KOMMISSARIAT DER DEUTSCHEN BISCHÖFE
Katholisches Büro in Berlin

JOINT STATEMENT
of the Commission of the Bishops' Conferences of the European Union (COMECE) and the Commissariat of the German Bishops - Catholic Office in Berlin

- **on the proposal for a regulation of the European Parliament and of the Council on quality and safety standards for substances of human origin for human use and repealing Directives 2002/98/EC and 2004/23/EC – [COM (2022)0338 final, 14.7.2022 - 2022/0216(COD)]**
- **on the amendments of the ENVI Committee of the European Parliament of 27.7.2023 - C9 0226/2022 [Report A9 - 0250/2023]**

We are concerned about the draft text and proposed compromise amendments of the "Regulation on quality and safety standards for substances of human origin intended for human use" [COM(2022)0338 - C9-0226/2022 - 2022/0216(COD)] - herein: SoHO regulation]. Unequivocally, this regulation will set the course for the future discussion regarding prenatal human life in European transplantation and pharmaceutical law and will thus influence the ongoing discussion on strengthening the EU Health Union and will raise numerous ethical and constitutional conflict issues in the EU Member States.

As Catholic Church we are convinced, with many others and for many reasons, that human life from the beginning, including unborn life, "*possesses its own dignity, right and independent right of protection …*"[1]. Therefore, we want to draw attention to the consequences of the SoHO regulation, considering the compromise amendments adopted by the ENVI Committee of the European Parliament

1. Human life is not just a "substance of human origin".

In view of the objective of the EU regulation, which will be directly applicable in all Member States, to "realise the full potential of novel forms of processing and use of blood, tissues and cells for patients" and to ensure "patient care", the newly introduced term "Substance of Human Origin" (herein: SoHO) is defined very broadly.

The definition of "SoHO" according to Article 3 No. 5 of the draft regulation not only refers to non-fertilised germ cells (sperm, oocytes and degenerated oocytes) in the field of reproductive medicine but also covers embryos and fetuses. This is relevant, for example, to the removal and use of deceased or killed embryos and fetuses as well as the alternative use of in-vitro-produced supernumerary embryos that are deliberately not implanted in the

[1] The German Bishops, Menschenwürde und Menschenrechte von Anfang an, No. 56, September 1996, p. 5.; COMECE, Position Paper on the "Report at the Situation of Sexual and Reproductive Health and Rights in the EU", June 2021, p.2

Square de Meeus 19
1050 Brussels, Belgium
Tel. +32 2 235 05 10
Mail: comece@comece.eu
www.comece.eu
EU transparency number: 47350036909-69

Hannoversche Straße 5
10115 Berlin, Germany
Tel.: +49 30 288 780
Mail: post@kath-buero.de
www.kath-buero.de
EU transparency number. 524375510752-92

woman's uterus. Due to the broad wording, it is to be feared that even naturally conceived children who are not yet independently viable in the prenatal stages of development may be subsumed under the term SoHO. It is also foreseeable that human life created by medical or laboratory assistance, not intended for the purpose of gestation, will be covered by the new EU regulation in the future.

In all these cases, the SoHO regulation degrades unborn human life to a mere "substance of human origin" or - depending on its origin - to a "SoHO preparation" equating it (in the regulation) on the same level as skin cells or blood plasma without any sort of differentiation. Human subjects are thus subdued to be mere objects in disregard of their inherent dignity.

As an important building block for other EU legal acts, the SoHO regulation will innately influence the further development of pharmaceutical and reproductive law with such definitions. It is hence to be feared that the equation of human life with skin cells, saliva or blood plasma, provided for in the SoHO regulation, will also be assimilated in these areas of law in the future.

Finally, it cannot be ruled out that - in conformity with Union law - the interpretation of such terms (such as "tissue" or "tissue preparation") in national law, particularly in Member States' legal systems which attach great importance to the protection of unborn human life, will be overridden by the degradation of human life enshrined in Union law.[2]

Therefore,

- it must be clarified in the wording of Article 3 No. 5 with legal certainty that neither embryos, nor foetuses or foetal tissue, irrespective of whether they have been created by natural conception or by artificial insemination for reproductive or other purposes, are covered by the term "SoHO";
- the addition of "embryos from fertilisation" and the introduction of a new definition of "SoHo for reproductive purposes" instead of "reproductive cells" within the meaning of Article 3 No. 61 contained in compromise amendment 80 must be deleted again.

2. Human life is not divisible

The Commission's draft of the SoHO regulation (provisions of Chapter VII of the SoHO regulation) makes special provisions only for the protection of the health of fetuses and born children who are the result of medically assisted reproduction. These relate, among other things, to protection against the transmission of pathogens, genetic diseases or against risks of non-communicable diseases. In the version of the ENVI compromise, the scope of these precautions is even further reduced and limited to born children. Human life, however, is not divisible. An embryo is designed to develop into a human being continuously and without qualitative jumps. Already with the fusion of the nucleus, an individual human being with its own unique DNA comes into being.

