European Economic and Social Committee

OPINION

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Standards of quality and safety for substances of human origin

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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
[COM(2022)0338 – 2022/0216 (COD)]

SOC/740

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Referral	European Parliament, 12/09/2022 Council of the European Union, 22/07/2022
Legal basis	Articles 168(4) and 304 of the Treaty on the Functioning of the European Union
Section responsible	Section for Employment, Social Affairs and Citizenship
Adopted at plenary	27/10/2022
Plenary session No	573
Outcome of vote (for/against/abstentions)	151/0/0

1. Conclusions and recommendations

1.1 The European Economic and Social Committee supports the European Commission's proposal for a regulation of the European Parliament and of the Council on standards of quality and safety of substances of human origin intended for human use and repealing Directives 2002/98/EC and 2004/23/EC, given its vital importance for the protection of public health, the well-being of patients in European Union countries and the innovation potential of the EU.

1.2 The definition of common basic quality and safety standards for substances of human origin (SoHO) in line with the current level of medical science is useful, and the EESC agrees that new coherent rules are needed in this area.

1.3 The EESC considers it appropriate to define the scope of the regulation in such a way that it will take into account not only SoHOs not yet regulated at European level (e.g. breast milk) but also any SoHO that may be used in the future.

1.4 The Committee supports legislative changes that will reduce the costs for the EU institutions, Member States and citizens, in particular by removing outdated tests and systematic screening tests from legislation. The effectiveness of the regulation's provisions should be continuously monitored, taking into account the need to preserve the safety and quality of SoHOs and to respect the standards deriving from the Charter of Fundamental Rights of the European Union.

1.5 The EESC welcomes the introduction of uniform basic standards for keeping registers of SoHO entities. These will be reinforced by the creation of an EU SoHO Platform, which will help improve the EU's public health security through the continuous and rapid exchange of information.

1.6 The Committee supports the adoption of solutions which strengthen the rights of SoHO donors and address shortcomings in the existing rules. In this regard, the EESC stresses that the reaffirmation in the draft of the principle of free SoHO donation is essential for the elimination of abuse and the safety of SoHO sourcing. The Committee would point out that strict compliance with this principle is a requirement under Article 3(2)(c) of the Charter of Fundamental Rights of the EU, according to which the fields of medicine and biology must respect "the prohibition on making the human body and its parts as such a source of financial gain".

1.7 In the EESC's view, particular attention should be paid to the need for reliable and systematic monitoring of SoHO entities in relation to safety, quality and the way in which SoHOs are sourced. Of particular importance is the continuous monitoring and control of the correct operation of entities that import SoHOs. SoHOs imported from outside the European Union should meet the same quality and safety standards as those sourced within the EU.

2. Introduction

2.1 This opinion concerns the European Commission's 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 SoHO Regulation").

2.2 As indicated in the explanatory memorandum, the SoHO Regulation will provide for the following safeguards and benefits: (1) ensuring safety and quality for patients treated with SoHO therapies and their full protection from avoidable risks linked to SoHOs; (2) ensuring safety and quality for SoHO donors and for children born from donated eggs, sperm or embryos; (3) strengthening and allowing for harmonisation of surveillance practices among Member States; (4) facilitating the development of safe and effective innovative SoHO therapies; and (5) improving the resilience of the sector and mitigating the risk of shortages. The proposed solutions respond to the incomplete protection of patients, donors of blood, tissues and cells, and offspring born from donated cells or embryos from avoidable risks associated with outdated technical rules, divergent approaches to oversight between Member States that hamper the cross-border exchange of blood, tissues and cells, exposure of patients to disruptions in the supply of blood, tissues and cells, and failure to use the full potential of blood, tissues and cells that are processed or used in new ways.

3. General comments

3.1 The EESC is aware of the demands of new developments in medical science, in particular biotechnology, which offer new opportunities for the use of SoHOs in many forms of patient therapy across the EU. At the same time, the Committee notes that, due to the development of new treatments, some of the existing standards are no longer valid.

