Introduction and Consent

The European Commission's Directorate General for Health and Food Safety (DG SANTE) has commissioned ICF, a consultancy, to support its preparation of an impact assessment on 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. ICF will assess the potential impacts of changes to the directives by exploring different policy options and the effect of these on stakeholders.

Details of the Commissions plans for revision of the legislation are available on DG SANTE's website here.

ICF will assess the potential impacts of changes to the blood, tissue and cells (BTC) directives by exploring the different policy options and their effect on stakeholders.

This survey cover costs of the proposed measures. A separate survey covers the other impacts of the proposals.

A document describing the proposed policy options and the measures they contain is available to download here. Additional links to this document are provided within the survey itself.

All views expressed in this survey will be anonymised. The data will inform ICF's report to the Commission and may be used in support of the impact assessment.

We recognize that your time is precious and thank you for your contribution to this process.

If you are unable to use the online questionnaire, please contact us at BTC@icf.com. If you would like a personalized link that will enable you to part-complete, save and return to your survey response please write to BTC@icf.com to request one

☐ I consent to the use of the data supplied in accordance with the Data Protection Notice

☐ I agree to be contacted by ICF if clarifications of the information provided would help the study

Profile

About you

Your name and e-mail address:

First name

Last name

We may wish to contact you for further information about a response to this survey. If you are content for us to do so please provide an email address here.

I am giving my contribution as a representative of:

A Blood or tissue establishment engaged in

- ◯ Blood (component) collection and/or blood (component) banking
- ◯ Plasma collection for manufacture of medicinal products
- ◯ Tissue or cell donation or banking for transplantation
- ◯ Tissue or cell donation or banking for assisted reproduction

A representative organisation for

- ◯ Blood establishments
- ◯ Tissue establishments
- ◯ Both blood and tissue establishments

Operational level of your organisation

- ☐ International
- ☐ EU/EEA
- ☐ National
- ☐ Regional
- ☐ Local

Organisation Name

Type of organization

- ◯ Public
- ◯ Not-for-profit

- ◯ Commercial

Organisation size

- ◯ Micro (1 to 9 employees)
- ◯ Small (10 to 49 employees)
- ◯ Medium (50 to 249 employees)
- ◯ Large (250 or more)

Country of origin

Please indicate your country of origin, or that in which your organisation is headquartered :

Austria
Belgium
Bulgaria
Croatia
Cyprus
Czechia
Denmark
Estonia
Finland
France

Please specify

Countries of operation

In which European countries does your organization operate (or, if you are a representative organization, in which countries are your members located)?

- [ ] All EU27
- [ ] Austria
- [ ] Belgium
- [ ] Bulgaria
- [ ] Croatia
- [ ] Cyprus
- [ ] Czechia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Iceland
- [ ] Ireland
- [ ] Italy
- [ ] Latvia
- [ ] Liechtenstein
- [ ] Lithuania
- [ ] Luxembourg
- [ ] Malta
- [ ] Netherlands
- [ ] Norway
- [ ] Poland
- [ ] Portugal
- [ ] Romania
- [ ] Slovakia
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] UK
- [ ] Other

Baseline

Baseline

Questions in this section ask about the basic structure and activities of the blood and tissue establishments and the related costs (personnel, and other relevant costs). Please provide data for the last year available (i.e. 2020/2021). If these are not available, please specify the year the data relate to.

How much effort (in person days) is typically required for your establishment to prepare for, receive and follow-up a single inspection from your blood/tissue regulator? If possible, please indicate a typical average annual salary for the grade of personnel involved (exclusive of pension, other non-salary employment costs and exclusive of overheads).

	Total person days	Annual salary [EUR]	Comment/additional information (optional)	Don't know
Staff				

If your establishment incurs additional costs when receiving an inspection (e.g. fees, consultancy support), please indicate the main costs and corresponding monetary values below.

	Monetary value [EUR]	Comment/ additional information	Does not apply/ Cannot say
Other costs (please specify)			

	Monetary value [EUR]	Comment/ additional information	Does not apply/ Cannot say
Other costs (please specify)			

How have the direct costs of BTC regulation (inspections, reporting) and the indirection costs of BTC regulation (e.g. changing operational practices to achieve compliance) incurred by your establishment changed over the last few years?

