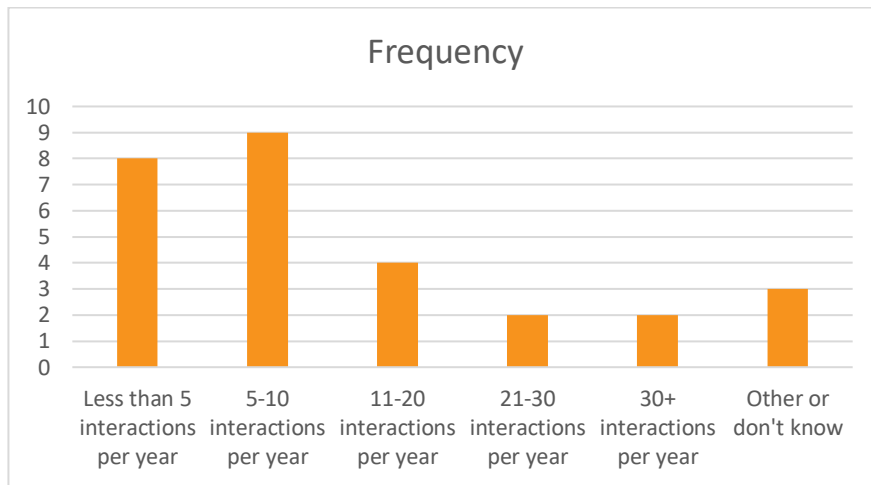
Figure 1. Engagement with the avenues of participation¹



Eleven respondents indicated that their organisations had taken part in all the studied activities, while one indicated that they had participated in conferences and public hearings only.

¹ Please note that this figure does not include the option “don’t know”, which was one of the possible answers.

Figure 2. Frequency of engagement with the consultation activities



Most of the respondents engage between 1 and 10 times a year with the consultation activities studied by the survey. About a third engages more than 10 times a year.

Qualitative analysis

1. Open Public Consultation (OPC)

This section refers to the 6-week open public consultations – usually taking the form of a survey questionnaire – that are published on the European Commission’s Have Your Say portal.

Overall, most of the respondents were positive about the opportunity to convey information through OPCs as it allows civil society to share their views. However, participants find the exercise limited in several ways, and overall provided divided opinions on the potential to being heard. First, in the design of the questions, as most questions are closed, with only a few open-ended options that provide enough space for detailed feedback. This can prevent the efficient conveying of messages, including points that have not necessarily been fully considered in the exercise yet, thus undermining the point of the exercise. Respondents indicate that by relying on such shaping, questionnaires can fail to address relevant perspectives and can occasionally steer responses towards predetermined outcomes. Some respondents indicated that being heard was a challenge, especially when representing a youth organisation as the consultations are not very youth-friendly or accessible.

In terms of content, the design of open-ended questions can limit the inputs from participants, with a low character limit (4 000 characters for instance). This results in inputs that cannot be very specific. However, there is often a possibility to include additional materials, which allows information to be conveyed. It was also flagged that roadmaps do not always include insights on the policy options, which in turn limits the impact of the feedback. In addition, respondents are sometimes not given enough information to provide feedback on. For instance, the assessment of the performance of the EU4Health Programme did not include performance indicators.

Although the consultation process is available in all languages, user friendliness, especially in terms of digital literacy, was pointed out by several respondents as an issue and barrier, as well as accessibility for marginalised groups and persons with disabilities. While in principle consultation is accessible to all, it requires a lot of time and resources, which can hinder the participation of smaller organisations. Two respondents indicated difficulties in engaging member organisations, or non-EU/non-Brussels organisations, in the process so that they would share their national or regional perspective.

Respondents have also identified a limitation in the lack of transparency and access to the results of the OPC and insight into its outcome and follow up. A respondent advised defining clear criteria on how the responses are assessed ahead and after the consultation, which would be helpful. The added value of the consultation process was also questioned, as evidence of impact is not made available. The restrictive nature of some of the consultations is also a barrier to feedback, according to the respondents. Providing information on this would support trust-building in the institutions.

Another related issue flagged was that the way consultations are operated can benefit well-resourced industry interests. The imbalances in resources between commercial lobbies and independent NGOs often influence public consultation responses, potentially tilting them toward the viewpoints of well-funded interest

groups and overshadowing the voices of NGOs and grassroots organisations acting in the interest of the public. Consequently, the feedback received may not accurately reflect the diverse perspectives within society, undermining the democratic process. For instance, a respondent flagged that in the case of tobacco, the current design of consultation has allowed corporate actors to delay the process of policy legislation. Respondents were divided on raising differences of treatments, while other respondents argued that all stakeholders' replies being given the same importance was an issue. Overall, a respondent flagged that the European Commission equally needs to be resourced to take in the feedback from the consultations, and to be able to engage with civil society and integrate the important input for developing policies.

