Standards of quality and safety for substances of human origin intended for human application

OVERVIEW

On 14 July 2022, the European Commission tabled a proposal to update and expand EU legislation on blood, tissues and cells. The aim is to establish high standards of quality and safety for substances of human origin (SoHOS) intended for human application, to improve the protection of donors, recipients, and offspring born from medically assisted reproduction, and to ensure that the legislation can respond to future challenges.


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<th>Committee responsible</th>
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<td>Rapporteur</td>
<td>Nathalie Colin-Oesterlé (EPP, France)</td>
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<td>Nicolás González Casares (S&amp;D, Spain) Andreas Glueck (Renew, Germany) Tilly Metz (Greens/EFA, Luxembourg) Joanna Kopcińska (ECR, Poland) Kateřina Konečná (The Left, Czechia)</td>
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Introduction

SoHO-based treatments are of high value. They provide large numbers of life-saving and life-enhancing therapies every year: 25 million units of blood for transfusion (e.g. for surgery or trauma care); 36 000 stem cell transplants for blood cancers, life-creating therapies (medically assisted reproduction treatments, e.g. 940 000 cycles of in vitro fertilisation), and life-improving therapies (e.g. 14 500 cornea transplants for restoring sight, and 2 000 skin transplants for burn wounds and other injuries).

In 2002 and 2004 the EU adopted legislation (the 'Blood Directive' 2002/98/EC and the 'Tissues and Cells Directive' 2004/23/EC, known together as the BTC legislation) to protect patients receiving blood, tissues and cells, and set minimum requirements for quality and safety for all activities, from donation to treatment and follow-up.

In the EU, collection, processing and supply systems for SoHOs are organised at national level, often on a local small-scale by public services, (academic) hospitals and non-profit actors. After almost 20 years in place, the BTC legislation is no longer fit for purpose. It needs to be updated, to: take account of advances in the sector (ranging from scientific and technological innovations to socio-demographic changes, such as late motherhood and higher demands for medically assisted reproduction); address the emergence of communicable diseases; and address the increasing commercialisation and globalisation of the sector. The COVID-19 pandemic highlighted some of these shortcomings, in particular those impacting on rules designed to prevent the risk of disease transmission by BTC, and the lack of measures to ensure sufficiency of supply.

In July 2022, the European Commission put forward a proposal to establish new rules to increase the safety and quality of substances of human origin and extend them to other substances of human origin, such as human breast milk, intestinal microbiota, as well as any other substances of human origin to be used for therapies in the future, which were previously unregulated at EU level. This proposal is a new step towards building a strong European health union.

Existing situation

Directive 2002/98/EC and Directive 2004/23/EC constitute the EU’s regulatory framework for blood and for tissues and cells, respectively. Although they have to a certain degree harmonised the national rules in the area of safety and quality of blood, tissues and cells, they allow a significant number of options for Member States in terms of how they implement the rules. Divergences between national rules can create obstacles to cross-border sharing of these substances. The two directives are interconnected and contain very similar provisions. As underlined by the Commission in its proposal, it would make sense to merge the revised provisions into one directly applicable legal act (a regulation).

Parliament's starting position

In its resolution of 11 September 2012 on the voluntary and unpaid donation of tissues and cells, Parliament underlined that donation should be voluntary, unpaid and anonymous (except in the case of procurement from a living person for a relative). It noted that Member States should ensure that compensation is limited to travel expenses, loss of earnings, or medical costs relating to the medical procedure and possible side effects. It called on them to establish public tissue and cell banks. It supported the creation of a Europe-wide database of donors and recipients to avoid shortages. In its resolution of 24 June 2021 on the situation of sexual and reproductive health and rights in the EU, Parliament called on the Member States to ensure that all people of reproductive age have access to fertility treatments, regardless of their socio-economic or marital status, gender identity or sexual orientation. Since 2002, Members of the European Parliament (MEPs) have asked more than 70 written questions relating to blood, tissues and cells, with topics ranging from deferral criteria for donors to sufficiency of supply, voluntary unpaid donation and cord blood banking.
Preparation of the proposal

The EU legislation on blood, tissues and cells was subject to an evaluation in October 2019, based on an independent study. The evaluation confirmed that the legislation had improved the safety and quality of blood, tissues and cells used for transfusion, transplantation or medically assisted reproduction. However, it highlighted a number of gaps and shortcomings to be addressed to ensure the framework was up to date, fit for purpose and future proof.