You may wish to consider factors such as the number or complexity of reporting obligations, change in costs due to increase in scope of your establishment's activity.

Please look back to the period before the Covid-19 pandemic.

- ◯ They have increased considerably
- ◯ They have increased slightly
- ◯ They have not changed
- ◯ They have decreased slightly
- ◯ They have decreased considerably

What has been the main cause of this change?

Does your establishment have the possibility to recover the costs generated by legislation by increasing your charges?

- ◯ Yes
- ◯ No

Please explain the cost recovery possibilities for your establishment

How, if at all, is the volume of activity carried out by your establishment expected to change in the future?

- ◯ It will increase considerably
- ◯ It will increase slightly
- ◯ It will not change
- ◯ It will decrease slightly
- ◯ It will decrease considerably

If you expect a change in activity levels, what is the main driver for this change?

Expected costs of the proposed measures for your establishment

This section asks for information on the cost of the proposed measures for your organisation.

Problem 1 – Patients are not sufficiently protected from avoidable risks

Problem 1: Patients are not fully protected from avoidable risks.

To protect patients from avoidable risks eight measures are being considered. They are grouped into three options, as described in **this** document and summarized in the table below. We recommend that you read Annex 1 of this document before answering the questions below

Problem 1: Patients are not fully protected from avoidable risks	Option 1.1	Option 1.2	Option 1.3
Principles for safety and quality principles in EU law	✓	✓	✓
EU law is changed so that all SOHO/BTC for which the EU has legal competence are covered by EU safety and quality rules (bringing breast milk, faecal microbial transplants, etc. under EU law)	✓	✓	✓
Member States are required to publish more stringent BTC rules in an accessible format		✓	✓
The European Commission builds an IT platform that provides information on quality and safety requirements	✓	✓	✓
National competent authority inspectors have to evaluate blood and tissue establishments' risk assessments to ensure that they have been conducted effectively and that the rules set adequately manage the identified risks	✓		
Blood and tissue establishments are required to assess the risks associated with their procedures, and to set technical rules for safety and quality, compliant with the principles defined in EU law. They must base the rules on risk assessment and scientific evidence, and update whenever the need arises. They can follow inter/national guidance or standards from other bodies in setting their rules.	✓		
Blood and tissue establishments are required to take into account ECDC/EDQM rules on quality & safety requirements. EDQM/ECDC update their guidance as required		✓	
Blood and tissue establishments are required to take into account of quality and safety requirements that are defined in EU law. There is a mechanism to provide regular updates in response to changing risks and technologies (using Comitology rules).			✓

This option requires **BTC establishments to assess risks** and develop rules in accordance with available guidance.

Does your establishment already carry out this kind of assessment?

- ◯ Yes
- ◯ No

What rules does your establishment follow when conducting the risk assessments and developing rules?

- ◯ Available scientific evidence
- ◯ Existing guidance at national level (please specify)
- ◯ Other (please specify)

How much effort (in person days) was required for your establishment to conduct the initial risk assessment and develop rules?

	Total person days to support the initial risk assessment	Comment/additional information	Don’t know

	Total person days to support the initial risk assessment	Comment/additional information	Don’t know
Staff			

If your establishment incurred additional costs related to establishing the risk assessment (e.g. fees, training, consultancy support), please indicate the main costs and an estimate of the monetary values (in Euros).

	Monetary value [EUR]	Comment/ additional information	Don't know
Other costs (please specify)			
Other costs (please specify)			

In your sector and location, what is a typical annual salary cost (in Euros) for the category of employee that would be assigned to support risk assessment and rule preparation.

- ○ €/year
- ○ Don’t know

How often is the risk assessment revised/updated? (times per year)

What prompts the revision/update of the risk assessment?

- [ ] Change in available scientific evidence
- [ ] Change in existing guidance at national level
- [ ] Time limits set in national legislation
- [ ] Other (please specify)

How much effort (in total person days) is typically required for your establishment to update/revise the risk assessment?

	Total person days	Comment/additional information
Staff		

If your establishment typically incurs in additional costs related to update/review your risk assessment (e.g. fees, consultancy support), please indicate the main costs and corresponding monetary values below.

