



## The regulatory status of Donor Human Milk within Europe

1. What is your professional background? (Multiple answers possible)

- ☐ Neonatologist
- ☐ Obstetrician
- ☐ Registered Nurse
- ☐ Midwife
- ☐ IBCLC
- ☐ Other (please specify)



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2. Do you represent your countries national human milk bank association?

- ☐ Yes
- ☐ No
- ☐ Not applicable - No national milk bank association



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3. How many preterm infants with a birth weight of less than 1500 g (VLBW infants) are born per year within your country? Please skip this question if this information is not present.



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4. How many donor human milk banks are operating within your country? Please skip this question if the information is not at hand.

Please note: For the purpose of this survey a donor human milk bank is defined as an institution that is officially known to collect, screen, store and distribute donated human milk in a hospital setting primarily serving premature infants and which is operating at predefined standards.



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5. Who is operating the milk banks within your country (multiple answers possible)?

- ☐ Neonatal departments
- ☐ Blood banks (e.g. Red Cross)
- ☐ Commercial providers
- ☐ I am not sure
- ☐ other



## The regulatory status of Donor Human Milk within Europe

6. Is there any legal classification for DONOR HUMAN MILK in the whole or in parts of your country?

*Legal classification is defined as any text issued by an authoritative organization that **classifies** DONOR HUMAN MILK in the area of its jurisdiction.*

This does not include a medical classification which may be issued by medical organizations even if these medical organizations have the authority to issue national guidelines.

- ☐ Yes
- ☐ No
- ☐ I am not sure



## The regulatory status of Donor Human Milk within Europe

7. How is DONOR Milk legally classified in your area of jurisdiction?

- ☐ Food product
- ☐ Tissue/cells
- ☐ Medication
- ☐ Blood product
- ☐ Health product
- ☐ Dairy product (comparable to animal milk)
- ☐ own classification system for human milk
- ☐ I am not sure
- ☐ Other (please specify)



## The regulatory status of Donor Human Milk within Europe

8. Which governmental department issued those regulations (e.g. Ministry of Health) ?



## The regulatory status of Donor Human Milk within Europe

9. Does this classification apply to the whole of your country or only to parts of your country (e.g. different regulations or lack of regulations in different federal states/autonomous regions) ?

- ☐ Applies to the whole country
- ☐ Different regulations within our country or lacking regulations in some parts of the country
- ☐ I am not sure



## The regulatory status of Donor Human Milk within Europe

10. Does this **classification** result in a special **regulation** of DONOR HUMAN MILK?

- ☐ No, everybody can officially sell or buy human milk informally or commercially once requirements for classification are being followed (e.g. food production guidelines if milk is being classified as food)
- ☐ Unclear, grey area, human milk is being sold informally/commercially
- ☐ Yes, aquisition and sale of human milk is strictly limited and controlled
- ☐ Other (please specify)



## The regulatory status of Donor Human Milk within Europe

11. Where are the requirements for DONOR HUMAN MILK handling defined (according to repective classification)? (Multiple answers possible)

Requirements are defined by:

- ☐ Own regulation for DONOR HUMAN MILK
- ☐ Food Law
- ☐ Infectious Diseases Prevention Law
- ☐ Hygiene Law
- ☐ Medication regulation
- ☐ Tissue/cell/donor organ regulation
- ☐ blood donation law
- ☐ I am not sure
- ☐ Other (please specify)



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12. What is the resulting strenght 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
- ☐ regulation defines a non binding framework
- ☐ The need to adhere to the regulation is unclear, regulation is not applied
- ☐ other



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13. Please let us know which aspects are covered and/or regulated concerning DONOR HUMAN MILK (DHM) by these regulations:

	Not mentioned in regulation	explicitly <b>NOT</b> part of the regulation (as stated in the text of regulation)	indirectly regulated (evident from context)	explicitly regulated
Registration for handling DHM	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Classification of DHM	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Reimbursement for providing DHM	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Organizational Aspects of DHM handling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hygienic aspects of of DHM handling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Screening of donors	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Microbial testing of DHM	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Informed consent for donors/recipients	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Number/Qualification of staff	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Specification of technical equipment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



## The regulatory status of Donor Human Milk within Europe

14. Is there a guideline by a medical society concerning the use of DONOR HUMAN MILK in your country?

- ☐ Yes
- ☐ No
- ☐ In preparation
- ☐ I am not sure



## The regulatory status of Donor Human Milk within Europe



15. Is there any legal classification for MOTHERS' OWN MILK in the whole or in parts of your country?

Legal classification is defined as any text issued by an authoritative organization that classifies and describes MOTHERS' OWN MILK and which in turn regulates the distribution and use of MOTHERS' OWN MILK in the area of its jurisdiction.

This does not include a medical classification which may be issued by medical organizations even if these medical organizations have the authority to issue national guidelines.

- ☐ Yes
- ☐ No
- ☐ I am not sure



## The regulatory status of Donor Human Milk within Europe

16. How is MOTHERS' OWN MILK legally classified in your area of jurisdiction?

- ☐ Food product
- ☐ Tissue/cells
- ☐ Medication
- ☐ Blood product
- ☐ Health product
- ☐ Lifestyle product
- ☐ Dairy product (comparable to animal milk)
- ☐ own classification system for human milk
- ☐ I am not sure
- ☐ Other (please specify)



## The regulatory status of Donor Human Milk within Europe

17. Which governmental department issued those regulations (e.g. Ministry of Health) ?



## The regulatory status of Donor Human Milk within Europe

18. Does this regulation apply to the whole of your country or only to parts of your country (e.g. different regulations or lack of regulations in different federal states/autonomous regions) ?

- ☐ Applies to the whole country
- ☐ Different regulations within our country or lacking regulations in some parts of the country
- ☐ I am not sure



## The regulatory status of Donor Human Milk within Europe

19. Is there a guideline by a medical society concerning the use of MOTHERS OWN MILK in your country?

- ☐ Yes
- ☐ No
- ☐ In preparation
- ☐ I am not sure



## The regulatory status of Donor Human Milk within Europe

20. What is the impact of the current regulation or the lack of current regulation on the use of DONOR HUMAN MILK within your country/jurisdiction?

Prevents the use of DHM

Effectively limits the use of DHM

Does not affect the use of DHM

Supports the use of DHM

Makes use of DHM mandatory





## The regulatory status of Donor Human Milk within Europe

21. Taking your personal experience into consideration: What would be the optimal classification for DONOR HUMAN MILK in YOUR country?

- ☐ Food product
- ☐ Tissue/cells
- ☐ Medication
- ☐ Blood product
- ☐ Health product
- ☐ Lifestyle product
- ☐ Dairy product (comparable to animal milk)
- ☐ own classification system for human milk
- ☐ I am not sure
- ☐ Other (please specify)



## The regulatory status of Donor Human Milk within Europe

22. What would be the benefits of this classification?  
(Multiple answers possible)

- ☐ Increase of Donor Human Milk (DHM) utilization
- ☐ Reimbursement of costs for DHM
- ☐ Increase in the number of Donor Human Milk Banks (see definition above)
- ☐ Increase in the hygienic quality of DHM
- ☐ Increase in the organizational quality of milk banking
- ☐ Other (please specify)



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We may get in contact with you to arrange  
an appointment for a short interview to discuss data

If you have any questions concerning this survey please contact

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