In its 2021 work programme, published in October 2020, the Commission announced the revision of the BTC legal framework. An inception impact assessment on the proposal was published on 17 November 2020 for public feedback up to 14 December 2020 (81 valid feedback instances were received). Two online public consultations were opened on 21 January 2021 and closed on 15 April 2021. The general consultation received responses from 214 stakeholders. Moreover, 160 organisations directly impacted by the legislation responded to a more technical targeted survey. The responses to both surveys were taken into account in the impact assessment. In addition to the online consultations, 14 stakeholder workshops were organised to gather input through direct interaction.

The impact assessment accompanying the Commission proposal was supported by an external study. It considered three policy options: i) decentralised regulation (blood and tissue establishments refer to national and international guidance when setting internal technical standards for their activities); ii) joint regulation (blood and tissue establishments must follow the technical standards defined in guidance developed and maintained by nominated EU expert bodies); and iii) central regulation (blood and tissue establishments have to follow the technical standards defined in EU law). The preferred option is option 2.

In September 2022, EPRS published an implementation appraisal of the EU legislation on blood, tissues and cells.

The changes the proposal would bring

The proposed regulation, based on Article 168(4)(a) of the Treaty on the Functioning of the European Union, establishes measures setting high standards of quality and safety for all substances of human origin intended for human application, and for activities related to such substances, in order to ensure a high level of human health protection, in particular for SoHO donors, SoHO recipients and children born from medically assisted reproduction. Member States would still have the possibility to add more stringent measures than those set out in the proposed regulation.

The proposal includes some provisions that mirror the old framework. For instance, Member States would retain full competence for any organisational and ethical decisions concerning the provision of SoHO-based treatments in their healthcare systems. In addition, the principle of voluntary and unpaid donation is upheld and improved in the proposal.

The framework envisaged would allow for more flexible updating of provisions in line with scientific and technical developments, to render the legislation future proof. It also aims to increase harmonisation to facilitate cross-border exchanges and access to SoHO therapies.

The proposal would introduce the following new rules:

- All substances of human origin would be covered (examples of new substances added include human breast milk and intestinal microbiota), with the exception of solid organs for transplantation, which are governed by Directive 2010/53/EU; other substances of human origin that may, in the future, be applied to patients would automatically fall within the scope of this legislation;
- Protection would be improved for recipients of SoHO therapies, as well as for donors of SoHO and offspring from medically assisted reproduction;
The expertise of existing technical bodies in Europe (notably the European Centre for Disease Prevention and Control and the European Directorate for the Quality of Medicines & Healthcare (Council of Europe) would be used to keep technical guidelines up to date;

Entities working with SoHOs would be required to report their annual activity data. This would allow Member States to implement measures to improve donation collection rates when needed. Entities working with critical SoHOs would need to alert their authority in the event of a sudden fall in supply and would be required to have emergency plans in place;

Provision is made for stronger support for innovation, with a common procedure to assess and authorise SoHO preparations, proportionate to the risks these bring; all entities carrying out activities affecting the safety and quality of SoHO would be required to register;

A SoHO coordination board would work with and for the Member States to support implementation of the new regulation; an EU SoHO platform would be set up to gather all required information, streamline reporting and increase transparency.

Advisory committees

The European Economic and Social Committee (EESC) adopted an opinion on the proposal on 27 October 2022 (rapporteur: Tymoteusz Adam Żych (Diversity Europe – Group III, Poland). It welcomed the proposal and stressed that it considers it appropriate to define the scope of the regulation in such a way that it will take account not only of SoHOs not yet regulated at European level but also of any SoHOs that may be used in the future. It welcomes the introduction of uniform basic standards for keeping registers of SoHO entities. It stresses that the reaffirmation in the draft of the principle of free SoHO donation is essential for the elimination of abuse and the safety of SoHO sourcing. SoHOs imported from outside the EU should meet the same quality and safety standards as those sourced within the EU.

The European Committee of the Regions decided not to issue an opinion.

National parliaments

The deadline for the submission of reasoned opinions on the grounds of subsidiarity was 13 October 2022. No opinion was issued within the given time limit.

