Basic information

2022/0216(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Standards of quality and safety for substances of human origin intended for human application **Subject** 4.20.01 Medicine, diseases 4.20.02 Medical research 4.20.02.06 Clinical practice and experiments 4.20.04.02 Safety of blood and transfusion 4.20.05 Health legislation and policy	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	COLIN-OESTERLÉ Nathalie (EPP)	20/10/2022
	Shadow rapporteur GONZÁLEZ CASARES Nicolás (S&D) GLÜCK Andreas (Renew) METZ Tilly (Greens/EFA) KOPCIŃSKA Joanna (ECR) KONEČNÁ Kateřina (The Left)	

Council of the European Union

European Commission

Commission DG	Commissioner
Health and Food Safety	KYRIAKIDES Stella

European Economic and Social Committee

European Committee of the Regions

Key events

Date	Event	Reference	Summary
14/07/2022	Legislative proposal published	COM(2022)0338	Summary

12/09/2022	Committee referral announced in Parliament, 1st reading		
18/07/2023	Vote in committee, 1st reading		
26/07/2023	Committee report tabled for plenary, 1st reading	A9-0250/2023	Summary
12/09/2023	Decision by Parliament, 1st reading	T9-0299/2023	Summary
12/09/2023	Results of vote in Parliament		
12/09/2023	Matter referred back to the committee responsible for interinstitutional negotiations		
14/02/2024	Approval in committee of the text agreed at 1st reading interinstitutional negotiations	PE758.999 GEDA/A/(2024)000898	
24/04/2024	Decision by Parliament, 1st reading	T9-0353/2024	Summary
24/04/2024	Results of vote in Parliament		
27/05/2024	Act adopted by Council after Parliament's 1st reading		
13/06/2024	Final act signed		
17/07/2024	Final act published in Official Journal		

Technical information

Procedure reference	2022/0216(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Legal basis	Treaty on the Functioning of the European Union TFEU 168-p4
Other legal basis	Rules of Procedure EP 165
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/9/09602

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE738.661	18/01/2023	
Amendments tabled in committee		PE740.835	14/03/2023	
Amendments tabled in committee		PE745.276	14/03/2023	
Amendments tabled in committee		PE745.277	14/03/2023	
Committee report tabled for plenary, 1st reading/single reading		A9-0250/2023	26/07/2023	Summary
Text adopted by Parliament, partial vote at 1st reading /single reading		T9-0299/2023	12/09/2023	Summary

Text agreed during interinstitutional negotiations		PE758.999	30/01/2024	
Text adopted by Parliament, 1st reading/single reading		T9-0353/2024	24/04/2024	Summary

Council of the EU

Document type	Reference	Date	Summary
Coreper letter confirming interinstitutional agreement	GEDA/A/(2024)000898	30/01/2024	
Draft final act	00008/2024/LEX	13/06/2024	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2022)0338	14/07/2022	Summary
Document attached to the procedure	SEC(2022)0304	14/07/2022	
Document attached to the procedure	SWD(2022)0189	14/07/2022	
Document attached to the procedure	SWD(2022)0190	14/07/2022	
Document attached to the procedure	SWD(2022)0191	14/07/2022	
Commission response to text adopted in plenary	SP(2024)394	08/08/2024	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	ES_PARLIAMENT	COM(2022)0338	10/10/2022	
Contribution	CZ_CHAMBER	COM(2022)0338	14/10/2022	
Contribution	PT_PARLIAMENT	COM(2022)0338	21/12/2022	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EDPS	Document attached to the procedure	N9-0084/2022 OJ C 450 28.11.2022, p. 0007	07/09/2022	
EESC	Economic and Social Committee: opinion, report	CES4815/2022	26/10/2022	

Additional information

Source	Document	Date
European Parliament	Briefing	12/02/2024

European Commission	EUR-Lex	

Meetings with interest representatives published in line with the Rules of Procedure