[2] In Germany, for example, according to the intention of the national legislator in the Embryo Protection Act, the transfer and donation of embryos is neither to be qualified as tissue according to § 1a No. 4 TPG nor as tissue preparation according to § 4 Para. 30 S.2 AMG and is thus excluded from the scope of application of both the Transplantation Act and the Medicinal Products Act (cf. BT-Drs. 16/3146, p.23)

The classification and division between SoHO (as human raw material) and offspring as considered in the draft SoHO regulation also reduces viable oocytes from the fertilisation stage – including those in process of development of a human being but (for whatever reason) are not born as a child – as mere raw materials without human quality. The consequence is that in proportionality assessments these oocytes will no longer have a particular consideration in the balancing with other conflicting interests (such as health of donors and recipients, freedom of research and trade).

Therefore,

1. compromise amendment 60, which introduces a new distinction in connection with the general concept of offspring according to Art.3 No.11 of the SoHO Regulation with Art.3 No.11a, namely that of "unborn offspring from medically assisted reproduction" in distinction to born offspring, which according to amendment 59 should only include children, must be deleted again.

- the definition of "offspring from medically assisted procreation" in Art.3 No.11 must be expanded to include the term embryo.

(11) 'offspring from medically assisted reproduction' means fetuses and children that are born following medically assisted reproduction;	(11) 'offspring from medically assisted reproduction' means ***embryos and*** fetuses ***conceived by medically assisted reproduction as well as*** children that are born following medically assisted reproduction;

3. Human life does not receive its value through purpose

Furthermore, it cannot matter for the protection of human life whether it has been created inside a laboratory or through medical intervention. Human life has value on its own. This becomes particularly relevant in questions of "embryo-consuming" research and pharmaceutical production.

Therefore,

- the extension inserted into Article 3 No. 10 in compromise amendment 59 must be deleted.
- the following addition needs to be inserted in Article 3 No. 10:

(10) 'medically assisted reproduction' means the facilitation of conception by intra-uterine insemination of sperm, in vitro fertilisation or any other laboratory or medical intervention that promotes conception;	10) 'medically assisted reproduction' means the facilitation of conception by intra-uterine insemination of sperm, in vitro fertilisation or any other laboratory or medical intervention that promotes conception ***or creates an embryo***;

4. Human life must not be selected

Finally, the design of the protection of SoHO recipients and offspring from medically assisted reproduction proposed in Chapter VII of the SoHO regulation raises further questions.[3] SoHO facilities will be obliged under Article 58 of the SoHO regulation to exclude the transmission of genetic diseases, among others, to recipients and offspring. How this will be possible without testing embryos or fetuses for such diseases for the purpose of selection is unclear. However, such a selection violates the human dignity. Furthermore, the question arises as to the extent of the required preliminary genetic testing and the compatibility of a possible genetic testing obligation with the right of self-determination of donor and recipient.

5. Deviating ethical decisions by EU member states must remain possible

Whether and to what extent an EU Member State can completely ban at least certain activities related to SoHO is so far only addressed in recital 16 of the draft regulation. Here it is stated that the regulation should not interfere with ethical decisions made by Member States concerning the use or restriction of the use of certain types of SoHO. This wording must be included in the operative text of the regulation, preferably in Article 1.

Furthermore, it must remain possible for each Member State to refuse not only the authorisation itself, but also the recognition of the authorisation of a SoHO preparation granted by another EU Member State when this preparation or further use has been prohibited within its territory. A clarification to this effect could be made in Article 20(3).

Finally, each Member State must be able to adopt stricter and more differentiated rules in the areas covered by the SoHO regulation.

This concerns, for example, special information and notification obligations which relate to the protection of the embryo - irrespective of its viability or the way in which it is created - such as the reference to the possibility of embryo adoption. Such stricter measures should still be possible under Article 4 of the draft SoHO regulation as proposed by the European Commission. If the ENVI compromise amendment 90 to Article 4(1) were to be adopted, such national requirements could be ruled out in the future, because stricter measures would only be possible when based on "scientific evidence".

Therefore,

- ENVI compromise amendment 90 on Article 4(1) should be deleted.
- The principle expressed in recital 2, sentence 2 and recital 16 should be made clearer in the operative text of the regulation - namely in Article 1, Article 4(1) and Article 20(3) - in order to anchor the national primacy in the area of ethical value decisions in a legally secure manner. The upcoming trialogue offers the opportunity to find suitable formulations together with the EU member states.

[3] For example, in Germany collisions arise with regard to the Gene Diagnostics Act, the Embryo Protection Act and the PGD regulation