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The legislative framework of donor human milk and human milk banking in Europe

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Abstract

Data about the regulatory approaches to donor human milk (DHM) in European countries are lacking. The aim of this study is to describe the various regulations of DHM within European countries, to assess its legislative context and its impact in relation to donor milk banking. We performed a cross-sectional survey using a semistructured online questionnaire addressing 29 national European milk-banking representatives from June 2020 to February 2021. Representatives of 26 national DHM services participated in this study. The legal classification and regulatory status of DHM were defined in 9 out of 26 areas of jurisdiction (35%) as either food product ($n = 6$), product of human origin according to a blood, tissue, cell regulation ($n = 2$), or medicinal product ($n = 1$). In the remainder, DHM remains unclassified. Most legislations did not provide a comprehensive framework concerning DHM and costs to cover milk bank operations were rarely reimbursed. In general, the lack of national legislative governance and the actual legislative regulations in place do not support the use of DHM in European countries. National medical guidelines for the use of DHM have been issued in only 11 countries. The current number and distribution of milk banks ($n = 239$) within participating countries may not provide an equitable access to DHM for eligible infants. These findings could guide stakeholders aiming to establish a regulatory framework for DHM.

KEYWORDS

classification, donor human milk, Europe, legislation, milk banking, preterm, regulation

1 | INTRODUCTION

Mothers own milk (MOM) is the nutrition of choice for premature infants (Parker et al., 2021). If MOM is not available despite adequate lactation support donor human milk (DHM) represents the next best choice as recommended by the WHO, AAP, ESPGHAN and other organisations (Arslanoglu et al., 2013; Parker et al., 2021; WHO, 2017). Worldwide, human milk banks (HMB) serve as facilities to protect, promote and support lactation, and breastfeeding (Shenker et al., 2021). They collect, screen, store, and provide DHM to institutions that care for premature infants in need of human milk (HM). According to the European Milk Bank Association (EMBA), there are currently 280 HMBs located in 26 European countries (EMBA, 2021).

However, despite unanimous recommendations, DHM remains underutilized in numerous health systems caring for premature infants (Ashina et al., 2019; Perrin, 2018; Sáenz de Pipaón et al., 2017). Uncertainties about the regulatory requirements for handling DHM and the lack of funding have been identified amongst other aspects as barriers for establishing HM banks in neonatal units in Germany (Klotz et al., 2020). Another recent survey, conducted by the EMBA, found that the operational procedures for the operation of donor human milk banks vary widely across European countries (Kontopodi et al., 2021). These differences may be due to lack of regulation as well as different regulations in each country.

The European Commission lists HM as a substance that is unregulated or regulated in divergent ways (European Commission, 2019). This may result in levels of protection for donors and recipients of these treatments that are lower than those for donors and recipients of other substances of human origin (European Commission, 2019). A new chapter about DHM has been recently added to the *Guide to the quality and safety of tissues and cells for human application* published in 2009 by the European Directorate for the Quality of Medicines & Health Care (EDQM, 2019). Furthermore, proceedings to issue a legislative framework for DHM for European Union member states are currently ongoing and have been supported by several HMB interest groups and advocates (European Commission, 2021).

A systematic assessment of the legal HM banking regulations, legal classifications and status of DHM within Europe is not available. This study aims to describe the various regulations of human milk within European countries, to assess its legislative context and to explore the specific impact in relation to human milk banking.

Key messages

- There is a lack of a legislative framework concerning the use of donor human milk in the majority of European countries.
- Available national legislative frameworks differed widely with gaps in the regulation of safety and quality of donor human milk, protection of donors and recipients, and cost recovery.
- Despite clearly demonstrated benefits and unequivocal recommendations for the use of donor human milk there is a lack of national guidance in many European countries.