Rapporteurs, Shadow Rapporteurs and Committee Chairs

Transparency				
Name	**Role**	**Committee**	**Date**	**Interest representatives**
GLÜCK Andreas	Shadow rapporteur	ENVI	31/01/2024	Plasma Protein Therapeutics Association Europe, international Association without lucrative purpose
GLÜCK Andreas	Shadow rapporteur	ENVI	30/01/2024	Pharma-Netzwerk Deutschland
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	05/12/2023	Epodin
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	16/11/2023	DKMS
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	10/11/2023	Blood and Beyond
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	04/09/2023	Alliance Promotion Microbiote
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	29/08/2023	Transform
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	12/07/2023	Plasma Protein Therapeutics Association Europe, international Association without lucrative purpose
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	06/07/2023	Grifols, S.A.
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	05/07/2023	Blood and beyond
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	26/06/2023	EPODIN
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	23/06/2023	Alliance Plasma
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	31/05/2023	BTA
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	31/05/2023	PPTA
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	22/05/2023	Hermann Drummer
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	16/05/2023	DG SANTE
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	19/04/2023	Grifols, S.A.
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	21/03/2023	European Sperm Bank
KONEČNÁ Kateřina	Shadow rapporteur	ENVI	01/03/2023	European public service union
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	22/02/2023	Croix-Rouge belge

KONEČNÁ Kateřina	Shadow rapporteur	ENVI	21/02/2023	Takeda Pharmaceuticals International AG
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	21/02/2023	Alliance for Regenerative Medicine
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	09/02/2023	Edwards Lifesciences
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	08/02/2023	Cerus Europe B.V.
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	03/02/2023	Spanish Ministry for Health
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	01/02/2023	Avis
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	01/02/2023	Spanish Ministry for Health
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	01/02/2023	German Permanent Representation
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	26/01/2023	IPOPI
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	25/01/2023	European Blood Alliance
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	25/01/2023	European Blood Alliance
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	25/01/2023	ESHRE
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	23/01/2023	Spanish Permanent Representation
GLÜCK Andreas	Shadow rapporteur	ENVI	18/01/2023	Bundesärztekammer
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	18/01/2023	AEMPS
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	12/01/2023	EDQM
GLÜCK Andreas	Shadow rapporteur	ENVI	11/01/2023	IPFA
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	11/01/2023	Dr. Miguel Angel Vesga
GLÜCK Andreas	Shadow rapporteur	ENVI	10/01/2023	Takeda
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	10/01/2023	CSL
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	04/01/2023	European Economic and Social Committee
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	04/01/2023	Dr. Mikel Sanchez
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	19/12/2022	European Sperm Bank
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	30/11/2022	MedTech Europe
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	28/11/2022	European Sperm Bank

COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	24/11/2022	Alliance for Regenerative Medicine
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	24/11/2022	International Plasma and Fractionation Association
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	24/11/2022	Présidence tchèque du Conseil
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	23/11/2022	ANSM
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	18/11/2022	Agence française de la Biomédecine
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	17/11/2022	Dr. Esteve Trias Dr. Silvia Cufi
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	16/11/2022	HERA
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	15/11/2022	Centre de Transfusion des Armées (CTSA)
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	15/11/2022	LFB
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	15/11/2022	EMA
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	14/11/2022	DG Santé
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	14/11/2022	EPODIN/AFNP
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	14/11/2022	DG SANTE
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	10/11/2022	Alliance of Regenerative Medicine
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	10/11/2022	Terumo Blood and Cell Technologies
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	10/11/2022	RPP Group
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	08/11/2022	ESHRE
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	08/11/2022	Blood and Beyond
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	08/11/2022	Cerus Europe B.V.
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	07/11/2022	Représentation permanente de l'Allemagne
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	07/11/2022	Blood Transfusion Association
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	04/11/2022	IRIS/IPOPI
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	04/11/2022	Pr Mahlaoui - Hôpital Necker
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	04/11/2022	Etablissement français du sang
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	27/10/2022	ECDC

COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	26/10/2022	Macopharma
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	26/10/2022	Représentation permanente de la France - chargée Santé
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	25/10/2022	European Blood Alliance
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	25/10/2022	DG Santé
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	25/10/2022	French Blood Establishment
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	24/10/2022	Blood and Beyond
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	19/10/2022	Commissionner Kyriakides
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	19/10/2022	Spanish Permanent Representation
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	12/10/2022	EUCOPE
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	12/10/2022	PPTA
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	12/10/2022	DG SANTE
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	12/10/2022	EUCOPE
COLIN-OESTERLÉ Nathalie	Rapporteur	ENVI	12/10/2022	Grifols, S.A. Plasma Protein Therapeutics Association Europe, international Association without lucrative purpose
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	11/10/2022	Grifols, S.A.
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	29/09/2022	European Blood Alliance
GONZÁLEZ CASARES Nicolás	Shadow rapporteur	ENVI	29/09/2022	SIOPE