Finally, the timing of consultations has been identified as a limit and a barrier, especially for smaller NGOs. Participants indicated that OPC falling on public holidays or taking place during holiday season, often with short deadlines, hinder the consultation process especially for member-based organisations that require internal consultations.

Overall, respondents indicated that the OPC pathway was a good way to be heard, with some caveats (accessibility, and being aware of the exercise and its timeline).

2. Feedback

This part refers to feedback on inception impact assessments, roadmaps (n.b. these are now part of the “call for evidence”) or draft legislation which can be submitted via the Have Your Say portal. This feedback is generally unstructured, written input that can be submitted by stakeholders and the general public. Inception impact assessment and roadmaps are opportunities for early feedback in the policy-making process, while late feedback refers to input on published legislation.

On whether they engage in early or late feedback, respondents provided various answers, with both early and late participation being mentioned. Organisations participating in both early and late feedback highlight the goal to have as much impact as possible, and mention that they do so if capacity allows. It can also depend on the legislation: if there is high relevance for the organisation, it is important to engage in all steps. Otherwise, the focus will be on the impact assessment stage. Both steps are important, the early stage to ensure the design of a strategy or framework is as complete and concrete as possible (including clear impact indicators and monitoring frameworks), while late stage is crucial to evaluate progress and offer concrete suggestions for adjustment or redirection. Respondents focusing on early feedback indicated that they do not necessarily have the resources to engage in all the steps in a later stage. Similarly, respondents indicating late participation in the feedback often mention the lack of capacity, time and resources as the main reason for not engaging in earlier steps. The timing of the feedback also depends on the experience and expertise level on the issue.

Respondents overall indicated that feedback-providing exercises are a good pathway in terms of conveying information. The pathway was labelled as quite open, allowing for free text and annexes, as well as the possibility to raise a number of issues.

Some respondents however indicated difficulties, such as a limited space to convey the complete picture, scope of questions and capacity to emphasise key elements.

Several barriers were identified, such as timeliness of the process (i.e., challenges of gathering feedback for late processes), accessibility, accountability of the feedback (i.e., how to best represent citizens and consumers), restrictive space, and lack of insights on how the feedback is used. The timelines were described as too short for CSOs to consult their members and provide answers, especially when the organisations do not have pre-formed expertise on the given issues. A few respondents shared concerns on whether the call for evidence is considered to a relevant level, and whose feedback is considered. Some respondents also indicated not being contacted by the legislator for such feedback processes, while other expressed concerns about the accessibility for marginalised groups and affected communities. Finally, one respondent indicated that to some extent, particular questions had been framed in both public consultations and other feedback processes as alcohol industry friendly, using language such as “misuse”, rather than “alcohol use”, which can steer the feedback in one direction. This relates to imbalance of resources as well, to take part in the consultation and be heard.

Respondents advised for clear criteria on how the call for evidence is assessed to make the decision-making process more transparent. One respondent advised for the publication of all EU legislative proposals in draft before being submitted to the European Parliament and the Council.

3. Conferences/public hearings

Conferences and public hearings refer to large public events, generally open to anyone who wishes to register and attend, that are directed at conveying information about the initiative to a larger audience of stakeholders. They may involve Q&A sessions but are primarily about dissemination. They can take place in-person or online.

Respondents tended to answer mainly negatively regarding the ability to convey information, exchange opinions and information through conferences and public hearings. However, some of the respondents felt that these events were a good pathway for the conveying of information. Overall, it seems to depend on the format and the role and space given to the different participants.

More negative replies from the respondents hinted at the fact that the efficiency of these events in taking in information and influencing decisions was uncertain. Often, respondents stressed the lack of time for in-depth interaction and being equally heard, the selection of speakers and participants, difficulties with having a representative and balanced set of stakeholders, and the framing of the guiding questions as issues that can hinder the conveying of information from civil society. Accessibility, especially for remote (i.e., outside of Brussels) participants, in terms of language or for representatives from marginalised groups, tends to be very limited, especially in regarding funds or travel. The dense agendas and the design of Q&A sessions focusing on the panel and not on gathering inputs from the audience were also flagged as barriers. The use of hybrid events was also labelled a barrier when contributions from online attendants are limited, therefore impacting NGOs that are not based in Brussels.

