Research Horizon

ISSN: 2808-0696 (p), 2807-9531 (e)

Research Horizon
Volume: 06
Issue: 03
Year: 2026
Page: 1155-1164

Citation:
Kashmir, A. K., & Anggraeni, H. Y. (2026). A legal analysis of freeze-dried human milk classification as functional food, human-derived substance, or medical product in Indonesia. *Research Horizon*, *6*(3), 1155-1164.

Article History:
Received: April 27, 2026
Revised: May 14, 2026
Accepted: June 16, 2026
Online since: June 25, 2026

A Legal Analysis of Freeze-Dried Human Milk Classification as Functional Food, Human-Derived Substance, or Medical Product in Indonesia

Arifin Kurniawan Kashmir[1*], Happy Yulia Anggraeni[1]

[1] Department of Law, Faculty of Law, Universitas Islam Nusantara, Bandung, Indonesia

[*] *Corresponding author: Arifin Kurniawan Kashmir (studio.kotakputih@gmail.com)*

Abstract

Freeze-dried human milk from donor milk poses a regulatory challenge in health law due to its human origin, clinical use, and unclear legal classification. This study aims to determine the appropriate legal classification of freeze-dried human milk under the Indonesian health law framework and to formulate a proportionate regulatory approach for its governance. The study uses a normative legal method with statutory, conceptual, comparative, and health policy approaches, based on Indonesia's Health Law Number 17 of 2023, Government Regulation Number 28 of 2024, and Regulation (EU) 2024/1938 on Substances of Human Origin, supported by literature on donor human milk, milk banking, processing, and commercialization of human-derived materials. The study finds that a purely food-based classification is legally underinclusive because it fails to address donor screening, traceability, and biovigilance obligations, whereas classification as a substance of human origin is normatively more coherent but remains insufficient unless coupled with enteral safety controls. By contrast, classification as a medical product may be justified only in limited clinical contexts and risks excessive medicalization. Freeze-dried human milk should be regulated under a hybrid framework combining human-origin substance governance, food safety, and clinical oversight to ensure infant safety, donor protection, equitable access, and prevent commodification.

Keywords

Freeze-Dried Human Milk, Health Law, Hybrid Regulation, Legal Classification, Substances of Human Origin.

1. Introduction

Breast milk remains the gold standard for infant nutrition, and the World Health Organization (WHO) recommends donor human milk for low-birth-weight infants when maternal milk is unavailable, provided safe and affordable human milk banking systems exist (World Health Organization, 2023). Advances in processing, particularly freeze-drying (lyophilization), have expanded its use by removing water through freezing and sublimation, resulting in a more stable and easily stored and distributed product (Sproat, 2023). From a health perspective, freeze-dried human milk offers logistical stability and may support exclusive breastfeeding patterns in preterm infants (Martysiak-Żurowska et al., 2022; Machado et al., 2025). However, this process also transforms its legal nature from a direct biological fluid into a processed, stored, labeled, and distributable human-derived material (Herson & Weaver, 2024; Unger & O'Connor, 2024).

Conceptually, freeze-dried human milk may be classified as food due to its nutritive and enteral function, as a substance of human origin because it originates from the human body and requires donor screening, quality assurance, traceability, and biovigilance, or as a medical product given its use in vulnerable infant populations within healthcare settings (Hahn et al., 2020; Romero-Bachiller & Santoro, 2023; McGrath et al., 2024; Shenker et al., 2024). Each classification carries distinct implications for licensing, quality standards, supervision, liability, labeling, and commercialization restrictions.