2 | METHODS

Within each European country, we identified national experts involved in policy making for human milk banking among the members of the European Milk Bank Association from personal knowledge or from internet research. Within each individual European country, one national expert received a structured online questionnaire (Supporting Information Material 1) containing up to 22 questions that was pretested for usability and technical functionality amongst the authors. Invited national experts were asked to review the existence and the impact of their respective national legislative regulation concerning donor human milk and human milk banking. Upon receiving the completed questionnaire, the main author performed video interviews with each participant or contacted them by E-mail to clarify any uncertainties and to discuss the actual and potential implications of the respective legal framework concerning DHM as perceived by the respective national representative. Data were collected from June 1, 2020 to February 28, 2021 after the survey was approved by the EMBA board and after ethical approval was waived by the Ethics Commission of the Albert-Ludwigs-University Freiburg, Germany.

The participants were informed about the purpose of this study, the intention of the investigators and provided informed consent to the publication of the collected data by providing a completed questionnaire. They did not receive any incentive for participation.

We performed a descriptive analysis; data are presented in totals and proportions. This survey was prepared and results reported according to the Equator CHERRIES checklist for reporting results of internet e-surveys (Eysenbach, 2004).

3 | RESULTS

Donor human milk services provided by human milk banks ($n = 239$) were identified in 29 European countries (Figure 1). Participants from 26 of those participated in this study by returning a completed questionnaire and providing further clarification by a follow up interview or e-mail. All respondents were actively involved in policy making capacity in their current national milk banking operations and represented their respective national human milk bank organisation where present ($n = 16$).

We could not establish contact with national human milk banking representatives from Hungary, Portugal, and Romania, even though DHM services were operating within these countries (personal communication). Therefore, we did not collect any data from these countries. Supporting Information Material 2 lists countries where we could rule out national DHM services ($n = 5$), countries where we could not obtain any data ($n = 7$) and those countries that were not addressed by this survey due to different reasons (population size and/or demographics, geographic location). However, it was beyond the scope of this study to ascertain the presence of donor human milk use within individual European neonatal units outside of established donor human milk services.

The scope and the framework of donor human milk services are given in Table 1. HMB were almost exclusively operated by neonatal care units, by tissue and blood banks, by hospital pharmacies or acted independently as autonomous, independent entities.