3.2 The EESC therefore welcomes the European Commission's proposal for a SoHO Regulation. This is because the proposed Regulation covers SoHOs in a blanket form as "blood, tissues and cells". This is an appropriate and far-sighted approach, as substances of which we currently have no knowledge and which may be applied therapeutically in the future will be covered by the existing safety and quality provisions in law.

3.3 The EESC welcomes the alignment of the legal framework with the principle of financial neutrality recommended by the Council of Europe's Committee on Bioethics. The proposal also harmonises the current legal framework and, in particular, strengthens the provisions on the protection and monitoring of donors and the reporting of genetic conditions in children born from medically assisted reproduction.

3.4 The EESC considers appropriate and supports the proposal for a single regulatory approach to be applied in all Member States. This will directly help ensure that SoHO quality and safety standards are respected in all EU countries.

3.5 The EESC welcomes the expected effects of the entry into force of the regulation, including the definition of common general safety and quality standards; the inclusion within the scope of the regulation of all SoHOs that are currently not regulated; facilitation of the exchange of SoHOs between Member States; the introduction of obligations to ensure crisis-preparedness measures at entity and national level and to monitor supply; and the creation of a regulatory environment

that is innovation-friendly, improves the safety, accessibility and effectiveness of SoHOs and is future-proof.

3.6 The EESC particularly welcomes the fact that the technical guidelines are based on the findings of European expert bodies. This is the most effective way to ensure that legislation remains up-to-date, in line with the evidence-based medical approach.

3.7 The EESC welcomes the fact that the principle of voluntary and unpaid donations, as clearly expressed in the current standards on blood donations, has been extended to all other SoHOs currently in use (e.g. breast milk) and to SoHOs which cannot currently be defined but might be used in the future. It should be noted that the regulation allows for compensation to ensure that donors are not financially disadvantaged by their donation, while stating that this compensation should never constitute an incentive that might induce potential donors to provide false information or donate more frequently than allowed. In this context, it should be recalled that the principle of free SoHO donation is essential for the elimination of abuse and the safety of SoHO sourcing. The Committee would point out that strict compliance with this principle is a requirement under Article 3(2)(c) of the Charter of Fundamental Rights of the EU, according to which the fields of medicine and biology must respect "the prohibition on making the human body and its parts as such a source of financial gain". Member States should take this into account when defining the rules on granting such benefits in their national legislation.

3.8 The EESC supports the introduction of uniform basic standards for the keeping of registers of SoHO entities by the Member States. These will be reinforced by the creation of an EU SoHO Platform, which will help improve the EU's public health security through the continuous and rapid exchange of information. The establishment of a SoHO Coordination Board is also to be welcomed, as this can be an effective instrument to effectively implement the quality and safety standards arising from the regulation.

3.9 The proposal indicates that the responsibility for ethical and organisational decisions lies with the Member States. This position should be considered appropriate in light of the Treaty-based scope of the competences of the EU and of the Member States, and logical in the context of the scope of the proposed regulation, which is of an organisational and technical nature. The aim of the SoHO Regulation is to ensure the quality, safety and availability of SoHOs and control of their manufacturing and transport processes. However, the EESC would like to point out that, as with safety and quality controls, the development of biotechnology needs to be assessed in light of the standards laid down in the EU Charter of Fundamental Rights.

3.10 The proposed regulation defines the competences of the staff of the competent authorities and the persons carrying out supervisory activities. The regulation refers to an appropriate professional background and regular training, including at EU level. However, the regulation does not set out details relating to staff training and experience (with the exception of Article 51, which defines the qualifications of physicians appointed by SoHO establishments). However, the specific nature of work with SoHOs requires the collaboration of many specialists within a team; in some cases the relevant competences will be held by a biotechnologist, in others by a doctor of the appropriate specialisation, and sometimes the support of an ethicist or

lawyer may be required. The EESC therefore proposes that the composition of the competent authorities be required to include an interdisciplinary team of specialists.