This debate is not merely speculative. The WHO has called for stronger global standards governing medical products of human origin, while the European Union, through Regulation (EU) 2024/1938, has established a legal framework for the quality and safety of substances of human origin intended for human application (European Parliament and Council, 2024; McGrath et al., 2024). Human milk banking is increasingly compared to blood, tissue, and cell programs because they share principles of donation, donor screening, processing, biovigilance, and traceability (Herson & Weaver, 2024). However, human milk differs fundamentally from blood and tissues due to its primary role as enteral nutrition and its inseparable connection to the protection of maternal breastfeeding (Israel-Ballard et al., 2024; McClanahan et al., 2024; Dogan et al., 2025). Moreover, freeze-dried human milk raises ethical concerns involving the human body, reproductive labor, altruistic donation, equitable access, public health interests, infant safety, and the risk of commodifying and exploiting women's bodies (Ross & Waltz, 2016; Modi, 2024; Rusi et al., 2024).

Recent literature shows that freeze-dried donor human milk challenges conventional legal categories, as it lies at the intersection of food, medical products, and Substances of Human Origin (SoHO) (Herson & Weaver, 2024; McGrath et al., 2024). While lyophilization improves logistical stability for vulnerable infants, it raises ethical and regulatory concerns related to donor consent, traceability, and potential commodification risks (Modi, 2024; Wu, 2024; Steele et al., 2025). Existing legal frameworks are considered inadequate to regulate processed donor milk, leading scholars to recommend a hybrid governance model to ensure safety, equitable access, and prevent covert commercialization (Rochow et al., 2025).

The urgency of this issue is increasing in Indonesia. Law Number 17 of 2023 concerning Health and Government Regulation Number 28 of 2024 provide a normative basis for human milk donation, requiring consent, clear donor identity, and health considerations, while prohibiting buying and selling practices (Republic of Indonesia, 2023; Rahman et al., 2025). However, this framework has not explicitly addressed how the law should treat donor milk that is further processed into freeze-dried human milk. Amid the absence of established formal human milk banks in Indonesia and the ongoing informal donor practices in society, this regulatory

vacuum potentially creates a gray area regarding process standardization, legal liability, cost-recovery limits, and the prevention of covert commercialization.

Therefore, this study aims to reorganize the preliminary discourse into a systematic and argumentative health law analysis by determining the appropriate legal classification of freeze-dried human milk under the Indonesian health law framework and proposing a proportionate hybrid regulatory approach, arguing that it is more appropriately governed through hybrid regulation rather than being confined to a single conventional legal category. This study analyzes the biomedical and technological nature of freeze-dried human milk, its contested legal classification as food, substances of human origin, or medical products, its ethical and socio-legal implications regarding consent, commodification, and equity, and the Indonesian regulatory framework's gaps, while proposing a hybrid governance model to ensure legal certainty, donor protection, infant safety, and public health objectives.

2. Methods

This research employs a normative legal research method with a multidisciplinary approach to examine the legal classification and regulatory positioning of freeze-dried human milk within the Indonesian health law framework (Negara, 2023). Normative legal research is selected because the study focuses on legal norms, regulatory interpretation, and conceptual categorization rather than empirical field data. The multidisciplinary perspective is applied to integrate legal analysis with relevant insights from health policy and biomedical considerations.

The study uses four main approaches. First, the statutory approach is used to analyze Indonesian legal instruments, particularly Law Number 17 of 2023 concerning Health and Government Regulation Number 28 of 2024, alongside relevant international frameworks such as Regulation (EU) 2024/1938 on Substances of Human Origin. This approach enables the identification of applicable legal norms and regulatory gaps. Second, the conceptual approach is applied to clarify and distinguish key legal categories, namely food, substances of human origin, and medical products, in order to assess where freeze-dried human milk may appropriately be situated within existing legal classifications. Third, the comparative approach is used to examine regulatory models governing donor human milk and related biological materials in other jurisdictions, providing contextual insight into alternative governance structures. Fourth, the health-policy legal approach is employed to evaluate the adequacy of existing and potential regulatory frameworks in achieving public health protection, ethical governance, and equitable access.