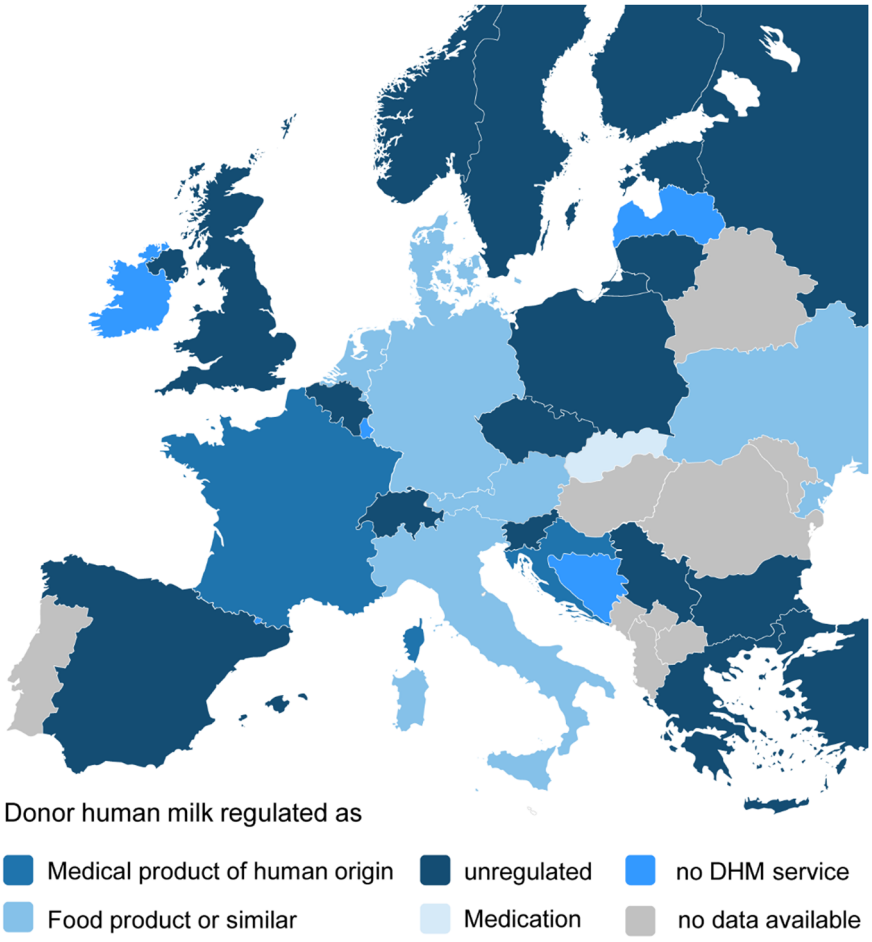

FIGURE 1 Classification of donor human milk within European countries

DHM was legally regulated in 9 out of 26 European countries and was classified as either food product ($n = 6$), as product of human origin ($n = 2$) or medicinal product ($n = 1$) (Table 1). In most countries those legislations were issued by the respective national ministries of health apart from Germany where different ministries on a federal level issued separate and divergent legislations, thus resulting in federal states with and without legislative frameworks for DHM.

The defining framework of the respective national regulation was derived from different regulations covering food law, infectious diseases and hygienic regulations or regulations also covering blood, tissue, and cells (BTC) of human origin among other statutory requirements (Table 2). The strength of adherence to this legislation and the subsequent regulation of DHM differed between those countries. The items that were covered by these legislations are given in Table 2, revealing gaps in many aspects of DHM management in most regulations.

The actual impact of the current regulations on the use of DHM in the respective countries is given in Table 3. In general, the current status quo did not appear to have an impact on the overall use of DHM as experienced by the participants (10/25) but the current legislative framework, or rather the lack thereof, was not supportive of the utilisation of DHM for the majority (16/25).

Participants cited different preferences for DHM classification. Most considered a classification sui generis, that is, within a unique category ($n = 15$), a classification according to BTC ($n = 9$), or as a food product ($n = 1$) as the most suitable category for DHM in their respective country. Interestingly, five out of nine participants with a regulation in place also would like to change their DHM classification.

In general, expectations associated with a preferred legislation did not differ much between participants, according to BTC or according to a DHM classification sui generis. The majority of the participants that favoured a DHM classification sui generis (73%) and the majority of the participants that favoured a DHM regulation according to BTC (53%) expected an increase in DHM utilisation within their preferred classification. Similar results were obtained for the participants' expectations from their preferred classification in increasing the number of HMB banks (sui generis 46% vs. BTC 45%), improvement in HMB organisation (80% vs. 78%) or hygienic quality of DHM (46% vs. 45%) and reimbursement of operational costs for procuring DHM (46% vs. 56%).

Data concerning funding of HMB operations were available for 10 national services. In those, funding of operations was mostly provided by the operating unit (i.e., the hospital budget of the respective Children's Hospital) or provided by the hospital operator or health care trust and was subsidised by charitable donations or the sale of milk to other hospitals in some cases. Only in three cases was the provision of DHM reimbursed by a third party (e.g., the Ministry

TABLE 1 Donor human milk services in European countries

	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Italy	Lithuania
VLBW/year x 10^3	0.81	1.15	n.a.	0.4	1.2	n.a.	0.15	0.5	12	9.5	n.a.	4.6	0.2
Number of operating DMB	8	4	1	1	4	3	1	17	19[e]	29	3	38	2
DMB operated by													
Neonatology	●	●			●	●	●	●		●	●	●	●
Blood/Tissue Bank				●						●			
Another[d]			●					●	●	●			
Legal classification DHM[a]	●	-	-	●	-	●	-	-	●	●	-	●	-
Legal classification MOM[a]	●	-	-	●	-	●	-	-	-	-	-	-	-
Medical Guideline DHM[b]	○	○	-	○	●	-	-	●	○	○	●	●	-
Medical Guideline MOM[b]	○	-	-	●	-	●	-	●	-	○	●	-	-

