

## STATEMENT

### on the EC Proposal for a Regulation on Standards of Quality and Safety for Substances of Human Origin intended for Human Application

Munich, 8 September 2022

In July 2022, the European Commission adopted the proposal for a regulation on standards of quality and safety for substances of human origin (SoHo) intended for human application. Previously unregulated at EU level, this new proposal has extended its scope of SoHo to “human breast milk”. We, the European Foundation for the Care of Newborn Infants, welcome and support the aims of ensuring safety and protection for recipients and donors by clarifying regulatory aspects of donor human milk.

In Europe and worldwide, preterm birth, low birthweight, asphyxia, congenital abnormalities, infections and birth trauma are the main causes of neonatal death. Mother’s own milk is the preferred option for infant nutrition of these vulnerable newborns to achieve optimal growth, development, and health. When mother’s own milk is not available, donor human milk is the next best alternative.

In light of the draft regulation and in order to guarantee that the highest level of safety for these infants and their nutritional needs are met, **we request European policy makers to ensure that this proposal:**

1. Recognises human milk as the best option for preterm, sick and low birthweight infants and has, at its core, the theme of ensuring a safe, secure supply for all mothers in need of donor human milk for their infants.
2. Notes that human milk is produced and expressed by the lactating mother with the sole purpose of feeding her own baby. Therefore, mother’s own milk must be excluded from the definition of SoHo as set out in this proposal and should emphasize donor human milk.
3. Ensures equitable access to safe donor human milk for preterm, sick and low birthweight infants as a key theme and accounts for the practical specifics of human milk and its donation.
4. Endorses recognition, support and regulation of human milk banks in Europe.
5. Ensures that the regulation does not endanger the functioning of already well-established donor human milk services across the European Union, particularly with regards to potential financial costs and perceived legal and administrative obstacles.
6. Includes the need for EU-wide research and data collection of human milk donation and use.

Making sure that preterm, sick and low birthweight infant conditions and consequent needs are recognized and best care is provided will save lives and improve quality of life. Human milk-based nutrition must be considered a European public health issue and a human right for all these infants.

**Signatories on behalf of the European Foundation for the Care of Newborn Infants (EFCNI)**



*Silke Mader, Chairwoman of the Directors Board and Founder*



*Prof. Dr. Luc Zimmermann, Senior Medical Director*



*Dr. Johanna Kostenzer, Head of Scientific Affairs*

**Further information**

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