

Save the date!

Making Human Milk Matter

The need for regulation in the European Union

Policy Recommendations



Hosted by MEP Professor Dr. Angelika Niebler and MEP Radka Maxová

Digital Workshop: <https://bit.ly/3ozLFLj>

Wednesday, 18 November 2020

2:00-3:30 p.m. (CET)

Language: English

Agenda

2:00 p.m.	Welcome and opening remarks MEP Professor Dr. Angelika Niebler & MEP Radka Maxová
2:10 p.m.	Presentations part 1 Why human milk should matter to policy makers: key facts Professor Hans van Goudoever , Founder and Director Dutch National Human Milk Bank; Emma Children's Hospital, Amsterdam UMC, The Netherlands Human milk donation in Europe Professor Enrico Bertino , President European Milk Bank Association (EMBA); Representative Union of European Neonatal & Perinatal Societies (UENPS); Neonatal Unit of the University, AOU City of Health and Science of Turin, Italy How human milk banking works – an example from a Member State Professor Jean-Charles Picaud , President French Milk Bank Association; Past President European Milk Bank Association; Department of Neonatology, Croix Rousse University Hospital, Lyon, France
2:30 p.m.	Questions & Answers
2:45 p.m.	Presentations part 2 Why action is necessary – challenges in human milk donation and banking Associate Professor Aleksandra Wesolowska , PhD, President Human Milk Bank Foundation, Poland; Laboratory of Human Milk and Lactation Research, Regional Human Milk Bank, Holy Family Hospital, Department of Medical Biology, Medical University of Warsaw, Poland Evaluation of the EU legislation on blood, tissues and cells Dr. Stefaan van der Spiegel , Head of Sector, Health Innovation and Substances of Human Origin, DG Santé, European Commission Saving lives across borders: the need for EU regulation Silke Mader , Founder & Chairwoman of the Directors Board, European Foundation for the Care of Newborn Infants (EFCNI)
3:10 p.m.	Questions & Answers
3:25 p.m.	Concluding remarks MEP Radka Maxová & MEP Professor Dr. Angelika Niebler

An initiative of the EFCNI Working Group on Human Milk Regulation.



European foundation for
the care of newborn infants

Collaborating organisations:



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Policy Recommendations – Executive Summary

In Europe and worldwide, preterm birth, low birthweight, asphyxia, congenital abnormalities, infections and birth trauma are the main causes of neonatal death. The extremely vulnerable category of patients – preterm, sick, and low birthweight infants – has very special nutritional needs. Mother's own milk is the preferred option for infant nutrition to achieve optimal growth, development, and health. When mother's own milk is not available, donor human milk is the next best alternative, especially for preterm, sick and low birthweight infants; the next and last option is a specifically designed infant formula.

Donated human milk is collected, processed, stored, and distributed in human milk services, often referred to as banks. There are an increasing number of these in the European Union delivering high quality work. Human milk banks are well-regulated in some European countries but unregulated in others. Today, human milk and its donation are not regulated at the level of the EU. A common regulatory framework, however, would ensure that human milk's procurement, storage, processing and distribution meet high quality and safety standards in a harmonised and safe manner. This would ensure a minimum standard and equitable access to safe donor human milk for preterm, sick, and low birthweight infants and would contribute towards better health outcomes for this highly vulnerable group of patients. In that regard, and in line with evidence-based and internationally acknowledged recommendations, a human milk diet should be promoted and a uniform regulatory framework on human milk and its donation should be adopted to this end.

To guarantee that the highest level of safety for preterm, sick and low birthweight infants and their nutritional needs are met and due to the rise in use of human milk banks, we request European policy makers to ensure that any revision of the Tissues and Cells Directive:



1. Recognises human milk as the best option for preterm, sick and low birthweight infants and has, at its core, the theme of ensuring a safe, secure supply for all mothers in need of milk for their infants. Mother's own milk is the first choice in infant feeding. When mother's own milk is not available, donor milk from a human milk bank is the preferred option.
2. Includes a delegated act on donor human milk to be developed in close cooperation with key stakeholders in infant care and human milk safety.
3. 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.
4. Endorses recognition, support and regulation of human milk banks in Europe.
5. Includes the need for EU-wide research and data collection of human milk donation and use.