	Monetary value [EUR]	Comment/ additional information	Don't know
Other costs (please specify)			

	Monetary value [EUR]	Comment/ additional information	Don't know
Other costs (please specify)			

Problem 2 – The divergent approaches to oversight cause unequal citizen protecti

Problem 2 – The divergent approaches to oversight cause unequal citizen protection

Definition Document that is **avalible to download here.** You may wish to read the document before answering these questions. A summary is provided in the table below .

Problem 2: Divergent approaches to oversight cause unequal citizen protection and barriers to the exchange of BTC across EU	**Option 2.1**
EU law incorporates oversight principles for the NCA and for staff	✓
EU law requires competent authorities to base their inspection regimes on a risk-based approach	✓
The European Commission will develop and maintain common guidance on oversight	✓
Commission audits of national control systems, accompanied by MS experts	✓
EU law is amended to implement a legal framework for Joint Member State inspections of blood and tissue establishments	✓
The European Commission will develop the relevant component of the IT platform for oversight	✓

This option introduces a **risk-based approach to inspections** carried out by competent national authorities, which is meant to affect the frequency (and possibly the effort) for establishments to prepare for, support and follow-up the inspections

Is your establishment already subject to a risk-based approach to inspections?

- ◯ Yes
- ◯ No

In what risk category is your establishment?

How often is your establishment inspected?

Problem 3 - Avoidable risks for BTC donors and for children born from donated eg

Problem 3 - Avoidable risks for BTC donors and for children born from donated eggs, sperm or embryos

To increase protection of BTC donors and children born from donated sperm, eggs or embryos from specific risks, seven measures are being considered. They are grouped into three options, as described in **this** document and summarized in the table below. We recommend that you read Annex 3 of this document to answer the questions below

Problem 3: Avoidable risks for BTC donors and for children born from donated eggs, sperm or embryos	Option 3.1	Option 3.2	Option 3.3

Problem 3: Avoidable risks for BTC donors and for children born from donated eggs, sperm or embryos	Option 3.1	Option 3.2	Option 3.3
EU law incorporates high level principles to protect BTC donors, including reporting measures (SARE/monitoring outcome)	✓	✓	✓
EU law incorporates high level principles to protect offspring born from donated gametes/embryos, including reporting measures (SARE/monitoring outcome).	✓	✓	✓
EU law incorporates new definitions (e.g. to include genetic disease transmission by medically assisted reproduction using donor gametes or embryos as an ‘adverse reaction’)	✓	✓	✓
The European Commission will develop the relevant component of an IT platform for quality and safety requirements	✓	✓	✓
EU law requires establishments to define detailed quality & safety requirements to protect donors and protect children born from donated gametes or embryos	✓		
EU law requires expert bodies to define detailed quality & safety requirements for donors and offspring of medically assisted reproduction, and requires establishments to 'take into account' the rules issued by the expert bodies.		✓	
EU law incorporates quality and safety requirements for donors and offspring of medically assisted reproduction, and a mechanism to update these as needed			✓

Does your establishment already adopt SARE reporting for donors, e.g. because of national legislation or national practices?

- ◯ Yes
- ◯ No

How much effort (in person days) was required for your establishment to set up the monitoring and reporting system for donors?

	Total person days to support the initial preparation	Comment/additional information	Don’t know

	Total person days to support the initial preparation	Comment/additional information	Don't know
Staff			

Please identify any additional costs typically incurred in maintenance of the monitoring and reporting system for donors.

	Monetary value [EUR]	Comment/ additional information	Does not apply/ Cannot say
Other costs (please specify)			
Other costs (please specify)			

This option requires **BTC establishments to define detailed quality & safety requirements** to protect donors and protect children born from donated gametes or embryos, in accordance with available guidance.

Does your establishment already follow quality & safety requirements to protect donors and children born from donated gametes or embryos, e.g. because of national regulations or practices?

- ◯ Yes
- ◯ No

What rules is your establishment following for quality & safety requirements?

- ◯ Available scientific evidence
- ◯ Existing guidance at national level (please specify)
- ◯ Other (please specify)

How much effort (in person days) was required for your establishment to set up the initial quality & safety requirements ?

	Total person days to support the initial quality & safety requirements	Comment/additional information	Don't know
Staff	☐		☐

If your establishment incurred additional costs related to the initial quality & safety requirements (e.g. fees, consultancy support), please indicate the main costs and an estimate of the monetary values (in Euros).