Stakeholder views

The European Association of Tissue and Cells Banks (EATCB) and its sister association – Asociación Española de Bancos de Tejidos – see the proposed regulatory framework for SoHOs as a great opportunity to improve quality and safety. However, they express concerns notably about the promotion of donation, and reliance on third countries to supply the EU health system, with relaxed safety and quality requirements and no methodologies to effectively assess the absence of financial gain.

The European Blood Alliance (EBA) is pleased with the general direction of the proposal; it nevertheless stresses that certain elements of the proposal could still be improved.

The European Society for Blood and Marrow Transplantations (EBMT) welcomes the introduction of a joint regulation approach, which will apply directly in all Member States, promote harmonisation across Member States and remove barriers to the exchange of life-saving SoHOs. It is glad that the principle of voluntary unpaid donations has been maintained.

On 22 May 2023, the Common Representation of Substances of Human Origin (CoRe SoHO), a consortium of professional scientific associations, including the EATCB, the EBA, the European Eye Bank Association (EEBA) and the EBMT, addressed a letter to the ENVI committee expressing some concerns.
The Plasma Protein Therapeutics Association (PPTA) welcomes the proposal but regrets the missed opportunities to support plasma donors and patients who rely on plasma-derived medicinal products.

The European Society of Human Reproduction and Embryology (ESHRE) welcomes the revision of the BTC legislation and calls on the legislators to correct the definition of a 'substance of human origin', to clearly include embryos and to clarify the terms 'donor' and 'recipient' in the field of medically assisted reproduction. On 22 May 2023, it wrote a letter to ENVI expressing some concerns.

**Legislative process**

The European Commission put forward its proposal on 14 July 2022.

In Parliament, the file was referred to the Committee on the Environment, Public Health and Food Safety (ENVI), which appointed Nathalie Colin-Oesterlé (EPP, France) as rapporteur on 20 October 2022. Her draft report was issued on 18 January 2023 and presented in ENVI on 2 March 2023. Further amendments were tabled in the committee by 8 March 2023.

On 9 December 2022, the Czech Presidency of the EU presented the work done so far in the Council’s preparatory bodies at the Employment, Social Policy, Health and Consumer Affairs Council configuration (EPSCO). On 13 June 2023, the EPSCO Council assessed the state of play of the proposal based on a progress report prepared by the Swedish Presidency.

ENVI adopted its report on 18 July 2023, with 59 votes in favour, 4 votes against, and 4 abstentions. ENVI committee MEPs want to reinforce measures to ensure improved protection for citizens who donate blood, tissues or cells, or are treated with these substances.

On 12 September 2023, Parliament voted (by 483 votes in favour, to 82 votes against, with 59 abstentions) amendments to the proposal, forming its negotiating mandate.

On 25 October 2023, the Council agreed its negotiating mandate.

Interinstitutional negotiations began on 6 November 2023. On 14 December 2023, Parliament and Council reached a provisional agreement on the proposal. They agreed that EU Member States can compensate donors, in line with the principle of voluntary and unpaid donation and based on transparent criteria. The conditions for this compensation would be established in national legislation, including by setting an upper limit for compensation that aims to guarantee that no financial gain or loss is incurred by the donor as a result of the donation (‘financial neutrality’). Member States would have to ensure that promotion activities in support of donations do not include references to compensation. Concerning safeguarding supply, Member States would establish national emergency plans, setting out measures to be applied when the ‘demand or the supply situation for critical SoHO present or are likely to present a serious risk to human health’.

The agreement, which was welcomed by the European Commission, will now have to be formally approved by Parliament and Council. On 30 January 2024, Coreper, for the Council, endorsed the agreement. A vote in Parliament’s ENVI committee is scheduled for 14 February, to be followed by a vote in plenary, expected in the spring.

The regulation would apply three years after its adoption.
EUROPEAN PARLIAMENT SUPPORTING ANALYSIS

Bacian I., Revision of the EU legislation on blood, tissues and cells, implementation appraisal, EPRS, European Parliament, 2022.

OTHER SOURCES

European Commission, Blood, tissues, cells and organs, website.

ENDNOTE

This section aims to provide a flavour of the debate and is not intended to be an exhaustive account of all different views on the proposal. Additional information can be found in related publications listed under 'European Parliament supporting analysis'.

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