Other Members

Transparency		
Name	**Date**	**Interest representatives**
DE MEO Salvatore	01/06/2023	Takeda Pharmaceuticals International AG
SCHNEIDER Christine	21/03/2023	GIRP PHAGRO
DE MEO Salvatore	07/03/2023	Takeda Pharmaceuticals International AG
DE LANGE Esther	07/03/2023	Takeda Pharmaceuticals International AG
WÖLKEN Tiemo	20/02/2023	Plasma Protein Therapeutics Association Europe, international Association without lucrative purpose
WÖLKEN Tiemo	09/02/2023	OSTWÄRTS
WÖLKEN Tiemo	08/02/2023	Grifols, S.A.
CLUNE Deirdre	08/02/2023	Grifols, S.A.

SCHNEIDER Christine	08/02/2023	Grifols, S.A.
WÖLKEN Tiemo	25/01/2023	Ständige Vertretung der Bundesrepublik Deutschland bei der EU
KYMPOUROPOULOS Stelios	12/01/2023	CSL
SOLÍS PÉREZ Susana	12/10/2022	Grifols, S.A.

Final act
Regulation 2024/1938 OJ OJ L 17.07.2024 Summary Corrigendum to final act 32024R1938R(01) OJ OJ L 26.07.2024

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

2022/0216(COD) - 17/07/2024 - Final act

PURPOSE: to improve the safety and quality of blood, tissues and cells used in healthcare and facilitate cross-border circulation of these substances in the EU.

LEGISLATIVE ACT: Regulation (EU) 2024/1938 of the European Parliament and of the Council on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC.

CONTENT: the regulation establishes measures that set **high standards of quality and safety** for all substances of human origin (SoHO) intended for human application and for activities related to those substances. It ensures a high level of human health protection, in particular for SoHO donors, SoHO recipients and offspring from medically assisted reproduction, including by strengthening the continuity of supply of critical SoHO.

Under the new regulation, Member States may choose to apply stricter measures to protect their citizens.

The regulation covers a wide range of activities from registration and testing of donors, collection and processing to human application and clinical outcome monitoring of substances of human origin.

Scope

This regulation will apply to blood and blood components, as well as to tissues and cells, including haematopoietic stem cells from peripheral blood, from umbilical-cord blood or from bone marrow, reproductive cells and tissues, embryos, foetal tissues and cells and adult and embryonic stem cells.

The scope of the regulation will be broadened to any SoHO, in order to prevent a situation in which certain groups of SoHO donors or SoHO recipients and offspring from medically assisted reproduction are not protected by an appropriate Union level quality and safety framework. This will, for example, ensure the protection of SoHO donors and SoHO recipients of human breast milk, intestinal microbiota, blood preparations that are not used for transfusion, and any other SoHO that might be applied to humans in the future.

A common EU framework

In addition to improving quality and safety, the regulation aims to increase harmonisation and facilitate cross-border exchanges and access to SoHO, including by:

- obliging Member States to designate the **SoHO competent authority** or authorities to which they confer responsibility for SoHO supervisory activities. These must act independently and impartially, in the public interest and free from public interest and free from any external influence, and will carry out supervisory activities in a transparent manner;

- introducing **common EU-wide procedures** for the authorisation and evaluation of preparations based on substances of human origin of substances of human origin;

- setting out **additional authorisation** and inspection requirements for establishments that both process and store, release, import or export substances of human origin;

- setting up a **SoHO coordination board** at EU level EU level to help Member States implement the regulation;

- establishing a new common IT platform, the **EU SoHO platform**, to register and exchange information on related activities.

The regulation also provides for a **rapid alerts system** to cope with serious incidents or reactions that are likely to pose a risk for recipients or donors.

General obligations on SoHo entities

These entities will: (i) register as a SoHO entity before commencing any of the SoHO activities; (ii) appoint a person responsible, within their entity, for ensuring that SoHO activities carried out by the SoHO entity comply with the requirements of this Regulation; (iii) establish, maintain and update a quality management system taking into account their SoHO activities; (iv) collect and report data relating to SoHO activities.

Donor and recipient protection

SoHO entities will: (i) ensure respect for the dignity and integrity of SoHO donors; (ii) ensure high levels of safety and protect the health of living SoHO donors from the risks related to the donation by identifying and minimising such risks before, during and after the SoHO collection.