	Netherlands	Norway	Poland	Russia	Serbia	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	Ukraine	United Kingdom
VLBW/year x 10^3	2	n.a.	25	n.a.	n.a.	0.6	0.18	3.4	n.a.	n.a.	25	n.a.	n.a.
Number of operating DMB	1	12	16	3	2	9	1	15	28	7	1[c]	1	14
DMB operated by													
Neonatology	●	●	●	●	●	●	●	●	●	●	●	●	●
Blood/Tissue Bank								●					
Another[d]													●
Legal classification DHM[a]	●	-	-	-	-	●	-	-	-	-	-	●	-
Legal classification MOM[a]	-	-	-	-	-	-	-	-	-	-	-	-	-

TABLE 1 (Continued)

	Netherlands	Norway	Poland	Russia	Serbia	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	Ukraine	United Kingdom
Medical Guideline DHM[b]	-	●	○	●	-	●	-	●	●	●	-	-	●
Medical Guideline MOM[b]	-	-	●	○	-	●	○	-	-	-	●	-	-

Note: ● in place; ○ in preparation.

Abbreviations: DHM, donor human milk; DMB, donor milk bank; MOM, mother owns milk; n.a., data not available; VLBW, very low birth weight (infants).

[a]According to a legislation issued by an regulatory body.

[b]Issued by a medical society.

[c]Currently not operating due to the need for religious clarification.

[d]Independent unit within health care facility, autonomous and independent non-profit HMB, hospital pharmacy.

[e]In total 35 milk banks procuring DHM (n = 19) and MOM.

of Health, health insurance company) according to the actual amount of DHM that was procured by the HMB or dispensed to the individual neonate.

National medical guidelines for the use of DHM are either available in 11, or being drafted in 7, out of 26 countries. National medical guidelines concerning use of MOM have been issued in six and being drafted in four more countries (Table 1).

4 | DISCUSSION

The term *donor human milk* points towards the challenges that surround its procurement and provision in the context of human milk banking. *Milk* is an easily perishable substance that can be spoiled during its handling and may serve as a vector of potential hazardous organic and inorganic substances to infants at risk (Blackshaw et al., 2020). As a product of *human* origin, it raises analogies to the use of BTC as medical products but, in contrast to those, is intended to be ingested by another human being. A *donation* implies a process that is propelled by an altruistic motive and based on an informed and autonomous decision of women and parents that should not be influenced by any profitable incentives (Miracle et al., 2011).

These characteristics of donor human milk partially explain its limited availability that has, as an economic principle, contributed to the ongoing commodification and commercialisation of human milk (Newman & Nahman, 2020).

The challenges detailed above have in part, led to the calls for a legislative framework for the use of DHM to avert any potential harm to donors and recipients alike (European Commission, 2019). In this study we aimed to describe the current fragmented legal regulations and framework surrounding the procurement and use of donated human milk within European countries.

4.1 | The need for regulation of donor human milk

Traditionally, the banking of mothers' own milk has been perceived as an extension of breast feeding one's own child in the neonatal intensive care units (NICU) mitigating the need for any regulatory oversight. However, the lack of clear regulatory guidance has been identified as a barrier to provide donor human milk to premature infants in need and to establish new milk banks (Klotz et al., 2020). From a practical point of view regulatory oversight authorities and health care providers are reliant on a clear framework guiding good manufacturing practice, harmonisation and standardisation when using DHM or establishing HMB (Kostenzer et al., 2021). This framework, however, is defined by the classification of its subject and should aim to set out rules and regulations for authorisation for procuring, manufacturing practice, allocation, and reimbursement of DHM. We could show that the current legal *status quo* of DHM within Europe in general does not contribute to achieving these aims.

