

Procedure file

Basic information	
COD - Ordinary legislative procedure (ex-codecision procedure) Regulation 2022/0216(COD)	Awaiting Parliament's position in 1st reading
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
	 Environment, Public Health and Food Safety	 COLIN-OESTERLÉ Nathalie Shadow rapporteur	20/10/2022
Council of the European Union	Commission DG	 GONZÁLEZ CASARES Nicolás	
		 GLÜCK Andreas	
		 METZ Tilly	
		 KOPCIŃSKA Joanna	
		 KONEČNÁ Kateřina	
European Commission	Health and Food Safety	Commissioner	KYRIAKIDES Stella
European Economic and Social Committee			
European Committee of the Regions			

Key events			
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	Results of vote in Parliament		
12/09/2023	Decision by Parliament, 1st reading	T9-0299/2023	Summary
12/09/2023	Matter referred back to the committee responsible		
30/01/2024	Act adopted by Council after Parliament's 1st reading		
14/02/2024	Approval in committee of the text agreed at 1st reading interinstitutional negotiations	PE758.999 GEDA/A/(2024)000898	

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 EU TFEU 168-p4
Other legal basis	Rules of Procedure EP 159
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Awaiting Parliament's position in 1st reading
Committee dossier	ENVI/9/09602

Documentation gateway

Legislative proposal	COM(2022)0338	14/07/2022	EC	Summary
Document attached to the procedure	SEC(2022)0304	14/07/2022	EC	
Document attached to the procedure	SWD(2022)0189	14/07/2022	EC	
Document attached to the procedure	SWD(2022)0190	14/07/2022	EC	
Document attached to the procedure	SWD(2022)0191	14/07/2022	EC	
Document attached to the procedure	N9-0084/2022 OJ C 450 28.11.2022, p. 0007	07/09/2022	EDPS	
Economic and Social Committee: opinion, report	CES4815/2022	26/10/2022	ESC	
Committee draft report	PE738.661	18/01/2023	EP	
Amendments tabled in committee	PE740.835	14/03/2023	EP	
Amendments tabled in committee	PE745.276	14/03/2023	EP	
Amendments tabled in committee	PE745.277	14/03/2023	EP	
Committee report tabled for plenary, 1st reading/single reading	A9-0250/2023	26/07/2023	EP	Summary

Text adopted by Parliament, partial vote at 1st reading/single reading	T9-0299/2023	12/09/2023	EP	Summary
Coreper letter confirming interinstitutional agreement	GEDA/A/(2024)000898	30/01/2024	CSL	
Text agreed during interinstitutional negotiations	PE758.999	30/01/2024	EP	

Additional information

Research document	Briefing	12/02/2024
-------------------	--------------------------	------------

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

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

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 EMAs 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

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.

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

WÖLKEN Tiemo	Member	25/01/2023	Ständige Vertretung der Bundesrepublik Deutschland bei der EU
--------------	--------	------------	---