Respondents indicated that they would like to be more automatically involved in events where they have expertise. If civil society is given an active role, such as speakers or panellists, it is efficient in conveying information. Respondents stressed

the capacity of NGOs to make coalitions to be better heard in such events. They also highlighted the need to sufficiently advertise the events, and work on the accessibility of the locations. One respondent suggested that the situation is more nuanced, indicating that the capacity to convey information and be heard is context-dependent, mainly shaped by who co-organises the conference, taking the example of the Platform for Roma Inclusion. The agenda can be very heavy and dense with very little space for input from participants; usually there will only be space to ask questions to the speakers. If the conference has workshops included, this is often the only way for any meaningful input from participants/civil society. Events organised by the European Economic and Social Committee (EESC) such as the Civil Society Week, are quite open and provide significant time and space for contributions. However, the audience tends to be mostly civil society itself, which limits direct feedback to policy-makers. One respondent recommended a check-in before finalising the agenda, following the Better Regulation guidelines, that the groups most affected by the decisions should be heard.

4. Workshops/seminars

Workshops and seminars refer to smaller events, generally “closed” (invitation-only), that are directed at gathering information about the initiative from a smaller audience of stakeholders. They are more interactive in style and can be in-person or online.

Some respondents provided positive feedback, indicating that seminars were enablers of participation in policy-making, and that it was an opportunity for in-depth dialogue. The summaries of the events are very useful as they include all comments, which is an added value compared to other types of events. Reflections from the respondents were overall positive on the efficient conveying of information, if they are invited to participate, especially as speakers, which sometimes requires prior involvement. One respondent added that, while the design can be biased or flawed, workshops usually allow more interaction between stakeholders, and enough space to do so. The groups are smaller, and the questions are often quite open, which improves the chances of interaction. Online versions often provide well-monitored chats, where participants can share inputs, work, activities and discuss with each other. The events require preparation from the participants’ side to ensure that their messages are heard and that the meeting is productive.

However, challenges were also mentioned, such as having a dense agenda, receiving the materials early enough to prepare interventions and questions, and therefore convey efficiently information and inputs. A respondent mentioned the difficulties to get their message across when it is rather alternative to the main position presented in the event. Respondents also highlighted that the agenda is often filled with presentations, with only time for a couple of questions from the audience. This can also lead to limited added value from the content in some cases, and limited information on how the feedback is taken into account. Meetings can also be too technical, with a barrier of “Brussels bubble” language that decreases accessibility.

There seems to be a lack of transparency on the selection of speakers and participants, according to one of the respondents. The planning of those events was also pointed out as an issue, especially their frequency, which limits capacity to prepare for all of them. Respondents stressed accessibility issues for organisation

with low budgets, located outside Brussels, but also marginalised groups and affected communities. Overall, lack of funding hinders participation. Respondents recommended smaller audiences to facilitate exchange and participation. It was also highlighted that hybrid, or fully online events are less effective in terms of participation.

Overall, conveying the information successfully and being heard seems to be context dependent, depending on whether the organisation participates as a speaker, or whether it has participated in the process before and receives direct information.

5. Interviews/Focus groups

This part refers to in-person or web-based activities to which selected stakeholders and experts are invited, aimed at collecting views and information on specific aspects of an initiative.

Most respondents indicated that the design of the interviews and focus groups was effective in allowing them to convey their information. Overall, respondents believe that interviews and focus groups offer adequate opportunities for those who wish to be heard.

However, several concerns were raised. Respondents highlighted that these consultations are very time-consuming, which can be challenging given limited resources, which is in itself a barrier. Moreover, marginalised groups and affected communities might not feel comfortable participating or may lack the necessary skills to engage meaningfully. Another critique was the lack of transparency on the criteria used to select focus group participants, with regional and local groups often excluded from the process. Finally, the frequent inclusion of industry representatives was highlighted as a significant concern, as it often leads to conflicts of interest.

To enhance the effectiveness of such consultations, respondents outlined several key conditions: the scope should be well-targeted, questions should be specific, and the format should facilitate more in-depth discussions. Additionally, the importance of engaging a skilled contractor with expertise in the field was emphasised, to ensure informed questioning and focus during the consultation.

6. Targeted surveys

Participants expressed mixed opinions on whether targeted surveys allow them to adequately convey their messages. About half of the participants responded favourably but did not provide further details.