The primary legal materials consist of national legislation and international regulations relevant to health governance and human-derived substances. Secondary legal materials include scholarly literature on donor human milk, human milk banking systems, freeze-drying technologies, medical products of human origin, and the commercialization of human-derived biological materials. The analysis is conducted using five evaluative dimensions: biological origin, intended use, degree of processing, risk profile, and distribution model. These dimensions function as an analytical framework to assess the most proportionate legal classification of freeze-dried human milk and to formulate a more coherent and context-appropriate governance model for Indonesia.

3. Results and Discussion

3.1. Freeze-Dried Human Milk as a Biological Object and Health Technology

Freeze-dried human milk is human milk that has undergone water reduction through freezing and sublimation. The primary goal of this process is to increase stability, extend shelf life, simplify storage, and facilitate transportation (Sproat, 2023). In food technology terminology, this appears to be a preservation strategy.

However, materially, the object being processed is not ordinary food, but a biological substance originating from the human body.

Scoping review literature indicates that lyophilization of human milk possesses potential benefits but also affects several components, including fat globule size, enzymes, vitamin C, and immunoglobulins. Available clinical data remains limited and insufficient to conclude its safety and efficacy across all preterm infant populations (Sproat, 2023). Rochow et al. (2025) conducted an observational study on preterm infants (gestational age >30 weeks) demonstrating good tolerability and anthropometric outcomes; however, the researchers emphasized limitations in its application for very-low-birth-weight infants due to suboptimal protein-energy ratios. Thus, from a health science standpoint, freeze-dried human milk is a promising innovation but is not yet mature enough to be transformed into a broad commodity without strict governance (Cohen, 2021; Machado et al., 2025).

Precisely because this product is most likely to be used in preterm infants, low-birth-weight infants, sick infants, or groups with high clinical vulnerability, its regulatory threshold cannot be equated with general food (Shenker et al., 2024; Unger & O'Connor, 2024). Beyond microbiological safety and nutritional quality, it requires systems for donor screening, process control, storage, labeling, batch identification, and traceability (Mattarozzi et al., 2023; Herson & Weaver, 2024). These characteristics shift freeze-dried human milk from merely a food technology issue to an issue of biological material governance and healthcare services.

3.2. Legal Qualification: Why a Single Category is Insufficient

If freeze-dried human milk is classified solely as food, there is an advantage of a simplified regulatory regime and proximity to its enteral function. However, this approach immediately reveals fundamental flaws. Human milk originates from the human body, involves donors, requires eligibility selection, and carries potential biological risks (Blackshaw et al., 2021). Ordinary food does not require donor consent, coding, traceability, or vigilance, which are critical for donor human milk. Therefore, a pure food regime is overly reductionist and incapable of capturing the full scope of risks and legal relationships inherent to this substance.

Conversely, classifying it as a substance of human origin possesses a stronger ontological and functional foundation. The WHO promotes global harmonization for medical products of human origin, while comparative studies highlight ethical and operational similarities between human milk banking and the governance of blood, tissues, and cells, specifically regarding donor suitability, quality assurance, coding, traceability, and biovigilance (Herson & Weaver, 2024; McGrath et al., 2024). Regulation (EU) 2024/1938 concerning Substances of Human Origin (SoHO) also signals that human-derived materials require specific quality and safety oversight. From a health law perspective, the substance of the human origin framework is best equipped to ensure the protection of donors and recipients during collection, processing, storage, and distribution.

Nevertheless, the substance of the human origin framework should not be applied mechanically. Human milk is not used like blood for transfusions or tissues for transplantation. It is administered enterally, and its dominant function remains nutritional (Sánchez et al., 2021; Israel-Ballard et al., 2024). If the regulatory model rigidly mimics tissue banking, there is a risk that regulations become too burdensome, losing sensitivity to nutritional composition, reconstitution instructions, and integration into neonatal feeding practices.

A third option is positioning freeze-dried human milk as a medical product. This category is appealing because the product is most likely used in healthcare facilities, for vulnerable patients, with high-quality requirements. However, doctrinally, the term "medical product" is broad and imprecise. It can overlap with pharmaceuticals, medical devices, or other health products, each carrying distinct licensing and claim consequences. If freeze-dried human milk is entirely drawn into the medical product

regime, there is a danger of excessive medicalization of a biological substance that remains rooted in the relationship of breastfeeding and altruistic donation (Modi, 2024; Rusi et al., 2024; Steele et al., 2025).