	Monetary value [EUR]	Comment/ additional information	Don't know

	Monetary value [EUR]	Comment/ additional information	Don't know
Other costs (please specify)			
Other costs (please specify)			

In your sector and location, what is a typical annual salary cost (in Euros) for the category of employee that would be assigned to support preparation of quality & safety requirements

- ◯ €/year
- ◯ Don’t know

How often are the quality & safety requirements revised/updated?

- ◯ Every 5 years or less often
- ◯ Between 2 and 5 years
- ◯ Between 1 and 2 years
- ◯ Every year
- ◯ More than once per year (please specify)
- ◯ Don't know

What prompts the revision/update of the quality and safety requirements?

- ◯ Change in available scientific evidence
- ◯ Change in existing guidance at national level (please specify)
- ◯ Time limits set in national legislation (please specify)
- ◯ Other (please specify)

How much effort (in person days) is typically required to revise/update the risk assessment?

	Total person days to support the initial quality & safety requirements	Comment/additional information	Don't know
Staff			☐

If your establishment typically incurs other costs when updating/revising the risk assessment (e.g. fees, consultancy support), please indicate the main costs and corresponding monetary values below.

	Cost per revision/update [EUR]	Comment/ additional information	Does not apply/ Cannot say

	Cost per revision/update [EUR]	Comment/ additional information	Does not apply/ Cannot say
Other costs (please specify)			
Other costs (please specify)			

How much time does it usually take from the need for an update being identified to the adoption of new or revised rules?

Please give an answer in months.

How much effort is typically required to implement the revised/updated safety & quality requirements?

	Total person days per implementation/revision	Comment/additional information	Don't know
Staff			

Can you provide your opinion on the effort (in total person days) that could be required for your establishment to set up and update/revise the risk assessment?

	Total person days	Comment/additional information	Don't know/cannot say

	Total person days	Comment/additional information	Don't know/cannot say
Set up	☐		☐
Update/revise	☐		☐

This option will ensure that **adverse outcomes for donors are reported and investigated**.

Has your establishment had any recent experience with investigating donor adverse outcomes?

- ◯ Yes
- ◯ No

How frequent are these investigations?

This option will ensure that **adverse outcomes for children born from donated gametes/embryos are reported and investigated**.

Has your establishment any recent experience with investigations of offspring adverse outcomes?

- ◯ Yes
- ◯ No

How frequent are these investigations?

Problem 4 – BTC legislation lags behind innovation

Problem 4: BTC legislation lags behind innovation

To facilitate innovation of safe BTC therapies 12 measures are being considered. They are grouped into three options, as described in **this** document and summarized below. We recommend you read section Annex 4 of this document before answering the questions below.

Problem 4: BTC legislation lags behind innovation	Option 4.1	Option 4.2	Option 4.3
The “same surgical procedure” exclusion for point of care preparations is refined/removed.	✓	✓	✓
An EU level advisory mechanism is established to recommend/advise MS on when/what BTC requirements should be applied in part or in full	✓	✓	✓
A mechanism is introduced to prompt regulators of 'adjacent' legal frameworks (SOHO/Pharma/Medical Devices) to better coordinate their rules, especially in respect of substances that are regulated under more than one legal framework.	✓	✓	✓

Problem 4: BTC legislation lags behind innovation	Option 4.1	Option 4.2	Option 4.3
An EU level advisory mechanism will advise where other frameworks (in particular medical devices and medicinal products) might be applied for particular novel BTC. Implementation might involve exchange/mutual consultation with advisory bodies for MP (EMA innovation task force, EMA CAT) and MD frameworks (Borderlines and Classification Working Party).	✓	✓	✓
EU law sets principles for authorisation procedure (good practice for authorisation procedures including validation of facilities, equipment and processing and clinical data requirement according to level of risk and novelty) to demonstrate safety and efficacy in patients.	✓	✓	✓
EU law requires that, for major changes in the steps of collection, processing and use of BTC, competent authorities have to grant prior authorisation based on data demonstrating safety and benefit for patients that justifies any risks associated with treatment with BTC prepared in innovative ways.	✓	✓	✓
EU law sets rules for implementing a clinical trial for BTC (if high level of risks)	✓	✓	✓
The European Commission will develop an exchange (IT) platform for competent authorities to exchange info regarding (novel) process authorisations (the platform would be used for (voluntary) acceptance of authorisations among MS). This includes clinical evidence collected by clinicians with the support of learned societies.	✓	✓	✓
EU law requires establishments to conduct risk assessments on novel processes. These are evaluated by the competent authority inspectors.	✓	✓	✓
EU law requires establishments to design the risk assessments on novel processes. Establishments could follow inter/national or standards from other bodies.	✓		
EU law requires establishments to conduct risk assessments on novel processes in compliance with technical guidance from expert bodies as referred to in EU legislation.		✓	
EU law requires establishments to conduct risk assessments on novel processes in compliance with technical rules set in EU legislation			✓

