

Specific Privacy Statement

PUBLIC CONSULTATION FOR THE EVALUATION OF THE EU LEGISLATION ON BLOOD, TISSUES AND CELLS referred as "consultation" in the text

1. OBJECTIVE

The objective of this consultation is to receive the views of stakeholders (administrations, associations, tissue and blood establishments, manufacturers of medicinal products using blood, cells or tissues as starting materials, and other organisations) and individual citizens (whether they are interested members of the general public or individuals who are working in one or all of the fields addressed) concerned by the topic of the consultation and to publish them on the Internet, under the responsibility of the Head of Unit 'B4 – Medical Products: quality, safety, innovation', Directorate-General Santé, acting as the Controller.

As this online service collects and further processes personal data, Regulation (EC) 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, is applicable.

The processing operations on personal data linked to the organisation and management of this consultation are necessary for the management and functioning of the Commission, as mandated by the Treaties, more specifically in Articles 5 and 13 TEU and Articles 244-250 TFEU, and in accordance with Article 1 and Article 11 TEU.

The processing operations of personal data in the context of consultations are necessary and lawful under Article 5 (a) of Regulation (EC) 45/2001. Stakeholders and the public at large send their contributions to public consultations on a voluntary basis.

2. WHAT PERSONAL INFORMATION DO WE COLLECT AND THROUGH WHICH TECHNICAL MEANS?

2.1 Identification data

The personal data categories collected in stakeholders' consultations are the following: name and surname of a contact person and e-mail address. In addition, the Transparency Register identity number of a given stakeholder is also collected.

The personal data categories collected in individual citizens consultations are the following: name, surname, country of residence, level of education, sector of employment and e-mail address and their views on the topics concerned.

2.2 Technical information

The on-line consultation tool (EU Survey) stores the following information when participants submit a contribution. By default, EU Survey does not save any user-related information. However, the IP of every connection is saved for security reasons for every server request. Using this information, it might be possible to reconstruct where a request originated.

EU Survey uses 2 kinds of "cookies" to save user-related data:

1. Affecting survey authors only: a cookie that contains session information to ensure reliable communication with the system. This cookie stays valid as long as the session is valid and is removed once the session is closed (maximum 24 hours after last contact).

2. Affecting any user: a cookie that contains IDs of selected responses to a survey and free-text responses in plain text until the user has submitted a valid contribution. Until a contribution has been successfully submitted, the system saves the user's draft contribution in a cookie at one-minute intervals, so that the contribution can be restored in the event of network congestion or a PC crash.

For offline answering the system uses session "cookies" in order to ensure communication between the client and the server. Therefore, your browser must be configured to accept "cookies". The "cookies" disappear once the session has been terminated. It is also possible to participate to a survey with "cookies" disabled, but in this case offline answering is not possible.

3. WHO HAS ACCESS TO YOUR INFORMATION AND TO WHOM IS IT DISCLOSED?

The recipients of your personal data are a defined population of members of the DG SANTE Unit organising the consultation and a contractor that is supporting the process. The access to all personal data, as well as all information collected in the context of this consultation, is only granted through User Id/Password, without prejudice to a possible transmission to the bodies in charge of a monitoring or inspection task in accordance with European Union law (namely the European Court of Auditors, the Internal Audit Service, OLAF, the European Ombudsman and the European Data Protection Supervisor).

The collected personal data, and all information related to the above mentioned consultation, may also be transferred to an external contractor that is supporting the Commission in the analysis of the responses and who, acting as processor, is contractually obliged to guarantee the protection of personal data and confidentiality required by Regulation (EC) 45/2001. Any such transfers will be conducted in accordance with the requirements foreseen in articles 8 and/or 9 of Regulation 45/2001.

Received contributions will serve as a basis for a report of the Commission which will be communicated to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

In addition, stakeholders are requested to consent to the publication of their replies to the consultation. In the case of replies by organisations, the personal data of the contact person (name, surname and email address) is not published, independently of whether consent for publication is provided or not. Please be aware, however, that your Transparency Register identification number is published, including any personal data available there regarding your employees.

In the case of individuals' replies, individuals are requested to consent: (i) on the full publication of their contribution (including personal data) in DG SANTE's website or (ii) on the publication of their contribution without their personal data (name, surname, country of residence, level of education, sector of employment and email address). A

possibility of non-publication is also offered, although the information, including personal data, remains subject to requests for access to documents under Regulation 1049/2001.

The European Commission will not share personal data with third parties for direct marketing purposes.

4. HOW DO WE PROTECT AND SAFEGUARD YOUR INFORMATION?

Your replies, together with your chosen language used for drafting the reply, are recorded in a secured and protected database hosted by the Data Centre of the European Commission, the operations of which abide by the Commission's security decisions and provisions established by the Directorate of Security for this kind of servers and services. The database is not accessible from outside the Commission. Inside the Commission, the database can be accessed using a User ID / Password.

The consultation is carried out via an online survey using the EU Survey platform (for which a privacy statement can be found here:

<https://ec.europa.eu/eusurvey/home/privacystatement>).

5. HOW CAN YOU VERIFY, MODIFY OR DELETE YOUR INFORMATION?

In case you want to have access to your personal data or to object to its processing, have it rectified, blocked or erased in the cases referred to under Articles 13, 14, 15, 16 and 18 of Regulation (EC) No 45/2001, you should contact the responsible Controller by using the "Contact information" provided under Section 7 below and by explicitly stating your request.

6. HOW LONG DO WE KEEP YOUR DATA?

The Data Controller only keeps the data for as long as any follow-up actions to the Consultation are necessary with regard to the purpose of the processing of personal data. All personal data will be deleted from databases 1 year after the last action in relation to the study in the framework of which the consultation activity was conducted.

Reports containing personal data will be archived according to the Commission's legal framework. Nevertheless, where needed, after this delay, personal data will be part of a list of contact details shared internally amongst the staff of Commission services for the purpose of contacting data subjects in the future in the context of Commission activities. If you do not agree with this processing operation, you may contact the controller by using the "Contact information" provided under Section 7 below and explicitly stating your request.

7. CONTACT INFORMATION

If you have comments or questions, any concerns or a complaint regarding the collection and use of your personal data, please feel free to contact the Data Controller using the following contact information:

The Data Controller:

European Commission
Directorate-General for Health and Food Safety (SANTE)

Unit B4 - “Medical Products: quality, safety, innovation”

B-1000 Brussels

Functional Mailbox: *SANTE-CLAIMS-EVALUATION@ec.europa.eu*

The Data Protection Officer (DPO) of the Commission: DATA-PROTECTION-OFFICER@ec.europa.eu

Complaints, in case of conflict, can be addressed to the [European Data Protection Supervisor](#) (EDPS): edps@edps.europa.eu.

8. WHERE TO FIND MORE DETAILED INFORMATION?

The Commission Data Protection Officer publishes the register of all operations processing personal data. You can access the register on the following link: <http://ec.europa.eu/dpo-register>.

This specific processing has been notified to the DPO with the following reference:
DPO-3411.4 DG SANTE Public consultations/Surveys/Questionnaires/Quiz