Thus, the primary problem is not choosing a single administrative label, but determining the regulatory configuration most capable of simultaneously protecting infant safety, donor dignity, service integrity, and legal certainty. From this viewpoint, freeze-dried human milk is more accurately understood as a hybrid legal object: it exhibits food-like properties as it is consumed enterally, properties of a substance of human origin because it derives from the human body, and dimensions of a health product because its use can be integrated into the clinical management of vulnerable infants (Herson & Weaver, 2024; Unger & O'Connor, 2024).

3.3. Ethical Dimensions of the Legal Qualification of Human Milk

The legal qualification of freeze-dried human milk cannot be separated from its ethical dimensions. Human milk is not merely a nutritional fluid, but part of reproductive labor, the female body, and care relations (Modi, 2024; Rusi et al., 2024; Steele et al., 2025). When human milk is processed into a stable form that is easier to transfer, store long-term, and exchange, its ethical meaning also changes. A donation initially understood as an act of direct solidarity can shift into the supply of raw biological material for a more institutionalized system, or even one with economic value.

In this context, a donor's informed consent cannot be adequately framed as a general agreement to "give human milk." Written consent must be specific regarding potential processing, long-term storage, cross-facility distribution, and use in the form of a freeze-dried product (Unger & O'Connor, 2024). If a donor only understands that her milk will be given altruistically to a specific infant, while the system subsequently processes it into a stable product for wider circulation, a mismatch occurs between the donor's intent and actual use. From a bioethics and health law perspective, such a mismatch invalidates the consent.

The aspect of distributive justice is equally critical. Globally, human milk banking remains inequitable and unevenly available (Israel-Ballard et al., 2024). Freeze-drying technology has the potential to improve logistics, but without an equitable priority design, it may exacerbate inequality, as more stable products tend to hold higher economic value. Justice demands that access priority be determined by clinical need and public health interests, not solely by purchasing power or institutional strength (Wiley, 2015).

The most serious concern is commodification. Recent literature defines the commercialization of human milk as the process wherein human milk or its components are packaged and sold for financial gain, posing the risk of shifting human milk from a social good to a biological commodity (Pramono & Hikmawati, 2024; Rusi et al., 2024). Critiques of the commercial human milk industry highlight strategies of market creation, marketing to hospitals, and the potential repetition of the historical patterns of the formula industry (Rollins et al., 2023; Modi, 2024; Shenker et al., 2024; Steele et al., 2025). In this framework, the prohibition of buying and selling donor milk is not merely a moral choice, but a legal instrument to prevent the potentially exploitative extraction of value from the donor's body.

Another ethical issue is ensuring that donor milk and its derivatives do not undermine support for the concept of a mother's own milk. Comparative studies emphasize that the need for donor milk can be reduced if the health system optimally supports maternal lactation (Israel-Ballard et al., 2024). Therefore, freeze-drying technology must be positioned as a limited, clinical buffer intervention, rather than a structural substitute for breastfeeding protection policies. Otherwise, innovation risks shifting the policy focus from mother-infant support to product-supply logic.

3.4. Indonesian Regulatory Gaps and Hybrid Governance Framework

Indonesia has laid an important foundation through Law Number 17 of 2023 and Government Regulation Number 28 of 2024 (Republic of Indonesia, 2024). Both instruments recognize human milk donation, require consent and clear donor identification, link donations to health considerations, and reject buying and selling practices. In principle, this demonstrates that the state views human milk donation as a permissible health act that must be ethically and legally bounded. The issue is that the current national framework remains at the level of normative recognition and has not yet established an oversight architecture for further-processed donor milk. Donation norms do not automatically answer questions such as: how freeze-drying processing standards should be determined; who the primary regulator is, whether facilities must be accredited, how batch identification and adverse event reporting are conducted, the extent to which cost recovery is permitted, and who bears liability in the event of contamination or mislabeling (Herson & Weaver, 2024; Unger & O'Connor, 2024).

