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.