They will also provide living SoHO donors or, where applicable, any person giving consent on behalf of a SoHO donor, with all appropriate **information** relating to the SoHO donation process, in accordance with national legislation. The living SoHO donor's rights to physical and mental integrity, non-discrimination, privacy and protection of personal data will be safeguarded.

SoHO entities will also protect the health of SoHO recipients and the health of offspring resulting from medically assisted reproduction against the risks presented by SoHO and its human application.

Voluntary and unpaid donation

The new regulation provides that donations of SoHO should be voluntary and unpaid as a matter of principle, and donors must not be provided with financial incentives to donate. Living donors may receive compensation or reimbursement as appropriate in line with national legislation.

Sufficient supply of critical SoHO

Member States will make reasonable efforts to ensure the sufficient, adequate and resilient supply of critical SoHO in their countries, including by drawing up **national emergency plans**, including measures to respond to critical shortages.

ENTRY INTO FORCE: 6.8.2024.

APPLICATION: from 7.8.2027.

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

2022/0216(COD) - 24/04/2024 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 461 votes to 56, with 66 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC.

The European Parliament’s position adopted at first reading under the ordinary legislative procedure amends the proposal as follows:

Subject matter and scope

This Regulation establishes measures that set **high standards of quality and safety for all substances of human origin (SoHO) intended for human application** and for activities related to those substances. It ensures a high level of human health protection, in particular for SoHO donors, SoHO recipients and offspring from medically assisted reproduction, including by strengthening the continuity of supply of critical SoHO.

The Regulation applies to: (i) SoHO intended for human application; (ii) SoHO donors, SoHO recipients and offspring from medically assisted reproduction; (iii) SoHO activities that have a direct impact on the quality, safety or effectiveness of SoHO.

It should not apply to: (i) organs intended for transplantation; (ii) breast milk when used exclusively for feeding one’s own child, without any processing carried out by a SoHO entity.

Competent authorities

Member States should designate the SoHO competent authorities to which they entrust responsibility for SoHO monitoring activities. The designated SoHO Competent Authorities should be independent from any SoHO entity. Member States should ensure that the SoHO competent authorities have sufficient human and financial resources, operational capacity and expertise, including technical expertise, to achieve the objectives of this Regulation.

When carrying out their tasks and exercising their powers, the SoHO competent authorities should act **independently and impartially**, in the public interest and free from any external influence, which could constitute political influence or interference by industry. They should carry out the SoHO supervisory activities for which they have been charged in a transparent manner and should make available and clear to the public any enforceable decision and the reasons for that decision, in cases where an SoHO entity fails to comply with this Regulation.

SoHO donor and recipient protection

SoHO entities should : (i) ensure respect for the **dignity and integrity of SoHO donors**; (ii) ensure high levels of safety and protect the health of living SoHO donors from risks related to the SoHO donation, by identifying and minimising such risks before, during and after the SoHO collection.

Where SoHO is collected from a SoHO donor, SoHO entities should:

- provide SoHO donors or, where applicable, any person giving consent on their behalf with: (i) information in a manner appropriate to their ability to understand; (ii) the contact details of the SoHO entity responsible for the collection, from which they may, where appropriate, request further information;

- safeguard the living SoHO donor's rights to physical and mental integrity, non-discrimination, privacy and the protection of personal data;

- verify the eligibility of the living SoHO donor on the basis of an assessment of his or her state of health aimed at identifying, with a view to minimising, the risk that SoHO donation could represent for his or her health;

- check that living donors do not donate more frequently than is indicated as safe;

- draw up a plan for monitoring the donor's health after SoHO donation in cases where the donation of a substance of human origin involves a significant risk for a living donor.

SoHO entities that collect SoHO from living SoHO donors should register such SoHO donors in a SoHO entity registry or, where available, in national or recognised international registries, to verify donation frequency.

Where Member States allow for the **compensation of living SoHO donors**, in accordance with the principle of voluntary and unpaid donation and based on transparent criteria, including through fixed allowances, or through non-financial forms of compensation, the conditions for such compensation should be established in national legislation, including by setting an upper limit for compensation that should endeavour to guarantee financial neutrality. Any promotion and publicity activities in support of the donation of SoHO should not refer to compensation.

SoHO entities should provide living SoHO donors or, where applicable, any person giving consent on behalf of a SoHO donor, with all appropriate **information** relating to the SoHO donation process. This information should cover the purpose and nature of the SoHO donation, the intended use of the donated SoHO, specifically covering proven benefits for the future SoHO recipients and any possible research or commercial uses of SoHO, and the obligation for consent, in accordance with national legislation, in order for SoHO collection to be carried out.

