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Beyond the pale? Why the EU is regulating breast milk

Donor breast milk is particularly valuable for nourishing premature or sick newborns.



Brussels bureaucrats want to homogenize the rules overseeing the donation and use of donor breast milk across the bloc | Diana Bagnoli/Getty Images

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The European Union regulates all sorts of banks: money banks, blood banks, sperm banks.

Its next target? Breast milk banks.

Brussels bureaucrats want to homogenize the rules overseeing the donation and use of donor breast milk across the bloc.

It's part of the European Commission's proposed revamp of the laws covering safety and quality standards for substances of human origin (SoHO) intended for human use. Currently, the laws cover blood, tissues and cells, but the EU wants to extend coverage to *all* SoHO — including donor breast milk.

While, at first glance, it might seem like the EU is trying to milk its regulatory powers, experts are largely in favor of the plan to set EU-wide standards, saying it will improve its availability and safety.

With lawmakers and EU countries debating the revamp, POLITICO walks you through the issue.

What are breast milk banks?

Women who make more breast milk than their babies need can donate it to a breast milk bank.

These banks screen donors and collect, process and distribute the milk to infants in need — those whose mother's own milk is not available or sufficient.

While exclusive breastfeeding is recommended for all babies in the first six months of their life, it's especially important for premature or sick newborns, experts say.

Among many other benefits, breast milk contains antibodies that are important for newborns' immune systems. Babies born before 30 weeks of pregnancy are especially susceptible to infections, particularly from necrotizing enterocolitis, a type of gut inflammation that can be fatal. Their survival rates improve when they get human milk as compared with formula, said Elien Rouw, a breastfeeding medicine specialist in Germany and president-elect of the Academy of Breastfeeding Medicine.

There are currently 282 breast milk banks in Europe, including Turkey and Ukraine, according to the European Milk Bank Association.

Aren't they already regulated?

Donor breast milk is regulated differently in different countries. For example, it's considered a health product in France, a food in Germany, and is uncategorized and unregulated in Romania. And while the safety standards are set at the national level in France, for instance, they are set at the regional level in Belgium.



▲ The Commission wants to harmonize breast milk safety standards across the EU | Kenzo Tribouillard/AFP via Getty Images

There is some level of convergence though. For example, most national guidelines in the world recommend donor breast milk should be pasteurized, according to the European Milk Bank Association.

In France, for example, the milk is first tested for bacteria and highly contaminated milk is thrown out, explains Jean-Charles Picaud, professor of pediatrics specialized in neonatology at Hôpital de la Croix-Rousse in Lyon, and president of the French Human Milk Bank Association. The rest is then pasteurized at precisely 62.5 degrees Celsius for exactly 30 minutes and then retested before being made available for babies.

What does the Commission want to do?

The Commission wants to harmonize safety standards across the EU, not only to ensure the safety of the babies that consume breast milk, but also to make it easier for donor breast milk — and other SoHO — to cross borders.

Donor milk banks are unevenly spread out across the Continent. There are over 30 in France, for example, but only four in Belgium and one in Romania. And parts of Europe are facing a shortage of donor breast milk, while it remains in limited supply elsewhere.

“There are children dying in Germany because they didn’t have, or didn’t have enough, human milk,” Rouw, the breastfeeding medicine specialist in Germany, said. Centers in Germany caring for extremely premature babies without direct access to a milk bank are buying it in part from Belgium and the United States, she added.

Experts agree that having harmonized safety standards would make the cross-border exchange of breast milk easier, improving babies’ access to it. These include things like donor selection criteria, maternal blood tests for infections, hygiene standards during collection, cold chain conditions during transport, and testing the milk for bacteria, said Picaud, president of the French Human Milk Bank Association.

However, while the Commission is setting out the principle of bloc-wide standards in its regulation, it aims to leave it to expert bodies — the European Centre for Disease Prevention and Control (ECDC) and the European Directorate for the Quality of Medicines & HealthCare (EDQM) — to hammer out the precise scientific and technical details so that these can be more easily updated should the need arise.

Should donors get paid?

The debate over paying for substances of human origin is a divisive one. Germany’s Human Milk Bank Initiative, a nongovernmental organization that promotes nonprofit donor milk banks, warned in a position statement to the Commission in 2020 that “ethically questionable approaches” have been used globally to acquire human milk from “lactating mothers in resource-limited regions or from socio-economically disadvantaged populations.”

EU countries take varying approaches when it comes to donor compensation for breast milk. Donors in France, for instance, receive no financial compensation. In Sweden, donating mothers receive a nominal 250 Swedish krona (€22.56) per liter of donated milk.

The Commission’s proposed revision includes guidance on compensation for all SoHO donors, to allow any financial losses to be covered — but leaves it to EU countries to determine whether to allow it and if so, the conditions for it, ensuring they remain “financially neutral.”

As well as human milk banks, the new law would also apply to any company looking to commercialize breast milk as an ingredient.

Given the growing body of research showing the clinical benefits of donor breast milk for premature babies, hospital-affiliated milk banks around the world are expanding their activities — and there's also growing commercial interest, a Commission spokesperson told POLITICO.

At least one company is using breast milk to make fortifiers for sick and premature babies in the neonatal intensive care unit, which are then added to either a mother's milk or donor milk.