TABLE 2 Framework of regulated donor human milk service in European countries

	Austria	Croatia	Denmark	France	Germany	Italy	Netherlands	Slovakia	Ukraine
DHM is legally classified as									
Food product or similar	●[a]		●[a]		●[b]	●	●		●
Medical/health product of human origin		●		●					
Medicinal product								●	
Does this classification result in a special regulation of DHM?									
Yes, acquisition and sale of human milk is strictly limited and controlled	●	●	●	●		●	●	●	
Unclear, grey area, human milk is being sold informally/commercially					●				●
Where are the requirements for DHM handling defined?									
Food law	●		●		●		●	●	●
Infectious Diseases Prevention Law					●				
Hygiene Law			●		●				
Blood/cell/tissue regulation		●	●						
Own classification system (sui generis)	●			●		●	●	●	●
Medicinal regulation								●	
What is the resulting strength of adherence from this regulation?									
Regulation is binding and following the regulation is mandatory	●	●		●		●	●	●	
Regulation defines a set of rules which can be adjusted according to local conditions			●		●				
The need to adhere to the regulation is unclear, regulation is not applied					●				●
Characteristics of donor human milk regulations within Europe									
Registration for handling of DHM	●	●	●	●	○	●	○	●	●
Classification of DHM	●	○	○	●	●[b]	●	○	●	○
Reimbursement for DHM procurement	●	●	ø	●	ø	●	ø	ø	ø
Organisational aspects of DHM handling	●	○	ø	●	○	●	○	●	●
Hygienic aspects of DHM handling	●	●	ø	○	○	●	●	●	●
Donor selection	●	●	ø	●	ø	●	○	●	●
Microbial testing of DHM	●	●	ø	●	ø	●	○	○	●
Informed consent for donors/recipients	●	●	ø	ø	ø	●	ø	ø	●
Staffing and qualification of personnel	●	○	ø	○	ø	●	ø	○	○
Specification of technical equipment	●	○	○	○	ø	●	○	●	○

Note: ●, in place, regulated; ○, indirectly regulated, evident from context; ø, not regulated or not mentioned within legislation.

Abbreviation: DHM, donor human milk.

[a]Considered and treated as food product but not included in the actual food legislation.

[b]Regulated in 5 out of 16 federal states.

TABLE 3 Effects of different regulations on donor human milk use as experienced by the participants ($n = 25$)

Regulation according to	Utilisation of donor human milk			
	Limits	No effect	Supports	Mandatory
Blood, tissue, cells of human origin	0	1	3	0
Food product or similar	2	2	1	0
Unregulated	4	7	5	0
Total	6	10	9	0

4.2 | Classifications of donor human milk

Within the nine countries that adopted a form of legislation, human milk is exclusively included within pre-existing classifications, that is, according to regulations that have been originally devised for food products, medications, and medical products of human origins. However, none of these categories reflects the above-mentioned complex properties of DHM, limiting its applicability to DHM. Furthermore, the assessment of the actual scope of the specific regulations reveals gaps that exist within each national regulation, limiting its impact and applicability.

In general, our data show that most participants of our study did not regard their current classification of DHM or the lack thereof as supportive of human milk banking in their country. Accordingly, most participants would prefer an alternative to the current classification for DHM within their country citing very different preferences.

Most participants preferred a classification other than according to products of human origin. Given the participants' preferences and the current status quo of DHM, legislation appears to be at odds with European plans of regulating DHM according to products of human origin (blood, tissues, and cells). However, we could show that expectations of health care professionals towards any DHM regulation was similar irrespective of the individually favoured DHM classification. Therefore, preferences may not only be shaped by expectations of regulatory outcomes but also by the anticipation of regulatory costs associated with a specific classification (e.g., for health authorities by providing governance and for health care facilities when preparing, obtaining or maintaining regulatory documentation and approvals). Such regulatory costs must be considered when devising a regulatory DHM framework and must not render milk bank operations unsustainable from a financial or operational point of view.

The specific benefits and disadvantages of classifying DHM according to one of the existing classifications have been discussed in detail elsewhere (PATH, 2019). Any legal classification may expedite DHM utilisation within a given health care system by providing a framework for procuring, handling, dispensing and reimbursing DHM.

However, certain aspects have to be considered in this context. Due to the basic diversity of regulatory legislation between countries, classifying donor milk may not necessarily result in a consistent regulatory outcome as shown in Table 2. For example, Denmark and Austria both classify DHM legally as a food product but, in each of these countries, their respective frameworks covered a very different range of issues and levels of guidance for regulators and health care professionals.

Heterogeneity in regulation on a legislative level, especially classification, may impede DHM delivery between different jurisdictions (international or subnational). This could limit the source of supply and subsequently the access to DHM for those units or countries that are currently not operating own donor milk services.