SoHO entities should **protect the health of SoHO recipients** and offspring from medically assisted reproduction from risks posed by SoHO and their human application, within the scope of their competences. They should do so by identifying and minimising or eliminating those risks. Procedures that achieve high levels of quality and safety of SoHO should be established to ensure that benefits for SoHO recipients and offspring from medically assisted reproduction outweigh residual risks.

Critical SoHO supply sufficiency

Member States should, within their territories and in collaboration with SoHO national authorities, SoHO competent authorities and SoHO entities, each within their respective competence, consider all reasonable efforts for achieving a sufficient, adequate and resilient supply of critical SoHO with a view to appropriately meet recipients' needs, and to contribute to **European self-sufficiency**.

Member States, in collaboration with SoHO national authorities, should draw up national **SoHO emergency plans** setting out measures to be applied without undue delay when the demand or the supply situation for critical SoHO present, or is likely to present, a serious risk to human health.

Critical SoHO entities should, without undue delay, send a **SoHO supply alert** to their SoHO competent authorities in the event of **significant shortages of supply** of critical SoHO, indicating the underlying reasons, the expected impact on recipients and any mitigating actions taken.

EU SoHO Platform

The Commission should establish, manage and maintain a digital platform to facilitate efficient and effective exchange of information concerning SoHO activities in the Union.

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

2022/0216(COD) - 14/07/2022 - Legislative proposal

PURPOSE: to ensure a high level of health protection for EU citizens and ensure access to safe and effective substances of human origin (blood, tissue and cells) (SoHOs).

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: every year, EU patients are treated with 25 million blood transfusions (during emergency surgery, cancer or other care), a million cycles of medically assisted reproduction, over 35 000 transplants of stem cells (mainly for blood cancers) and hundreds of thousands of replacement tissues (e.g., for orthopaedic, skin, cardiac or eye problems).

The EU framework for safety and quality of substances of human origin (SoHOs) has currently three main Directives, respectively for **Blood, Tissues and Cells, and Organs**, together with implementing legislation.

Although these Directives have harmonised to a certain degree the rules of Member States in the area of safety and quality of blood, tissues and cells, they include a significant number of options and possibilities for Member States to implement the rules they laid down. This results in **divergences between national rules**, which can create obstacles to cross-border sharing of these substances.

A fundamental revision of those Directives is needed for a robust, transparent, up-to-date and sustainable regulatory framework for these substances, which achieves safety and quality for all parties involved, enhances legal certainty and supports continuous supply, whilst facilitating innovation for the benefit of public health. In addition, the proposal aims to tackle concerns regarding the sufficiency of supply highlighted by the COVID-19 pandemic.

This initiative is part of the EU's ambition to build a stronger European Health Union.

CONTENT: the proposed Regulation aims to establish measures setting high standards of quality and safety for all substances of human origin intended for human applications and for activities related to these substances, in order to ensure a high level of human health protection, in particular for donors of substances of human origin, recipients of substances of human origin and offspring of medically assisted reproduction.

All substances of human origin would be covered, with the exception of solid organs. Human breast milk is one of the new substances covered by the proposal.

More specifically, the proposal provides for measures to:

- ensure **safety and quality for patients** receiving SoHO therapies and fully protect them from avoidable risks related to substances of human origin;

- ensure **safety and quality for donors** of substances of human origin and for **children** born from donated eggs, sperm or embryos;

- empower the EU and its Member States to **better prevent and combat future pandemics** (surveillance, data analysis, risk assessment, early warning and rapid response);

- facilitate the development of **innovative, safe and effective SoHO therapies**;

- improve the **resilience of European health systems** (sufficient supply of human-derived substances) by mitigating the risk of shortages.

Specifically, the proposal:

- improves the **protection of patients** treated with SoHO (recipients) and offspring from medically assisted reproduction, with standards, and how to implement these standards concerning recipient and offspring protection;

- contains provisions on the competent authorities for substances of human origin, which are responsible for the supervisory activities;

- covers all activities that competent authorities undertake in relation to SoHO entities or registration procedures, with the obligation to maintain a register of SoHO entities and to establish a procedure for their **registration**;

- describes all general obligations on SoHO entities, namely their registration, the nomination of a Responsible Person if they release substances of human origin for clinical use, as well as obligations regarding the export of SoHOs;

- requires blood and tissue establishments to meet safety and quality standards by following **guidelines** developed and updated by **designated expert bodies** such as the European Centre for Disease Prevention and Control (ECDC) and the European Directorate for the Quality of Medicines and Health Care (Council of Europe);

- lays down provisions to ensure the **continuity of supply of SoHOs**. It covers the obligation for Member States to have national SoHO emergency plans (for SoHOs that are critically important for patients) and the responsibilities of competent authorities and entities regarding supply alerts for critical SoHOs.

