

CLOSING THE GAP – Increasing the Availability of Donor Human Milk

Position Statement of the Human Milk Bank Initiative (FMBI)
on the Revision of the European Union Legislation on Blood, Tissues and Cells



Human Milk Bank Initiative

The German Human Milk Bank Initiative (Frauenmilchbank-Initiative, FMBI) is a charitable non-governmental organization that promotes non-profit donor milk banks through supporting the establishment of new milk banks, organising scientific meetings, public awareness-raising and advocacy. We work towards a world where all newborns have equitable access to human milk thanks to dedicated lactation support and a network of human milk banks.

The organization represents the institutional human milk banks in Germany. Its members include physicians and nurses caring for premature babies in neonatal departments, lactation experts and parents of premature infants.

These policy recommendations were prepared and authorized by the FMBI Executive Board:

Dr Daniel Klotz, Neonatologist, Member of the Global Alliance of Human Milk Banks and Associations, University Hospital Freiburg, Germany

Associate Professor Anja Lange, Neonatologist and International Board Certified Lactation Consultant, University Hospital Greifswald, Germany

Judith Karger-Seider, Neonatal Intensive Care Nurse and International Board Certified Lactation Consultant, University Hospital Hamburg, Germany

Anne Sunder-Plassmann, FMBI Managing Director, Human rights researcher and advocate, Hamburg, Germany

Dr Corinna Gebauer, Neonatologist, International Board Certified Lactation Consultant, Member of the board of Directors of the European Milk Bank Association, University Hospital Leipzig, Germany

Professor Christoph Fusch, Neonatologist, Executive Board Member of the German Society of Neonatology and Paediatric Intensive Care Medicine, Paracelsus Medical University Hospital, Nürnberg, Germany

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Position Statement Summary

The European Commission has identified donor human milk as a substance that is unregulated or regulated in divergent ways within the EU. The Human Milk Bank Initiative welcomes and supports the European Commission's intention to regulate the use of donor human milk in order to ensure that patients and donors are not exposed to avoidable risks but emphasises that availability of donor human milk must not be reduced as a result.

Currently,

- Donor human milk is severely underutilized within European health care systems; the majority of European premature infants in need have no access to donor human milk and so are potentially deprived of its benefits
- Uncertainties about regulations have been identified as a barrier for the widespread implementation of donor human milk programs within health care facilities
- Therefore, creating a common legal framework for the use of donor human milk may contribute to closing the gap between recommended and actual use of safe human milk for premature babies without mother's own milk

The Human Milk Bank Initiative believes that future legislative frameworks should

- Acknowledge that multiple donor human milk characteristics are not reflected by the classifications within the current EU legislation pertaining to blood, tissues and cells
- Consider classifying donor human milk as a separate entity rather than attempting to subsume it in any of the existing classifications
- Be devised in such a way that they do not inevitably result in unsustainable financial or organizational requirements on institutions operating human milk banks, which could lead to reduced availability of donor human milk for fragile infants
- Ensure equitable access to donor human milk prioritized for infants in need independent of their parents' socio-economic and other background
- Preclude commercially oriented informal human milk sharing but should probably not aim to regulate informal peer-to-peer milk sharing
- Ensure that donor human milk from institutionalized human milk banks is not placed at a disadvantage compared to commercially processed products

We call on policy makers at the EU level and in Germany to carefully consider the impact of any classification of donor human milk across Europe and closely consult with all relevant stakeholders when revising regulatory frameworks on human milk banking.

Human milk for premature infants

Mother's own milk is the first choice for feeding newborns.

Over the last decades, the immense benefit of human milk for preterm infants has become increasingly evident.¹ Research has confirmed that human milk has significant advantages for preterm infants and their mothers.² Reducing the acute complications of prematurity translates into an improved long-term outcome because acute complications are associated with impaired long-term development of premature babies.³ Those unique effects of human milk on newborns cannot be replicated by infant formula.