When revising or devising new legislative frameworks concerning, these aspects and the current national *modus operandi* must be considered as future legislative action should not detrimentally affect human milk banking and the use of donor milk in a given setting.

4.3 | Reimbursement of milk bank operations

Recent data generated within different health care systems substantiate the expenses of procuring DHM (Daili et al., 2020; Fengler et al., 2020). Those data show that costs for procuring DHM far exceed the costs of preterm formula. Our data revealed that a third party payer reimburses those costs for the procurement of DHM in only three out of 10 countries (France, Austria, and Poland). However, actual costs may only be partially refunded to the facility responsible for milk bank operations (Wesolowska et al., 2020). Since we demonstrated that the overwhelming majority of European HMBs are operated by neonatal departments, our data indicate that the respective health care facility covers the costs of its DHM services and for establishing HM banks. This inevitably results in a conflict where DHM services need to compete with other objectives of health care providers for financial funding. In the presence of an apparent cost saving alternative consisting of preterm formula, the lack of funding has been identified as a major barrier for establishing HMB. Reimbursing the costs of milk bank operations and DHM procurement by a third party payer other than the medical health facility operating the DMB may increase the use of DHM for premature infants.

4.4 | National medical guidelines and the need to change local practice

In the context of extreme prematurity, the use of human milk is unequivocally recommended and has been labelled and perceived not only as a source of nutrition but also as a medical treatment (WHO, 2017). Against this background, there is a remarkable lack of medical guidelines outlining and guiding the respective national policy around the use of human milk for premature infants in the participating countries. It appears that the use of the single most effective intervention for the prevention of necrotising enterocolitis is haphazardly applied throughout Europe. Additionally, the number of HMB appears to be limited and unequally distributed within individual European countries and Europe as a whole. This may result in a limited access to DHM in most

participating countries compared to the potential number of eligible infants. Comparing the number of premature infants that may be eligible to DHM in countries covered by our survey with the number of HMB available to the health care facilities caring for these infants we hypothesise that the access to DHM and therefore its utilisation may be restricted within many European health care systems. However, appropriately designed studies are needed to test this hypothesis.

The current development of relevant medical guidelines in some countries could improve the recognition of the provision of human milk as a basic human right and may be a step towards a universal policy in the use of MOM and DHM. However, we must reiterate that MOM and DHM are not interchangeable and that MOM must be prioritised when pursuing strategies to increase the supply of human milk. This needs to be part of any policy recommendation addressing this issue.

There are some limitations to our study. The DHM experts' assessment of the legal effects of any given regulation does not represent a judicial expert opinion of legal ramifications but represent a medical expert opinion reflecting on the impact of any given regulation on the everyday practice concerning human milk services. Legal classifications may be issued by different levels of the legislative process ranging from federal laws to regional by-laws. Oversight might be provided by different regulatory bodies within the same and within different European countries. We therefore did not attempt to ascertain the exact legal nature of the respective legislations but focussed on its main regulatory effects on handling donor human milk within a given area of jurisdiction. We focused on the issue of DHM regulation from a pragmatic view as these regulations are impacting everyday operations of human milk banks and DHM services within health care settings and cannot substitute a comprehensive debate about the regulation of human milk in general as discussed in detail elsewhere (Cohen, 2019).

In conclusion, DHM is rarely and heterogeneously regulated within European countries. Available regulations are insufficiently covering important DHM aspects. DHM services are unevenly spread within Europe limiting the access to DHM for vulnerable infants; most countries are lacking a national human milk policy.

A harmonised regulation and classification as well as national guidelines implementing unequivocal recommendations into national policy may be beneficial for the further implementation of DHM services across Europe.

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CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

AUTHOR CONTRIBUTIONS

DK conceived the study. DK, AW, J-C P, GW designed the questionnaire. DK, AW, and GW performed the data collection and analysis. EB, GEM, and AG contributed to the questionnaire and data collection. DK wrote the first draft of the paper. All authors provided input to the overall direction and content of the paper, reviewed each draft of the paper, and reviewed and approved the final version.

DATA AVAILABILITY STATEMENT

The data reported on here are not publicly available due to privacy or ethical restrictions; participants did not consent to data sharing when they agreed to participate.

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