A SoHO Coordination Board (SCB) would be established with and for the Member States to support a common implementation of the new Regulation.

The creation of the **EU SoHO Platform**, to gather all required information, streamline reporting and increase visibility to citizens will give a new impetus to digitalisation.

BUDGETARY IMPLICATIONS: the financial impact of the proposal is estimated at **EUR 55.411 million** in commitment appropriations for the period 2024-2027. The appropriations will be reallocated within the financial envelope of the EU Health Programme in the Multiannual Financial Framework (MFF) 2021-2027.

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

2022/0216(COD) - 26/07/2023 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Nathalie COLIN-OESTERLÉ (EPP, FR) on the proposal for a regulation of the European Parliament and of the Council on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC.

The committee responsible recommended that the European Parliament's position adopted at first reading under the ordinary legislative procedure should amend the proposal as follows:

Scope

The amended text establishes provisions on:

- **exchange of information** on availability and stocks of SoHOs, and promotion of actions relating to the security of SoHO supply;

- **coordination** between competent authorities and the Commission and Union agencies in the event of SoHO related health emergencies.

It should be noted that Members stipulated that this Regulation should not apply to breast milk that is expressed by a mother solely for the purpose of feeding her own child.

More stringent measures

Members stressed that the protection of donors and recipients should be ensured through the highest quality and safety standards. They suggested that the principle of **voluntary and unpaid donation** should be harmonised, in particular with a view to stopping differences in national rules from encouraging citizens to donate in other countries than their own for financial reasons.

Members insisted that EU countries should allow for **compensation or reimbursement** for losses or expenses, related to their participation in donations, to living donors. This could be facilitated through for example, compensatory leave, tax reductions or flat rate allowances set at the national level. They stressed that compensation should not be used as an incentive to recruit donors, nor lead to the exploitation of vulnerable people. The report also called on the EU to enforce strict rules on **advertising** around SoHO donations, which should prohibit any references to financial rewards. Moreover, recruitment campaigns and advertisements should not refer to any compensation.

The report also called for greater efforts to harmonise **donation frequency** rules between the Member States by giving the European Commission the power to adopt delegated acts on this specific matter.

Safeguarding supply

To ensure the autonomy of the EU's supply of these substances, EU countries should establish national **emergency and continuity of supply plans**, which should include measures to ensure a resilient donor base, monitoring of the supply of critical SoHOs and proposals to improve cooperation between countries with excess stocks and those experiencing shortages. Members also called for the EU to establish a digital communication channel as part of these national plans, to store and analyse information on SoHOs availability, fluctuations and potential shortages.

EU strategy

Members called for the development of a strategy for the promotion of European SoHO supply autonomy. The strategy should set out a roadmap with ambitious targets for each critical SoHO. It should promote actions to:

- support and coordinate communication campaigns at European and national level on the various types of SoHO donations that are available;

- support, through relevant programmes, the training of healthcare workers in hospital and healthcare facilities, to raise awareness concerning SoHO donations;

- coordinate the exchange of best practices linked to optimisation of the use of critical SoHOs.

The strategy should include actions to establish a **Union list of critical SoHOs**.

SoHO platform

To limit administrative burden on competent authorities and the Commission, the latter should establish an online platform (EU SoHO Platform) to facilitate timely submission of data and reports, to make it possible to share the elements used to determine the regulatory status of a substance, to improve the transparency of national reporting and supervisory activities and ensure better communication, collaboration and coordination in relation to, and exchange of, SoHOs between Member States.

In order to prevent supply tensions and to ensure donor and recipient security, the Commission should ensure that the EU SoHO Platform is interoperable with the other existing Union platforms, in particular the EMA's European Shortages Monitoring Platform. The EU SoHO Platform should also be the main intermediary for reporting SoHO shortages, for cross-border requests for SoHOs and for import and export of SoHOs.