The absence of detailed regulations is dangerous because the Indonesian context is also characterized by the immaturity of formal human milk banks and the persistence of informal donor practices within society (Sproat, 2023; Pramono & Hikmawati, 2024). Under these circumstances, the regulatory void can trigger two simultaneous risks: first, unsafe informal practices; second, covert commercialization using terms like "processing fees," "distribution fees," or "service fees." Substantively, these mechanisms can be utilized to circumvent the prohibition on buying and selling (Modi, 2024; Steele et al., 2025).

The subsequent gap relates to consent. Government Regulation Number 28 of 2024 mandates consent but has not differentiated the scope of consent between liquid donor milk for immediate use, pasteurized milk, long-term frozen milk, or lyophilized (freeze-dried) milk (Republic of Indonesia, 2024). The higher the degree of processing, the greater the need for detailed and informational consent. Without this differentiation, donor protection remains minimal. Consequently, it can be stated that Indonesian law has recognized human milk donation but is not yet equipped to regulate freeze-dried human milk as a modern health regulatory object. This vacuum must be filled before technological innovation outpaces the law.

Based on the analysis, a hybrid governance model is proposed in which freeze-dried human milk is not confined to a single legal category but regulated through three interconnected layers. The first layer is the governance of substances of human origin, which prioritizes donor-recipient protection through donor selection, screening, specific informed consent, processing controls, testing, coding, traceability, storage, distribution logs, and biovigilance systems (Herson & Weaver, 2024; McGrath et al., 2024). The second layer is an enteral food safety interface that ensures standards for composition, stability, labeling, reconstitution instructions, and storage management, reflecting its mode of administration while maintaining its human-derived specificity (Shenker et al., 2024; Unger & O'Connor, 2024). The third layer is clinical governance, which links its use to clinical indications for preterm, low-birth-weight, or sick infants, alongside facility competence, quality assurance, access prioritization, and integration with lactation support policies to prevent market distortion (Rochow et al., 2025; Sproat, 2023). This framework is complemented by a tiered classification distinguishing mother's own milk, donor milk within clinical systems, processed donor milk including pasteurized and freeze-dried forms, and potential commercial derivatives, where each tier reflects different risk levels, consent requirements, distribution mechanisms, and regulatory intensity, with stricter controls justified as human milk moves further from direct mother-infant relations toward more processed and transferable forms.

Table 1. Matrix of the Legal Qualification of Freeze-Dried Human Milk in Indonesia

Regime	Strengths	Weaknesses	Regulatory Implications
Food	Aligns with enteral function and nutritional aspects.	Inadequate for donor screening, traceability, and vigilance.	Prone to being under-regulated.
Substance of Human Origin	Strongest for donor suitability, quality assurance, coding, and biovigilance.	Risks closely mimicking tissue banking if applied rigidly.	Most appropriate as the primary layer of governance.
Medical / Health Product	Captures the clinical context for vulnerable infants in healthcare facilities.	Has the potential to cause excessive medicalization.	Relevant for limited clinical usage.

Table 1 shows that the food regime is inadequate due to weak donor screening, traceability, and biovigilance, making it prone to under-regulation despite aligning with nutritional function. The substance of the human origin regime is the most appropriate primary framework as it ensures donor suitability, quality assurance, coding, and safety monitoring, though it risks overly rigid application similar to tissue banking. The medical/health product regime is relevant for clinical use in vulnerable infants but may lead to excessive medicalization of a biologically derived nutritional substance (Herson & Weaver, 2024).