However, others criticised the design of these surveys, noting that they are often too restrictive, particularly due to an overreliance on multiple-choice questions, which may not accurately capture an organisation's standpoint. Overall, participants believe that the design of targeted surveys does not consistently ensure that all respondents are heard equally. Additionally, some respondents pointed out that the questions or available answers are sometimes irrelevant or vague, with limited opportunities to provide feedback. They also observed that the questionnaires often appear to be directed at other stakeholder groups rather than civil society organisations.

In terms of access, while some see potential for equal representation, concerns are raised about inequalities, with certain subpopulations potentially excluded due to

survey distribution issues or complexity, which may favour well-resourced organisations. Additionally, there is a perception that the emphasis on numerical data may undermine the quality of responses, leading to imbalances among stakeholder groups with differing interests. Furthermore, biases may occur if the opportunity to participate is not extended to all relevant stakeholders. Smaller organisations with limited labour capacity may struggle to engage fully, leading to disparities compared to larger entities.

Finally, barriers evoked include time constraints, unclear or overly simplistic questions, and a lack of opportunities for detailed input. Other challenges include language barriers and the misalignment of survey topics with the organisation's primary interests, which can further hinder effective participation.

7. Bilateral and small group meetings with policy-makers

Bilateral and small group meetings refer to closed meetings with European Commission officials that organisations may attend (virtually or in-person) to exchange views on an initiative. Such meetings can be arranged or accepted by the European Commission.

Participants generally find that bilateral or small group meetings effectively allow them to convey their inputs, with many reporting that these meetings provide a valuable platform for detailed information exchange and focused discussions. They often offer a platform for all attendees to be heard, but equal participation is not guaranteed. While most participants find these meetings generally effective when the group size and topics are appropriate, some challenges persist.

Some participants note that these meetings do not always facilitate open dialogue, often due to a top-down approach or a lack of genuine interest in the input shared. Additionally, there can be challenges when specific issues are not considered or when there is insufficient room for in-depth discussion. Reportedly, access to these meetings is dependent on organisation's resources and the level of attention from the European Commission. Barriers such as limited availability of meetings, time constraints, and strict agendas can affect the level of engagement and equality among participants. Additionally, the lack of a current database for identifying relevant European Commission staff has created disparities between larger and smaller organisations.

Participants report varying levels of engagement and invitations from European Commission officials in closed meetings. While some organisations are frequently approached or actively seek out these opportunities, others find that such meetings are relatively rare and require considerable effort and resources to arrange. The frequency and success of securing these meetings reportedly depend on the specific Directorate-General and the organisation's capacity for follow-up.

Despite these challenges, participants who manage to arrange such meetings generally find them valuable for advocacy, noting that European Commission representatives are typically open and approachable. The format of such meetings is generally viewed positively for allowing in-depth discussions and clear action points.

8. Overall analysis

Confidence in being heard

Confidence in whether stakeholder inputs are being considered by the European Commission in the various consultation exercises varies significantly. While some respondents express a reasonable level of confidence, particularly when their feedback is reflected in final documents, many are sceptical about how their views are considered, and on how much interest there is in civil society's views. A common concern is the lack of a transparent feedback mechanism, which leaves stakeholders uncertain about the impact of their contributions. Without clear communication on how inputs are used, many feel consultations are more of a formality or a "tick-box" exercise rather than a meaningful engagement. Additionally, some note that larger, more established or previously involved organisations may have a better chance of being heard, while smaller entities or those offering alternative perspectives often feel sidelined. Improving transparency, creating a feedback loop, and ensuring all voices are equally valued would enhance confidence in the consultation process. The key role of CSO networks in conveying messages and being heard was stressed.

To summarise, one input highlighted five key points affecting this confidence: the lack of feedback loops, issues with transparency on decision making, the depth of engagement which can feel superficial, imbalance of representation sidelining the perspectives of smaller groups, and having historical precedents, i.e., when minimal impact from previous participation is felt.

Quality of consultation

The European Commission's approach to stakeholder consultations is perceived as generally well-functioning, but participants highlight areas for improvement to ensure more meaningful and inclusive participation.

While some respondents feel the system works well, especially for those with adequate resources, expertise and "political literacy", others raise concerns about barriers that hinder full engagement, particularly for vulnerable or less-resourced groups such as youth and civil society organisations. Issues like the need for better access, more timely information, being listened to, and transparency in how feedback is used are repeatedly mentioned across the various avenues analysed. Additionally, some participants believe that the current settings of the consultation process can favour well-established stakeholders or be reduced to a "tick-boxing" exercise, limiting its inclusivity and impact. In some areas like alcohol, respondents indicated that consultations with the industry were "out of proportion" in comparison to civil society. Some respondents reported having reached out to the Ombudsman to raise concerns. Finally, a respondent indicated that the consultation process seems to work well for policy initiatives, but less when it comes to discussing funding. Bilateral meetings seem to be the most effective form of consultation overall.

