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Bundesverband
Das frühgeborene Kind

Donor Human Milk as Substance of Human Origin (SoHO)

Joint Statement

on the EC Proposal for a Regulation on Standards of Quality
and Safety for SoHO intended for Human Application
25th August 2022

Human milk is the preferred enteral feeding of choice for extremely premature infants as it reduces mortality and morbidity compared to formula. Donor human milk (DHM) represents the next best choice if mother's own milk is not available. However, despite universal recommendations by the WHO and medical societies worldwide, DHM is used only by a small fraction of hospitals caring for extremely premature infants. In several countries including Germany, financial costs and perceived legal obstacles have been identified as barriers for the widespread implementation of DHM services, although some human milk banks are operational for more than hundred years.

We therefore welcome and support the European Commission’s aims of ensuring protection and safety for donors and recipients by clarifying regulatory aspects of DHM. The classification of human milk as substance of human origin (SoHO) and its inclusion in this proposed Regulation may provide a helpful regulatory framework for regulatory authorities, medical professionals, scientists, parents, and other relevant stakeholders.

However, human milk contains several properties that sets it apart from all other SoHOs that are included within the scope of this legislation. Given the unique properties of human milk and therefore its unique position within this proposed Regulation, we feel that following clarifications are needed:

- I. By nature, human milk is produced and expressed with the sole intention of nurturing an offspring. Therefore, a lactating mother providing milk for her own biological or legal child (maternal milk) shall not be viewed as a milk donor. Mother’s own milk must be explicitly excluded from the definition of SoHOs for the purposes of this Regulation and, thus, from its scope.
- II. Subsequently, this Regulation must clarify that its scope covers only “donated human milk”, i.e. milk procured from a donor with the explicit intention to dispense it to another than the biological or legal child of this donor.
- III. In Germany, Donor Human Milk is legally classified as a food product according to Regulation (EC) No 178/2002. Its use is guided by interprofessional recommendations of the European Milk Bank Association ([doi: 10.3389/fped.2019.00053](https://doi.org/10.3389/fped.2019.00053)) and a consensus guideline ([AWMF 024-026](#)) currently developed by various medical professional societies in Germany under the auspices of the Society for Neonatology and Pediatric Intensive Care. Well-established and regulated national donor milk banks have been operating in Germany for more than 100 years. EU member states with DHM services in place should be permitted to apply national guidelines and established regulatory frameworks while adopting this proposed Regulation.

- IV. The administrative burden associated with the DHM classification as SoHO should be proportionate to the low level of risk associated with its application. Disproportionate regulatory requirements for existing and future DHM services may limit the availability of DHM for extremely premature infants extensively. This contradicts the specific objective of this proposed Regulation aiming to optimize access to SoHO therapies and avoid shortages of SoHOs. Certification of hospital-based human milk banks must proceed in a timely fashion and without additional charges to hospitals or milk bank users.
- V. While human milk is a substance of human origin, competent authorities overseeing human milk banks should be those that regulate either hospitals or food production/distribution, but not those involved in regulating interpersonal transfer of blood, cells, or tissue.

It is our urgent and unanimously joint recommendation to consider these above-mentioned aspects when adopting a final text of this Regulation.

These aspects may be pivotal for ensuring ready and equitable access to donor human milk for fragile infants in Europe.

Signatories:

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