These options will **remove the ‘same surgical procedure’ exclusion** currently provided in the T&C Directive for point of care preparations

Please provide an estimate of the number of procedures conducted by your establishment each year that would be affected by this proposal

In what way do you think that this proposal will influence the costs incurred by your establishment?

- ◯ It is likely to increase costs significantly
- ◯ It is likely to increase costs slightly
- ◯ It is likely not to change costs
- ◯ It is likely to reduce costs slightly
- ◯ It is likely to reduce costs significantly

Please explain your answer to the question above

How much effort (in total person days) could be required for your establishment to establish procedures to comply with this provision?

	Total person days	Comment/additional information	Don't know
Staff	☐		☐

If you think that your establishment is likely to incur in additional costs to set up procedures to comply with this provision (e.g. fees, consultancy support), please indicate the main costs and your estimation of the corresponding monetary values below.

	Monetary value [EUR]	Comment/ additional information	Don't know
Other costs (please specify)			
Other costs (please specify)			

Do you think that this measure will influence the scope of activity of your establishment, e.g. broaden the scope to include more activities (due to a more consistent legal treatment of such preparations) or reduce it?

- ◯ Yes, broaden the scope of the activity
- ◯ Yes, reduce the scope of the activity
- ◯ No, no change in the scope of the activity
- ◯ Don't know

Please explain your answer to the question above

This option will require establishments to apply for a **Strengthened Preparation Process Authorisation** for major changes in the steps of collection, processing and use of BTC ('novel BTC applications'). Establishments will also have to provide a proportionate set of data demonstrating safety and benefit for patients that justifies any risks associated with treatment with BTC prepared in innovative ways

Does your establishment develop high-risk novel BTC applications?

- ◯ Yes
- ◯ No

Does your establishment already apply for a similar preparation process authorisation, e.g. because of national legislation or national practices?

- ◯ Yes
- ◯ No

How many times a year does your establishment make such an authorisation application, on average?

What effort (in person days) is typically required for your establishment to apply for a preparation process authorisation?

Total person days to support the initial preparation	Comment/additional information	Don't know

	Total person days to support the initial preparation	Comment/additional information	Don't know
Staff			

How much effort (in person days) was required for your establishment to set up the process you use to apply for a strengthened preparation authorisation?

	Total person days to support the initial preparation	Comment/additional information	Don't know
Staff			

If your establishment typically incurs in additional costs related to seeking authorisation for novel BTC applications (e.g. fees, consultancy support), please indicate the main costs and corresponding monetary values below.

	Monetary value [EUR]	Comment/ additional information	Don't know
Other costs (please specify)			
Other costs (please specify)			

When requesting an authorisation application, does your establishment submit documentation and/or clinical data to demonstrate safety and benefits of the novel BTC applications?

- ◯ Yes
- ◯ No

Please describe the documentation and/or clinical data submitted

Is this option likely to influence the activity of your establishment, e.g. increase the likelihood that you will participate in the development of novel BTC applications or reduce it, and why?

- ◯ Increase the participation in developing novel BTC applications
- ◯ Reduce the participation in developing novel BTC applications
- ◯ No changes

Please explain your answer to the question above

This option requires **BTC establishments to conduct risk assessments of novel BTC applications**, in accordance with available guidance.

Does your establishment already conduct risk assessments of novel BTC applications, e.g. because of national regulations or practices?

- ◯ Yes
- ◯ No

What guides these risk assessments?

- ◯ Available scientific evidence
- ◯ Existing guidance at national level (please specify)
- ◯ Other (please specify)

How much effort (in person days) was required for your establishment to establish the initial risk assessment criteria and procedures?