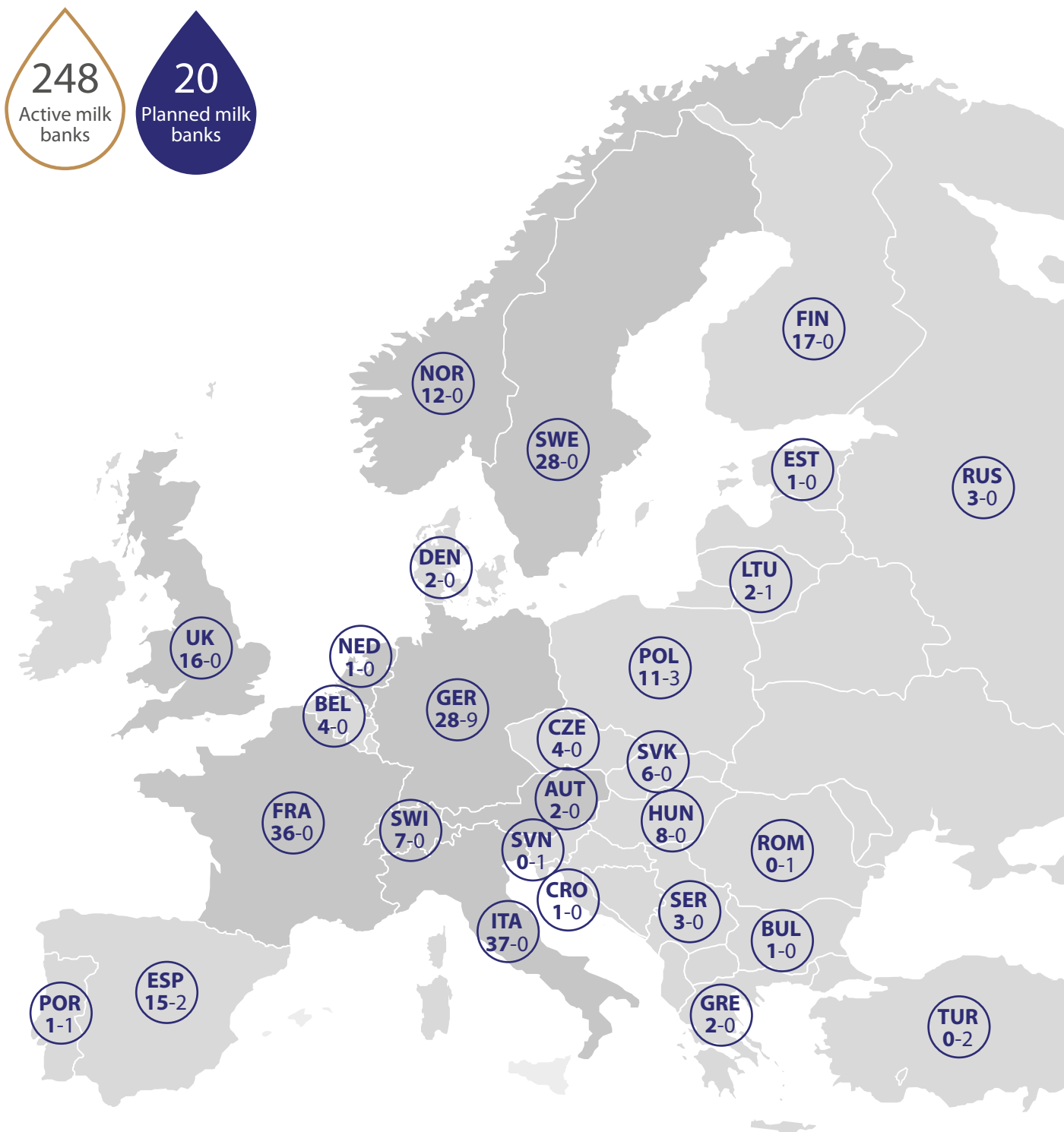
Making sure that preterm, sick and low birthweight infant conditions and consequent needs are recognised and best care is provided, will not only relieve the pressure from the already challenged healthcare systems but more importantly – save lives and improve quality of life. Morbidity and mortality of sick and preterm infants can only be reduced if their specific medical and nutritional needs are met. Given the scientific evidence and many advantages of human milk for preterm, sick and low birthweight infants, human milk based nutrition must be considered a European public health issue and a human right for all these infants.

For more information please see: www.efcni.org/human-milk-regulation

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Human Milk Banks in Europe



Source: adapted from EMBA, 2016, available at: <https://europeanmilkbanking.com/map>

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