Furthermore, computing these factors into a health-cost-benefit equation, positive economic consequences for health facilities were demonstrated.^{4,5}

Unfortunately, mother's own milk is not always sufficiently available for premature infants even after exhausting any means of lactation support. In these cases, donor human milk from human milk banks represents the next best choice of infants feeding as those fragile infants without mother's own milk will not miss out on the beneficial aspects of donor human milk on their health.⁶

Therefore, international feeding guidelines recommend mother's own milk as the first choice for feeding preterm infants. If mother's own milk is not available despite adequate lactation support donor human milk from an established human milk bank represents the best alternative.^{7,8}

History of human milk banking in Germany

In Germany human milk banking started over 100 years ago and has a longstanding tradition.⁹ More than a third of the currently existing milk banks have been operational for over 50 years.¹⁰

A once dense network of human milk banks was gradually closed down in the 1970s in Western Germany but continued to operate and was further promoted in the former German Democratic Republic. Regular milk banking meetings have been held since the late 1990s, organized by the largest human milk bank at the Children's University Hospital in Leipzig (Saxony) but otherwise activities aimed at expanding human milk banking were dormant in reunified Germany for many years.¹¹

The foundation of a human milk bank in 2012 at the Bavarian LMU University Hospital in Munich was instrumental in the rapid establishment of further human milk banks throughout Germany. Cooperation between academic heads of these milk banks resulted in a first scientific workshop dedicated to human milk banking at the meeting of the German Neonatal Society in 2017. Further cooperation resulted in the foundation of the Human Milk Bank Initiative in 2018 to strengthen and promote milk banking in the country.¹²

Another impetus has been given by the Germany-based European Foundation for the Care of Newborn Infants which organized round table meetings of an expert group and in 2018 published a toolkit and recommendations on human milk banking, organized regular workshops on this subject and called for the strengthening of human milk banking in Germany.^{13,14}

A national publicly funded research consortium has been set up by the University of Cologne to study the impact and feasibility of a comprehensive national human milk program commencing in 2021.¹⁵

Current situation of human milk banking in Germany

Currently, 31 human milk banks are operating in Germany. All human milk banks are affiliated with health care facilities, almost exclusively by Children's Hospitals, and are located in proximity to the perinatal units and to the recipients, namely very preterm infants and sick newborns. Other modes of operation include cooperation of Children's Hospitals with a blood bank of the Red Cross in one case, and with a hospital pharmacy in another.¹²

All human milk banks cater to their own inpatients; only a few additionally provide donor human milk to other perinatal centers depending on actual supply. Human milk banks in Germany do not provide milk to outpatients due to limited supply and organizational issues but frequently receive requests from members of the public.¹⁶ German medical societies and authorities unequivocally advise against buying human milk from private individuals and via the internet.¹⁷

In general, the number of milk banks and the supply is insufficient to cover the potential need of about 10.000 preterm infants with a birth weight of less than 1500 g born per year in one of the over 200 German perinatal centers caring for the most immature infants. At present the overwhelming majority of perinatal centers have to resort to preterm formula if the supply of own mother's milk is insufficient. The utilization rate of donor human milk within German neonatal units caring for premature infants is around 16%.¹⁶ Saxony and Saxony-Anhalt are the only federal states where all perinatal centers that provide maximum level neonatal care are equipped with human milk banks or have access to donor human milk.

The size of human milk banks in Germany varies from very small ones in which about 60 liters of donor human milk per year is processed to larger ones that process around 1000 liters per year.¹⁸ Accordingly, some handling practices vary between human milk banks.¹⁶ A national guideline on human milk banking and the use of donor human milk for preterm infants and newborns, initiated by the Human Milk Bank Initiative, is currently being drafted, aiming at harmonization of indication and procedures.¹⁹

Donors are recruited from the community or from mothers of hospitalized newborns with a surplus of milk. Mothers of infants that are treated in the neonatal intensive care units may become donors themselves. For screening purposes, a combination of a health history questionnaire and serological testing is applied by all milk banks. Screening for adulteration

or substance abuse is not generally applied. German donor milk banks do not pay for milk donations although some may reimburse expenses that are directly associated with the donation.¹⁶ Therefore, there is no financial incentive for milk adulteration that has been reported from commercially oriented milk sharing models.