4. Level and scope of regulation

4.1 The EESC is pleased to note that the regulation properly respects the principle of subsidiarity. Indeed, the objectives set by the regulation would be much more difficult for Member States to achieve themselves or could not be achieved in a comparably efficient way. The regulation therefore brings clear added value. The benefits include, in particular, basing the implementation of standards and guidelines on the work of expert bodies such as the ECDC or EDQM and the sharing of data through the EU SoHO Platform.

4.2 The proposed definition of "medically assisted reproduction" is "the facilitation of conception by intra-uterine insemination of sperm, in vitro fertilisation or any other laboratory or medical intervention that promotes conception". In the EESC's view, this could be clarified. It seems logical that the scope of the regulation should cover procedures in which SoHOs are used or during which SoHOs are created. However, the use of the phrase "any other [...] medical intervention that promotes conception" in the above definition leads to the inclusion in its scope of other methods not related to the use of SoHOs and not linked to the standards of the regulation.

5. Safety of preparations and control of SoHO entities

5.1 The EESC welcomes the clarification of SoHO quality and safety standards and the introduction of effective control mechanisms in relation to SoHO entities. The proposed solutions will improve patients' access to quality treatment and will have a positive impact on the state of public health in the European Union.

5.2 In this connection, the Committee points out that quality and safety standards should apply to all SoHOs used in the European Union, including SoHOs imported from outside the EU. The EESC draws attention to the need for effective and systematic application of the control mechanisms provided for in the regulation in relation to entities importing SoHOs, particularly as regards the quality and safety of preparations. This is particularly important in view of facilitating imports of SoHOs from outside the EU. The EESC calls on the EU authorities to take all necessary steps to prevent the development of a paid cell and tissue donation industry, such as is developing in some parts of the world.

5.3 According to the provisions of the draft regulation, where a Member State chooses to allow a new practice, the safety and quality of this practice is governed by the EU rules on quality and safety contained in the SoHO Regulation. The EESC points out that new practices implemented outside the EU should also be subject to ongoing assessment by the competent expert bodies at European Union level.

5.4 Article 7 of the proposed regulation requires the competent authorities to ensure the impartiality of their personnel in order to avoid situations of conflict of interest. In order to achieve this

objective effectively, the EESC proposes that this requirement be extended to cover the period immediately prior to the personnel taking up the position.

5.5 Article 29(7) of the proposed regulation lays down the powers of inspectors to verify that SoHO entities meet the standards on donor and recipient protection, information provision and the voluntary and unpaid nature of donation. In the EESC's view the powers of inspectors should be strengthened, and should entail a comprehensive inspection procedure.

6. SoHO donors' rights

6.1 The EESC commends the inclusion in the draft SoHO Regulation of solutions that systematically strengthen the rights of SoHO donors and fill gaps in the existing legislation.

6.2 In Article 53, which lays down standards for the protection of donors, point 1(b) states that information provided to donors or persons acting on their behalf should be communicated in a manner adequate in view of their ability to understand it. In order to avoid any doubts as to interpretation, the EESC believes that the information provided must be complete and clearly communicated in order to enable the condition of informed consent to be met, as generally accepted in medicine.

6.3 Article 55(3)(c) lays down an obligation for operators to provide information to donors on the right to withdraw consent and any restrictions on the right to withdraw consent. In the EESC's view, the right to withdraw consent can only be limited by factual circumstances, e.g. in the case of an already initiated procedure. In order to prevent violations of one of the fundamental rights of the patient, namely the right to autonomy, it seems reasonable to set out an exhaustive list of situations in which the right to withdraw consent may be restricted.

7. Data protection

7.1 The EESC welcomes the fact that the regulation reaffirms the need to maintain strict confidentiality requirements arising from the GDPR in relation to the processing of personal data of SoHO donors and recipients, including limiting the purpose of processing personal data and data minimisation.

7.2 In the EESC's view, it is reasonable to distinguish between the requirement on free and informed consent for donation contained in the draft regulation and the separate requirement on consent for the processing of personal data concerning the health of the donor within the meaning of the GDPR. The two requirements are not identical.

Brussels, 27 October 2022

Christa Schweng
The president of the European Economic and Social Committee