Indonesia requires a tiered operational definition distinguishing mother's own milk, donor human milk, processed donor human milk, and human milk derivative products to prevent both over- and under-regulation. Minimum national standards should be established for further-processed donor milk, including freeze-dried forms, covering donor selection, rejection criteria, health and laboratory screening, processing methods, quality parameters, batch identification, labeling, storage, transportation, recall, and adverse event reporting (Herson & Weaver, 2024; Unger & O'Connor, 2024). A tiered informed consent model is also necessary, ensuring that consent for donor milk explicitly covers processing such as lyophilization, storage duration, and cross-facility distribution, rather than being treated as equivalent to simple milk donation.

The prohibition of buying and selling donor milk must be operationalized through clear rules distinguishing legitimate cost recovery from profit-based commercialization, supported by transparency requirements, financial audits, and restrictions on profit-oriented markups (Modi, 2024; Shenker et al., 2024; Steele et al., 2025). Regulatory oversight should be assigned to a designated authority with cross-sectoral coordination, given the hybrid nature of freeze-dried human milk, integrating governance of substances of human origin, enteral safety standards, and neonatal care regulation. The overall framework must also reaffirm that mothers' own milk remains the priority, while donor milk, including freeze-dried variants, functions only as a clinical buffer and not as a substitute for breastfeeding protection policies (Israel-Ballard et al., 2024; Rochow et al., 2025).

4. Conclusion

Freeze-dried human milk exists at the intersection of food, substances of human origin, and health products, making single-category classification inadequate. A food regime is too limited to capture donor-related biological risks; a substance of human origin framework provides the strongest foundation for biological safety but requires integration with enteral consumption safeguards, while a medical product regime is relevant in clinical settings, yet risks excessive medicalization of a primarily nutritional biological substance. In Indonesian health law, the most defensible

position is therefore a hybrid regulatory approach that integrates these three dimensions. Although Indonesia has established a normative basis for human milk donation, it has not yet developed a comprehensive framework for further-processed donor milk, resulting in regulatory gaps concerning safety standards, consent specificity, traceability, and governance mechanisms.

The implication of this study is that regulatory development should move beyond rigid legal categorization toward a layered hybrid governance model that simultaneously ensures infant safety, protects donor rights, guarantees equitable access, and prevents exploitative commodification of human-derived biological materials. Such an approach is necessary to accommodate technological developments in human milk processing while maintaining ethical and legal safeguards within the health system. However, this study is limited to normative legal analysis and does not include empirical data on implementation practices, institutional readiness, or stakeholder experiences within Indonesia's human milk donation ecosystem. Future research is therefore needed to examine empirical governance capacity, regulatory enforcement challenges, and comparative practices in jurisdictions with established human milk banking systems to further validate and refine the proposed hybrid model.

References

Blackshaw, K., Valtchev, P., Koolaji, N., Berry, N., Schindeler, A., Dehghani, F., & Banati, R. B. (2021). The risk of infectious pathogens in breast-feeding, donated human milk, and breast milk substitutes. *Public Health Nutrition*, *24*(7), 1725–1740. https://doi.org/10.1017/S1368980020000555.

Cohen, M. (2021). *Freeze-dried bodies: the return of powdered human milk*. Counter Magazine. Retrieved on January 20, 2026, from https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3986379.

Dogan, A. B., Marsh, S. R., Tschetter, R. J., Beard, C. E., Amin, M. R., Jane Jourdan, L., & Gourdie, R. G. (2025). Stabilizing milk-derived extracellular vesicles (mEVs) through lyophilization: A novel trehalose and tryptophan formulation for maintaining structure and bioactivity during long-term storage. *Journal of Biological Engineering*, *19*(1), 4-15. https://doi.org/10.1186/s13036-024-00470-z.

European Parliament and Council. (2024). *Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC*. Retrieved on October 24, 2025, from http://data.europa.eu/eli/reg/2024/1938/oj.

Hahn, W. H., Bae, S. P., Song, S., Park, S., Lee, J., Seo, J. B., & Kang, N. M. (2020). The freeze-drying does not influence the proteomic profiles of human milk. *The Journal of Maternal-Fetal & Neonatal Medicine*, *33*(12), 2069–2074.

