Position paper on the proposed regulation on quality and safety standards for substance of human origin (SoHO) intended for human use

The European Parliament adopted in its plenary session of 12 September 2023 the **proposed regulation on quality and safety standards for substance of human origin (SoHO) intended for human use** [COM(2022)0338 - C9-0226/2022 - 2022/0216(COD)] - herein: SoHO regulation

This regulation aims to ensure a high level of health for EU citizens through quality and safety standards of substances of human origin. Aware of the great importance of substances of human origin for modern medical care of EU citizens the European Union should ensure adequate supply through measures of monitoring and support. We expressly welcome the general necessity of this regulation and its underlying alignment of the principle of voluntary and unpaid donation of substances of human origin, which is based on the altruism of the donor and the solidarity between donor and recipient (recital 18).

But we are **concerned** about some essential regulatory contents of the proposed regulation:

A. 1) The **definition of „SoHo "–** given in the draft regulation - is very broad. In Art.3 Nr. 5 the definition 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 can be relevant, for example, for the removal and use of deceased or killed embryos and fetuses as well as the alternative use of in-vitro-produced supernumerary embryos.

2) Due to **Art. 3 Nr. 12 ,15** of the SoHO regulation the human embryo can also be seen as a "SoHo preparation". Art. 3 Nr.15 defines the term "processing" by including fertilization.

This is ethically unacceptable. The human embryo is not just a substance of human origin, it is endowed with independent human dignity. We suggest to clarify in the regulation 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" or “SoHO preparation” and that they are therefore excluded from the subject matter of the regulation.

B. 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. 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. This will be only possible by testing embryos or fetuses for such diseases. We see the danger of a selection of human life which would violate the human dignity. Furthermore, the Member States have developed multiple and complex legislation under which appropriate testing of offspring is possible. We see the danger of a collision between EU law and Member States law. Also, questionable is how the compatibility of a possible genetic testing obligation with the right of self-determination of donor and recipient will be balanced.

C. **Art. 1** of the proposed regulation mentions that the EU Member States can establish rules relating to aspects of SoHOs other than their quality and safety and the safety of SoHO donors. But only recital 16 of the SoHO regulation expresses that the regulation should not interfere with ethical decisions made by Member States.

We suggest including in the operative text of the regulation, preferably in Article 1, the possibility of the Member States to establish different legal rules based on ethical decisions so that the EU regulation does not effect in these cases national law. This will be necessary for anchoring the national primacy around ethical value decisions in a legally secure manner.