	Total person days	Comment/additional information	Don't know
Staff			

If your establishment incurred in additional costs related to establishing rules and procedures to carry out risk assessment of novel BTC processes (e.g. fees, consultancy support), please indicate the main costs and corresponding monetary values below.

	Monetary value [EUR]	Comment/ additional information	Don't know
Other costs (please specify)			☐
Other costs (please specify)			☐

In your sector and location, what is a typical annual salary cost (in Euros) for the category of employee that would be assigned to support preparation of risk assessment criteria and procedures? (€/year)

○ €/year

○ Don’t know

How often are the risk assessment criteria and procedures revised/updated?

What prompts the revision/update of risk assessment criteria and procedures?

- ◯ Change in available scientific evidence
- ◯ Change in existing guidance at national level (please specify)

- ◯ Time limits set in national legislation (please specify)

- ◯ Other (please specify)

How much effort (in person days) is typically required to revise/update the risk assessment criteria and procedures?

	Total person days	Comment/additional information	Don't know
Staff	☐		☐

If your establishment typically incurs other costs when updating/revising the risk assessment (e.g. fees, consultancy costs), please indicate the main costs and corresponding monetary values below.

	Cost per revision/update [EUR] :	Comment/ additional information	Does not apply/ Cannot say

	Cost per revision/update [EUR] :	Comment/ additional information	Does not apply/ Cannot say
Other costs (please specify)			
Other costs (please specify)			

How much time does it usually take from the need for a revision/update being identified to the adoption of revised/updated risk assessment criteria and procedures?

Please give your answer in months

What level of effort (in person days) do you believe would be required for your establishment to set up and update/revise risk assessment criteria and procedures?

	Total person days per implementation/revision	Comment/additional information	Does not apply/ Cannot say
Set up			
Update/revise			

Problem 5 – EU vulnerable to interruptions in some BTC supply

Problem 5 - EU vulnerable to interruptions in some BTC supply

The measures planned to avoid shortages of BTC therapies are grouped into three options, as described in **this** document and summarized in the table below. We recommend that you read Annex 5 of this document before answering the questions below. The schedule of 'critical' BTC is given in Annex 6

Problem 5: EU vulnerable to interruptions in some BTC supply	**Option 5.1**	**Option 5.2**	**Option 5.3**
EU law is amended to impose mandatory monitoring obligations on blood and tissue establishments for critical BTC	✓	✓	✓
EU law is amended to require mandatory notification of sufficiency data for certain critical BTC in case of shortage/drop in supply (rapid notifications)	✓	✓	✓
EU law is amended to require mandatory emergency plans, for certain critical BTC	✓	✓	✓
The European Commission will develop the relevant component of the IT platform for exchange of information on supply and activity	✓	✓	✓
EU law is amended to strengthen MS ability to intervene to control and adjust supply, as necessary, under their national competence, and allow evidence-based support action at EU level.	✓	✓	✓
EU law is amended to obligate BE/TEs to develop monitoring and notification systems and contingency plans. These will be reviewed for adequacy by the authority during inspection.	✓		
EU law is amended with references to guidance from expert bodies for rules on sufficiency data reporting (incl monitoring and notifications) and on emergency preparedness/contingency.		✓	
EU law is amended to include rules on sufficiency data reporting (incl monitoring and notifications) and on emergency preparedness			✓

Measures under this policy options will require establishments to prepare **contingency plans for use in the event of problems with critical BTC supplies.** The definition of critical BTC follows EDQM recommendation PA/PH/TO (21) 02 for tissues and cells and current discussion on blood (these include plasmapheresis, SD-plasma and PDMPs).

Does your establishment already maintain contingency plans to be used in case of problems with critical BTC supplies, e.g. because of national legislation or national practices?

- ◯ Yes
- ◯ No

What rules does your establishment follow to define the contingency plans?

- ◯ Scientific evidence available
- ◯ Existing guidance at national level (please specify)
- ◯ Other (please specify)

How much effort (in person days) was required for your establishment to set up the initial contingency plan?

	Total person days	Comment/additional information	Don't know
Staff	☐		☐

If your establishment incurred in additional costs related to establishing the contingency plan (e.g. consultancy fees), please indicate the main costs and corresponding monetary values

below.

