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.