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

2022/0216(COD) - 12/09/2023 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted by 483 votes to 82, with 59 abstentions, **amendments** to the proposal for a regulation of the European Parliament and of the Council on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98 /EC and 2004/23/EC.

The matter was referred back to the committee responsible for inter-institutional negotiations.

Scope

The amended text establishes provisions on:

- exchange of information on availability and stocks of SoHOs, and promotion of actions relating to the security of SoHO supply;

- coordination between competent authorities and the Commission and Union agencies in the event of SoHO related health emergencies.

Members stipulated that this Regulation should not apply to breast milk that is expressed by a mother solely for the purpose of feeding her own child.

Voluntary and unpaid donation

Parliament stated that '**SoHO donation**' means a process by which a person voluntarily and altruistically gives SoHOs from their own body to people in need, or authorises their use after their death. This includes the necessary medical formalities, examination and treatments and monitoring of the SoHO donor, irrespective of whether that donation is successful or not; it also includes when consent is given by an authorised person in accordance with national legislation.

Members stressed the fact that Member States may allow for the **compensation or reimbursement from the SoHO entities to living SoHO donors** for losses or expenses related to their participation in donations, in accordance with the principle of voluntary and unpaid donation, and for example taking the form of compensatory leave, tax reductions or flat rate allowances set at national level. Compensation or reimbursement should **not serve as an incentive for donations** or engender financial competition, including cross-border competition, between institutions and entities that are seeking donors. It should not lead to exploitation of **vulnerable persons in society**. Member States should regulate the advertising of the collection of SoHOs. Any advertising of SoHO donations linked to a financial reward should be prohibited. Recruitment campaigns and advertisements shall not refer to any compensation.

SoHO entities should provide the information in an accurate and clear manner, using terms that are easily understood by the prospective donors or the persons to consent or authorise the donation, and ensure that the consent given is **informed consent**.

Protection of recipients

SoHO entities **should not discriminate** against SoHO recipients on any of the grounds listed in Article 21 of the Charter of Fundamental Rights of the European Union, unless it is necessary to protect the health of the SoHO recipient or of the SoHO donor. Such discriminatory action shall be based on scientific evidence.

Where possible, SoHO entities should use technologies to reduce clinical risks for SoHO recipients and offspring from medically assisted reproduction, and to improve the quality of SoHOs.

Members introduced the possibility of a derogation from the obligation to authorise preparations based on substances of human origin in **emergency situations** or in situations where there is no therapeutic alternative.

Establishment of national emergency plans

In order to ensure EU self-sufficiency in SoHO supply, Member States should draw up national plans to strive for sufficiency of supply of critical SoHOs and contribute to European autonomy in the context of a resilient supply chain.

The national plans should in particular include measures to ensure that the donor base is resilient, actions to make a more efficient use of SoHOs, monitoring of trends in the supply of critical SoHOs as well as measures for cases where national SoHO stocks exceed the national demand and SoHOs are exported to other countries with SoHO shortages.

Members also called on the EU to establish a **digital communication channel** as part of these national plans, enabling information on the availability of substances of human origin on national territory to be exchanged quickly and efficiently.

EU strategy

By two years after the date of entry into force of this regulation, the Commission should publish a **strategy for the promotion of European SoHO supply autonomy**. That strategy should set out a **roadmap with ambitious targets** for each critical SoHO, laid down by the Commission in coordination with national competent authorities, the SCB, the ECDC, the European Parliament, scientists from professional associations and patient associations, as well as with all other relevant stakeholders.

The strategy should set out a roadmap with ambitious targets for each critical SoHO. It should promote actions to:

- support and coordinate communication campaigns at European and national level on the various types of SoHO donations that are available;

- support, through relevant programmes, the training of healthcare workers in hospital and healthcare facilities, to raise awareness concerning SoHO donations;

- coordinate the exchange of best practices linked to optimisation of the use of critical SoHOs.

The strategy should include actions to establish a Union list of critical SoHOs.

SoHO platform

To limit administrative burden on competent authorities and the Commission, the latter should establish an online platform (EU SoHO Platform) to facilitate timely submission of data and reports, to make it possible to share the elements used to determine the regulatory status of a substance, to improve the transparency of national reporting and supervisory activities and ensure better communication, collaboration and coordination in relation to, and exchange of, SoHOs between Member States.

The EU SoHO Platform should also be the main intermediary for reporting SoHO shortages, for cross-border requests for SoHOs and for import and export of SoHOs.