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.