	Monetary value [EUR]	Comment/ additional information	Don't know
Other costs (please specify)			☐
Other costs (please specify)			☐

In your sector and location, what is a typical annual salary cost (in Euros) for the category of employee that would be assigned to support the preparation of the contingency plan? (€/year)

○ €/year

○ Don't know

How often is the contingency plan revised/updated?

What prompts the revision/update of the contingency plan?

○ Change in available scientific evidence

- ◯ Change in existing guidance at national level (please specify)

- ◯ Time limits set in national legislation (please specify)

- ◯ Other (please specify)

How much effort (in person days) is required for your establishment to revise/update the contingency plan?

	Total person days	Comment/additional information	Don't know
Staff	☐		☐

Please identify any additional costs typically incurred due to the revision/update of the contingency plan.

	Monetary value [EUR]	Comment/ additional information	Don't know

	Monetary value [EUR]	Comment/ additional information	Don't know
Other costs (please specify)			☐
Other costs (please specify)			☐

How much time time does it usually take from the need for an update/revision being identified to the adoption of a revised/updated contingency plan?

Please give your answer in months

Can you provide your opinion on the effort (in total person days) that could be required for your establishment to set up and update/revise a contingency plan on critical BTC supplies as described?

	Total person days	Comment/additional information	Don't know/cannot say
Set up			☐
Update/revise			☐

Measures under these policy options will require establishments to **monitor their supply and demand status** of the sub-set of critical BTC supplies and to **notify competent authorities in case of shortage/drop in supply.** The definition of critical BTC follows EDQM recommendation PA/PH/TO (21) 02 for tissues and cells and current discussion on blood (these include plasmapheresis, SD-plasma and PDMPs). Details are provided in Annex 6 of the Option Definition Document supplied with this survey.

Does your establishment already monitor supply and demand of certain critical BTC supplies, e.g. because of national legislation or national practices?

- ◯ Yes
- ◯ No

What rules define how your establishment monitors supply and demand data?

- ◯ Existing guidance at national level (please specify)
- ◯ Other (please specify)

How much effort (in person days) was required for your establishment to set up the monitoring system for critical BTC supplies?

	Total person days to support the initial preparation	Comment/additional information	Don't know

	Total person days to support the initial preparation	Comment/additional information	Don't know
Staff			

If your establishment incurred in additional costs related to setting up the monitoring system for critical BTC supplies (e.g. fees, consultancy support), please indicate the main costs and an estimate of the monetary values (in Euros).

	Monetary value [EUR]	Comment/ additional information	Does not apply/ Cannot
Other costs (please specify)			
Other costs (please specify)			

How often is the monitoring system for critical BTC supply revised/updated ?

What prompts the revision/update of the monitoring system for critical BTC supply?

- ◯ Change in available scientific evidence

- ◯ Change in existing guidance at national level (please specify)

- ◯ Time limits set in national legislation (please specify)

- ◯ Other (please specify)

How much effort (in person days) is required for your establishment to revise/update the monitoring system for critical BTC supply?

	Total person days	Comment/additional information	Don't know
	☐		☐

Please identify any additional costs typically incurred due to the revision/update of the monitoring system for critical BTC supply.

	Monetary value [EUR]	Comment/ additional information	Does not apply/ Cannot

	Monetary value [EUR]	Comment/ additional information	Does not apply/ Cannot
Other costs (please specify)			☐
Other costs (please specify)			☐

How much time does it usually take from the need for an update being identified to the adoption of the revised/updated monitoring system for critical BTC supply?

Please give your answer in months

Does your establishment already notify national competent authorities of sufficiency data for certain critical BTC in case of shortage/drop in supply?

- ◯ Yes
- ◯ No

How often does you establishment notify national competent authorities of shortages/drop in supply of certain critical BTC supplies in a year?

What procedure does your establishment use to notify competent authorities in case of shortage/drop in supply of critical BTC?

- ◯ Notification upon request from competent authorities
- ◯ Period notification at pre-determined frequency (please specify)
- ◯ System of continuous notification
- ◯ Other (please specify)

Can you provide your opinion on the effort (in total person days) that could be required for your establishment to set up and update/revise the monitoring system for critical BTC supplies as described?

	Total person days	Comment/additional information	Don't know
Set up	☐		☐
Update/revise	☐		☐

See more

Thank you for your answers. Do you have time to answer question about the impacts of another of the proposed policy options?

- ◯ Yes
- ◯ No