The decision to use donor human milk in the nutrition of a preterm infant is made by the attending neonatologist in accordance with local standards, once a limited supply of the mother's own milk has been identified despite optimal lactation support. The benefits and risks of formula compared to donor human milk are discussed with the parents and informed consent is obtained. The donation is anonymous for both the recipients and the donors however data around the donation is kept in accordance with the hospital's required archiving criteria e.g. personal data and medical history of the donors, blood test results and microbiological screening of the donor human milk.²⁰

Using raw donor human milk, i.e. human milk that has never been treated with heat (pasteurization) and has at best been kept refrigerated and not frozen is a unique feature of human milk banking in Germany and is only otherwise practiced in Norway.²¹ Raw milk must meet strict requirements concerning donor eligibility, milk handling and donated milk quality.

Parents are not charged for donor human milk. The operating hospital covers all the costs which far exceed the costs of using specialized formula.²² There is no specific reimbursement to the health care provider when utilizing donor human milk. It is the opinion of the German regulatory authority that these expenses are included in the lump sum refunded by health insurance providers to cover the general treatment of premature infants.²³ However, the increased financial burden has been identified as one of the main obstacles preventing hospitals from establishing further human milk banks.¹⁶

A detailed overview of German donor human milk programs has been published recently.¹⁶

Current donor human milk regulation in Germany

The former German Democratic Republic issued its own laws to regulate milk banks in 1951. In 2004 the Federal Republic of Germany repealed legislation on human milk banks that had been issued by its legal predecessor in 1941.

After all human milk banks had closed down in West Germany in the 1970s colleagues at the Bavarian LMU Children's University Hospital were the first to open a human milk bank in the Western part of reunified Germany, in 2012. The milk bank was informed by the regional authorities that donor human milk is classified as a food product, in line with Article 2 of the European Union Regulation No. 178/2002.¹⁴

In the context of the emergence of internet-promoted commercially oriented milk sharing, the German Federal Ministry of Food and Agriculture declared in 2016 that human milk intended for the use of any recipient other than the mother's own infant should be regarded as a food product and be subjected to the Infection Protection Act and respective food laws.

As food regulation falls under federal jurisdiction most German states follow precedent and subject human donor milk to the Infection Protection Act and respective food laws, regulations and oversight when being approached for clarification in the context of establishing human milk banks. As a result, especially those human milk banks that have been founded in recent years are registered as food processing facilities.

The classification of donor human milk as a food product can have undesirable and unintentional side effects. Currently, human milk can be commercially sold and obtained from individuals via the internet within Germany.²⁴ There is no clear legal basis to prohibit such practice. The use of legal loopholes pertaining to the potentially unsafe distribution of human milk may be easier to avoid if regulations other than those for food products were applied.

As human milk bankers and medical experts, we are aware that the current classification of donor human milk as a food product is debateable as it does not entirely encompass the unique characteristics of donated human milk for infants in need. These characteristics include that it is part nutrition, part medical treatment, part life-saving but part insufficient without processing and that it is of human origin but intended to be ingested by nature and represents a deliberate donation of a woman propelled by altruistic motives.

However, this classification is the current basis for the mode of operation in German human milk banks. In conclusion, we suggest considering to classify donor human milk as a separate entity that meets its aforementioned unique characteristics and at the same time enables milk banks to continue to provide safe donor human milk.

Commodification and commercialisation of human milk

Informal milk sharing between mothers that have an immediate personal relationship with each other (peer-to-peer sharing), where the donor does not seek remuneration, may be as old as mankind. Human milk in this context should not be regarded as a disembodied product and even if not condoned, regulation should probably not be attempted. Commercially oriented informal milk sharing, however, exposes infants to potentially harmful human milk that has been repeatedly shown to be unfit for consumption by infants.²⁵⁻²⁷ Therefore, any new regulation should target and effectively preclude commercially oriented informal milk sharing.

