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.