

# Regulation of Donor Human Milk at European level: a new bridge for successful breastfeeding of sick preterm infants

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*“... equitable access to safe Donor Human Milk for preterm, sick, and low-birthweight infants, as a key theme of the Legislation ...”*  
Kostenzer J; EFCNI Working Group on Human Milk Regulation.  
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It is well known that Human Milk Banks thrive in countries where they are protected, promoted, and supported as a vital component of national breastfeeding policies and newborn care. The government has an especially important role in successfully integrating human milk banking with newborn care. When governments integrate Human Milk Banks with national infrastructures, support services, networks, and guidelines, they are fulfilling an ethical responsibility to improve child health and reduce mortality [1].

In the European Union (EU), we currently have 280 active Human Milk Banks. A recent study by Kontopodi et al. [2] has observed that national medical guidelines for the use of Donor Human Milk have been issued in 11 countries. This survey showed a huge variation in practices, not only between but also within countries. Moreover, a recent survey showed that the use of Donor Human Milk is rarely and heterogeneously regulated at a legislative level in Europe [3]. In Italy, since 2002, we have specific guidelines for the establishment and operation of a Donor Human Milk Bank, lastly updated in 2021, and since 2014 a specific Legislation has been issued [4]. However, at present, in the EU there is a specific Legislation on Blood, Tissue and Cells (BTC), but there is a lack of regulation on Donor Human Milk and Human Milk Banks.

This legal uncertainty regarding the status and handling of Donor Human Milk works as a disincentive to adopt evidence-based practices about human milk-based nutrition. This uncertainty leads to scant access, concerns about safety, questions about funding and reimbursements, an increased administrative burden, and underutilization of Donor Human Milk in many Neonatal Units.

In a recent comment published on *The Lancet – Child & Adolescent Health*, in March 2021 [5], an international working group, supported by the European Foundation for the Care of Newborn Infants (EFCNI) and that also included members of the European Milk Bank Association (EMBA), published the following call to action:

“We call on European Policy Makers to ensure that any revision of the Human Tissue and Cells Directive:

- Recognizes that human milk is the best option for preterm, sick, and low-birthweight infants and promotes the development of Human Milk Banks ensuring a safe, secure supply for all mothers in need of milk for their infants. The mother’s own milk is the first choice in infant

feeding. When the mother’s own milk is not available, Donor Milk from a Human Milk Bank is the preferred option.

- Includes a delegated act to be developed in close cooperation with key stakeholders in infant care and human milk safety on Donor Human Milk.
- Ensures equitable access to safe Donor Human Milk for preterm, sick, and low-birthweight infants, as a key theme of the Legislation, and accounts for the practical specifics of human milk donation.
- Endorses the recognition, support, and regulation of Human Milk Banks in Europe.
- Includes the need for a EU-wide research and data collection for human milk donation and use”.

The 2020/2021 Impact Assessment [6] for the Revision of the European BTC Legislation made by the European Commission stated:

“... while new therapies have emerged since the BTC Legislation was adopted, it is not always clear whether, and if so which, of the BTC Directives apply, leaving these substances unregulated or regulated in divergent ways (e.g. breast milk and faecal microbiota transplants)”;

“... the scope of the BTC Legislation will be clarified to include novel substances of human origin currently used but not regulated at the EU level”.

From the January-April 2021 online stakeholder consultation promoted by European Commission [7] it emerged that:

“There are substances of human origin that should be in the scope of the Legislation but currently are not (breast milk, serum eye drops, etc.).”

In addition to the online consultations, 14 stakeholder workshops were organised to gather focused/specific input through direct interaction. A summary of this workshops is now available [8], and in Section 9 it states:

“There are several substances of human origin that are not included in the scope of the BTC Legislation because of the wording of the definitions included there, even though the EU Treaty provides a mandate to regulate their safety and quality. Examples included human breast milk and intestinal microbiota”;

“The key messages emerging from the discussions were the following. There was strong support among participants for expanding the scope of the Legislation to include new substances and therapies. FMT [faecal microbiota transplantation], Donor Human Milk and serum eye drops were all

seen as substances to be included in the revised Legislation, along with several other substances such as platelet rich plasma prepared and used in hospitals”.

We are now in the first Phase of the Legislative Process for the Revision of the BTC Legislation that is expected to include Donor Human Milk and human milk banking regulation. The Commission will draft a legislative proposal based on the results of the Impact Assessment. Once adopted by the Commission, the proposal will proceed through the co-decision process in the European Parliament (EP) and the European Council (Phase 2). If the EP and Council agree, the proposal will be adopted. Once adopted, in Phase 3, a Commission proposal for a Delegate Act will follow, in consultation with expert groups that will be approved if there is no negative opinion from EP and Council.

EMBA and the other stakeholders are following this process very carefully: we are confident we will have this regulation by the end of 2022 to improve the availability, quality and safety of Donor Human Milk for preterm and sick infants.

### Declaration of interest

The Author declares that there is no conflict of interest.

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