



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical Products and Innovation
Medical Products: Quality, Safety, Innovation

Brussels
SANTE.D.2/MA

TERMS OF REFERENCE

1. Purpose and set-up

The Commission services may convene meetings ('stakeholder meetings') to bring together stakeholders and representatives of members of the Competent Authorities on Substances of Human Origin Expert Group ('the Expert Group').

The purpose of the stakeholder meetings shall be to provide an opportunity for an informal exchange of views between relevant stakeholders and representatives of members of the Expert Group, and the Commission services on topics of mutual interest at EU level.

The stakeholder meetings shall be convened by the Commission services on an ad-hoc basis, based on the perceived need for an informal exchange of views on topics related to EU legislation on safety and quality of substances of human origin and of relevance for stakeholders and the Expert Group.

The stakeholder meetings shall be organised in association with the meetings of the Expert Group. However, the stakeholder meetings shall be administratively separate from the meetings of the Expert Group. Members of the Expert Group shall be free to decide whether to participate in the stakeholder meetings.

2. Call for interest and applications

The Commission services shall launch an open call for interest to select a list of stakeholders eligible for participation in the stakeholder meetings. The call shall be published on the public health section of the Commission's Europa website ¹, along with the terms of reference and privacy statement.

¹ https://health.ec.europa.eu/blood-tissues-cells-and-organs_en

Interested stakeholders shall reply to the call, by completing and sending to SANTE-SOHO@ec.europa.eu the application form accompanying these terms of reference and considering the privacy statement provided.

3. Selection of stakeholders

Stakeholders shall be selected by the Commission services, based on representativeness for and impact on the Substances of Human Origin ('SoHO') sector. Professional associations and organisations representing multiple stakeholders shall be given preference. Priority shall be given to European (Union)-level associations and organisations or even those at international or global level, being able to bring insights on SoHO activities in multiple European countries and beyond. Inclusion in the Transparency Register² shall also be considered when selecting stakeholders.

Stakeholders shall represent legal or natural persons with an involvement or interest in the SoHO sector such as establishments, clinicians, healthcare professionals, patient representatives, researchers, companies, or dedicated organisations offering one or more support services or using human blood, tissues, or cells in their processes.

The Commission services shall inform the members of the Expert Group and all applicants of the list of selected stakeholders. The list shall be re-evaluated regularly and updated in line with further applications from interested stakeholders. Selected stakeholders may make a request to the Commission services to be taken off the list at any time. The list of selected stakeholders and any further updates of this list shall be published on the public health section of the Commission's Europa website.

4. Participation in the stakeholder meetings

Participation of stakeholders will be on a voluntary basis and shall not be reimbursed or remunerated.

Stakeholders from the list of selected stakeholders shall be invited by the Commission services, based on the main topics to be discussed, to send a limited number of representatives (typically not more than two), to any given stakeholder meeting.

Representatives of invited stakeholders shall confirm their participation to the Commission services at the latest two weeks prior to the stakeholder meeting. The Commission services shall share a list of confirmed participating stakeholders with the Expert Group prior to the stakeholder meeting.

² <https://ec.europa.eu/transparencyregister/public/homePage.do?redir=false>

Representatives of members of the Expert Group shall be invited to stakeholder meetings in their field of expertise i.e., blood, tissues and cells, or organs. The Commission services may also choose to invite observers to the Expert Group to attend stakeholder meetings.

The Commission services may choose to limit the number of invited stakeholders to any given stakeholder meeting in line with its organisational and logistical capacities.

5. Stakeholder meeting agendas

In line with meetings of the Expert Group, each stakeholder meeting will focus on topics relating to blood, tissues and cells or organs. Potential agenda points for stakeholder meetings may be proposed at any time by stakeholders as well as by members of the Expert Group and the Commission services. Proposals for agenda points should be sent to the Commission services via SANTE-SOHO@ec.europa.eu with a description of the topic to be discussed and an explanation of its relevance for the SoHO sector.

The Commission services shall select draft agenda points based on their relevance for discussion at EU-level, considering previous discussions on the same topic(s) in meetings of the Expert Group or in bilateral meetings between stakeholders and the Commission services. Preference will be given to proposed agenda points which are considered to have most relevance for the greatest number of participants.

Proposed agenda points which are relevant for, or in, only one Member State or for one stakeholder shall not be considered unless they are deemed to be of particular importance. Such topics should be discussed between the stakeholders and the relevant national competent authority or authorities of the Member State concerned. Proposed agenda points on the internal organisation of health services in a particular Member State shall not be discussed.

The Commission services shall consult the Expert Group on the draft agenda. The final draft agenda shall then be sent to all participants at the latest five working days before the date of the stakeholder meeting. The final draft agenda shall be published on the public health section of the Commission's Europa website prior to the stakeholder meeting.

6. Meeting arrangements

The Commission services shall chair the stakeholder meetings.

Interventions by participants at stakeholder meetings shall be constructive and references to situations or practices applied in individual Member States should be avoided. The Chair shall intervene when discussions become too focused on specific Member States.

7. Minutes and meeting documents

The Commission services shall draft summary minutes of the stakeholder meetings. The draft summary minutes shall be shared for comments with all participants. The final version of the summary minutes shall be published on the public health section of the Commission's Europa website.

Participating stakeholders may use supporting documents to present agenda points. Such documents shall be sent to the Commission services via SANTE-SOHO@ec.europa.eu at least five working days prior to the stakeholder meeting. All submitted documents shall be sent to all participants in the stakeholder meeting and members of the Expert Group. Final versions of such documents shall be published on the public health section of the Commission's Europa website.

8. Personal data protection

The Commission services shall publish the list of selected stakeholders, the final draft agenda, and the summary minutes of all stakeholder meetings on the public health section of the Commission's Europa website. The published list of selected stakeholders, the agendas, and summary minutes shall not include the names or other personal data of the individual representatives of stakeholders, members of the Expert Group or observers to the Expert Group. Exceptions³ to publication shall be provided for where disclosure of a document would undermine the protection of a public or private interest as defined in Article 4 of Regulation (EC) N° 1049/2001⁴.

Personal data collected shall be processed pursuant to Regulation EU 2018/1725⁵ on the protection of individuals regarding the processing of personal data by the EU institutions and bodies and the free movement of such data. It shall be processed solely for the purposes of the performance, management and follow-up of this call for expression of interest and for the organisation of stakeholder meetings by the Controller without prejudice to possible transmission to the bodies charged with a monitoring or inspection task in conformity with Union law.

Natural persons shall have the right of access to their personal data and to rectify any such data that is inaccurate or incomplete. An appeal shall be possible at any time to the European Data Protection Supervisor. Queries concerning the processing of personal data can be sent by e-mail to: SANTE-SOHO@ec.europa.eu.

³ These exceptions are intended to protect public security, military affairs, international relations, financial, monetary, or economic policy, privacy and integrity of the individual, commercial interests, court proceedings and legal advice, inspections/investigations/audits and the institution's decision-making process

⁴ <https://eur-lex.europa.eu/eli/reg/2001/1049/oj>

⁵ <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32018R1725>