From a business perspective human milk has developed into a profitable commodity which is processed on an industrial scale and traded worldwide.²⁸ The commodification of human milk increases the availability of and the access to human milk products that can be utilized for premature infants in need. However, the commodification of human milk has in the past resulted in ethically questionable approaches to acquire human milk from lactating mothers in resource-limited regions or from socio-economically disadvantaged populations.^{29,30} This has raised the issue of vulnerability to exploitation and the limits of self-determination of women of economic uncertainty when faced with the opportunity to market their breast milk.³¹

The working principle of European institutionalized non-profit human milk banks is fundamentally different from the business practices outlined above because the donations are solely motivated by altruism.³² European human milk banks are almost exclusively operating within health facilities caring for preterm infants. Therefore, every human milk bank within our initiative is subject to rigorous internal hospital quality controls and they are also controlled by federal or local food safety authorities on a regular basis.

Furthermore, as detailed previously, providing adequate lactation support is the prerequisite for procuring donor human milk. Thus breastfeeding rates are increased in those units with their own donor human milk programs.^{33,34}

Importantly, safety, quality and promotional effect on breastfeeding of commercially processed human milk has not been proven to be superior to donor human milk from institutionalised human milk banks.

The expenses of health facilities for purchasing commercially processed human milk products exceed the costs for procuring donor human milk from institutionalized human milk

banks by far.³⁵ This cannot solely be attributed to quality control measures of commercially produced milk products but will, understandably, incorporate a profit margin. As a result, commercially processed human milk products may not be affordable for many of the more than 200 German health care facilities caring for the most premature infants.

Therefore, it is the urgent recommendation of the Human Milk Bank Initiative that any legal framework must avoid disadvantaging donor human milk from institutionalized human milk banks in favour of commercially processed products. This may create a situation where the utilization rate of human milk for preterm infants might actually decrease across Europe and other positive effects from human milk banks promoting lactation are lost.

Even though this will ultimately in part be dependent upon national implementation, this aspect should be considered when devising a regulatory framework for donor human milk.

A call to policy makers and key stakeholders

We call on policy makers to consider carefully the possible impact of any EU-wide regulation of donor human milk on the availability of safe donor human milk from established non-profit human milk banks in all Member States.

We are also calling on our colleagues engaged in human milk banking and on European national human milk bank societies to independently assess any potential impact a revision of the current blood, tissue and cell regulation that includes donor human milk would have on their operating abilities and to share their insights in order to support the work of the European Commission.

We believe it to be important that recommendations and concerns from relevant stakeholders in Member States are taken into account during this process. These include, but are not limited to parents of infants in need, members of medical and nursing professions, breastfeeding and lactation experts, advocates for women and infant's rights and the human milk banking community.

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Imprint

Frauenmilchbank-Initiative e.V.

Püttkampsweg 5

22609 Hamburg

Germany

www.fmbi.de

info@fmbi.de

Represented by the Executive Board:

Professor Christoph Fusch

Dr Corinna Gebauer

Judith Karger-Seider

Dr Daniel Klotz

Associate Professor Anja Lange

Anne Sunder-Plaßmann (Managing Director)

Register of associations: VR 23814

Officially accredited non-profit organisation

Registration court: Amtsgericht Hamburg, Hamburg, Germany

Cite as:

Closing the gap – Increasing availability of donor human milk. Position Statement of the Human Milk Bank Initiative (FMBI) on the planned revision of the European legislation on blood, tissues and cells. Klotz D, Lange A, Karger-Seider J, Gebauer C, Sunder-Plassmann A, Fusch C.

DOI: 10.13140/RG.2.2.19619.68646

Available at:

<https://www.frauenmilchbank.de/neuigkeiten/2020/12/15/fmbi-position-statement>

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