9. Other consultations pathways

Other pathways

Respondents indicated direct contact, bilateral contacts with Members of the European Parliament (MEPs), committees and the European Commission, reaching out to Member States, and participating in expert groups as other consultations

pathways. Participation in platforms (e.g., Disability Platform), events organised by stakeholders, were also mentioned. Finally, some respondents indicated participating in networks, consortia and umbrella organisations at the European level. It happens that NGOs engage with the European Commission on a same topic through different pathways, between events, Civil Dialogue Groups or Advisory Groups, sharing publications and publishing statements.

Other areas

On consultations in other sectors, most respondents either indicated that the processes were similar, or that it was difficult to compare. One respondent added that relying on the EU Health Policy Platform for consultation does not allow for meaningful engagement. One respondent provided the example of the EU Civil Society Forum on Drugs and the EU Civil Society Forum on HIV, HCV and TB, concluding that the consultations in the drugs field feels more meaningful, with variations across the years.

Some respondents indicated that it is easier to be heard on health consultations rather than on environmental ones, which was discussed by other respondents. The processes in health consultations were deemed “better” than in education and culture, especially compared to UNESCO consultations.

Unused consultation pathways

Where respondents indicated that they had not engaged with some of the analysed consultation pathways, the reason was most often lack of capacity, know-how and resources to engage, lack of awareness of the process, or because the institutions have not reached out to the given organisation for this exercise. Such exercises require a lot of time and capacity that could be used on other advocacy activities. In some cases, this task has been delegated by the NGO to a wider umbrella organisation that it is active at the European level.

Recommendations

Based on the input provided by civil society organisations in the survey, the project team has developed 10 key recommendations for the EU institutions to consider when improving consultation processes, articulated around three core priorities:

- Improve design and planning to make it more accessible
- Make the processes more meaningful, inclusive and diverse
- Increase transparency to build trust

Design and planning

Overall, civil society organisations called for enhanced accessibility of the consultation exercises, especially regarding their planning and design:

1. Improve the written feedback designs: improve questionnaires' design, make them more user-friendly, and allow for more in-depth feedback. Provide more information in advance on the specific topic/piece of legislation, to support the preparation of feedback.
2. Improve planning: Adapt the timelines taking into consideration the needs of respondents, including those of networks/consortia. Make the consultations long enough to secure the legitimacy of the processes.
3. Improve the design of events: foresee input gathering in smaller group discussions and consider in person events for more meaningful participation of civil society in decision-making processes. Improve the opportunities for exchange in online/hybrid events, that are more inclusive.

A more meaningful participation

Civil society organisations stressed the importance of their participation in those processes to be meaningful, but also inclusive:

4. Foresee more meaningful participation: move away from the tick-box exercise model/framework, and, specifically, envisage stronger citizen involvement in policy-making processes.
5. Ensure more balance, inclusivity and diversity in feedback and representation in events between private and public interest stakeholders and provide possibilities to be heard equally. This involves creating more opportunities to meet with civil society, or at least a balanced number of meetings. Provide greater diversity and transparency in the selection of participants, by focusing on underrepresented groups.
6. Improve participation: strengthen the visibility and accessibility of the process, make it more user-friendly, particularly for marginalised, vulnerable groups and smaller organisations. Provide resources to support the involvement of civil society in regular meetings and activities, particularly for smaller organisations from outside of Brussels.

7. Allocate more time for interaction: Secure sufficient time for civil society views in every conference. Ensure the participation of groups most affected by decisions discussed in the events.

Transparency

Civil society organisations also called for more transparency in the processes, which would support building trust:

8. Enhance transparency: Strengthen transparency of the consultation process, including by providing information on how stakeholder input will be used and ensuring that feedback is acted upon in a timely manner. Ensure that the Transparency Register publishes further details about the European Commission's bilateral meetings.
9. Integrate feedback loops: Communicate back to the stakeholders on how their input was considered. Allow participants to understand the impact of their input, to learn from the decision-making process, and to refine their future contributions making them more effective, increasing the confidence in the process.
10. Build trust: by implementing the recommendations above, especially on transparency and feedback loops, to enhance trust.