

An invitation to contribute to the revision of the EU legislation on blood, tissues and cells

The European Commission is preparing proposals for revision of the European Union's legislation on blood, tissues and cells (BTC). These changes are intended to protect patients and donors from avoidable risks, strengthen oversight arrangements, support innovation and improve the EU's resilience to interruptions in BTC supplies. Details of the process are available on the Commission's [website](#).

The proposals will create new obligations for blood, tissue and cells establishment, and the competent authorities that regulate them. It is important that the decisions about adoption of the changes are informed by robust analysis of their benefits and costs.

You are invited to contribute to that analysis by:

- **Completing this [online survey](#) on the impacts of the proposals;**
- **Providing information that will inform calculation of the costs of the proposals on BTE establishments, such as your organisation, by completing the [online cost inquiry](#).**

[ICF](#), a consultancy, has been retained by the European Health and Digital Executive Agency to assist with the research. A letter confirming our credentials is attached. Documents supplied with this invitation show you the questionnaires, and provide details of the options that are being considered by the European Commission.

The survey will be open for responses from **28 June to 24 July 2021**. The links to the [online survey](#) and [cost inquiry](#) provided here will require you to complete each questionnaire in one session. If you would like to be able save a partial response and return to it later (or arrange for colleagues to contribute to the same response) then please write to ICF at BTC@icf.com to request a pair of personalised links unique to your organisation.

Your responses will be treated as confidential - all the information provided will be anonymised by ICF before it is used in the analysis.

If you have any questions about the survey and cost inquiry, or need assistance with completing it, please write to us at BTC@icf.com.

We hope that you will take up this opportunity to provide your input, and thank you in advance for your contribution to these important reforms.

Regards

[Andrew Jarvis](#)

Study Director

ICF





EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical products: quality, safety, innovation

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To whom it may concern,

ICF was contracted by the European Health and Digital Executive Agency (HaDEA) to conduct a *'Study supporting the Impact Assessment of the Revision of Directive 2002/98/EC on safety and quality of human blood and blood components and of Directive 2004/23/EC on safety and quality of human tissues and cells and of their implementing acts'* (the BTC legislation).

The overall purpose of the study is to assess the potential impacts of changes to the Directives by exploring different policy options and the effects of these on relevant stakeholders. More information about the process of the revision is available on our webpage¹.

Within the data collection task, and to gather evidence on specific topics to support the impact assessment, ICF will run consultations with relevant stakeholders. ICF² will soon contact you to schedule a phone interview and/or to invite you to fill in an online questionnaire.

As this is a key study for the Commission, your involvement and contribution will be highly appreciated. This will support the ICF study team in the problem identification, as well as the shaping and assessment of the impacts of the policy options. This evidence is needed to make robust and reliable conclusions in the impact assessment.

Yours faithfully,

Sylvain GIRAUD
Head of Unit

¹ https://ec.europa.eu/health/blood_tissues_organs/policy/revision_en