Herson, M., & Weaver, G. (2024). A comparative review of human milk banking and national tissue banking programs. *Maternal & Child Nutrition*, *20*(S4), 1-8. https://doi.org/10.1111/mcn.13584.

Israel-Ballard, K., LaRose, E., & Mansen, K. (2024). The global status of human milk banking. *Maternal & Child Nutrition*, *20*(4), 35-52. https://doi.org/10.1111/mcn.13592.

Machado, D. H. F., Vignoto, M. F. M., da Silva, L. M., Bombonato, L. M., dos Santos, A. C. B., Bolognese, M. A., ... & Alexandre, V. (2025). Human milk and human milk banks: advances, challenges, and innovations in neonatal food conservation and safety. *Editora Impacto Científico*, *8*(4), 1-10.

Martysiak-Żurowska, D., Rożek, P., & Puta, M. (2022). The effect of freeze-drying and storage on lysozyme activity, lactoferrin content, superoxide dismutase activity, total antioxidant capacity and fatty acid profile of freeze-dried human milk. *Drying Technology*, *40*(3), 615–625. https://doi.org/10.1080/07373937.2020.1824188.

Mattarozzi, M., Laski, E., Bertucci, A., Giannetto, M., Bianchi, F., Zoani, C., & Careri, M. (2023). Metrological traceability in process analytical technologies and point-of-need technologies for food safety and quality control: Not a straightforward issue. *Analytical*

and Bioanalytical Chemistry, *415*(1), 119–135. https://doi.org/10.1007/s00216-022-04398-5.

McClanahan, K. G., Reese, J., Weitkamp, J. H., & Olivares-Villagómez, D. (2024). Effects of pasteurization on osteopontin concentrations in human breastmilk. *Pediatric Research*, *95*(3), 641–646. https://doi.org/10.1038/s41390-023-02838-1.

McGrath, E., Herson, M., Kuehnert, M., Moniz, K., Szczepiorkowski, Z., & Pruett, T. (2024). A WHO remit to improve global standards for medical products of human origin. *Bulletin of the World Health Organization*, *102*(10), 707–714. https://doi.org/10.2471/BLT.24.291569.

Modi, N. (2024). Repeating the errors of the past: The hazards of a commercial human milk industry. *Pediatric Research*, *95*(6), 1480–1482. https://doi.org/10.1038/s41390-023-03004-3.

Negara, T. A. S. (2023). Normative legal research in Indonesia: Its originis and approaches. *Audito Comparative Law Journal (ACLJ)*, *4*(1), 1-9. https://doi.org/10.22219/aclj.v4i1.24855.

Pramono, A., & Hikmawati, A. (2024). Donor human milk practice in Indonesia: A media content analysis. *Frontiers in Nutrition*, *11*(5), 144-164. https://doi.org/10.3389/fnut.2024.1442864.

Rahman, F., Margaretha, & Sapsudin, A. (2025). Legal issues in limiting authority of health professional organizations after Indonesia's 2023 health law enactment. *Research Horizon*, *5*(4), 1501–1512. https://doi.org/10.54518/rh.5.4.2025.704.

Republic of Indonesia. (2023). *Law Number 17 of 2023 concerning Health.*

Republic of Indonesia. (2024). *Government Regulation of the Republic of Indonesia Number 28 of 2024 concerning the Implementing Regulation of Law Number 17 of 2023 concerning Health.*

Rochow, N., Weiss, G. A., Knab, K., et al. (2025). Freeze-dried donor milk for fortification of mother's own milk in preterm infants: A preliminary observational study. *Nutrients*, *17*(19), 30-57. https://doi.org/10.3390/nu17193057.

Rollins, N., Piwoz, E., Baker, P., Kingston, G., Mabaso, K. M., McCoy, D., ... & Hastings, G. (2023). Marketing of commercial milk formula: a system to capture parents, communities, science, and policy. *The Lancet*, *401*(15), 486-502. https://doi.org/10.1016/S0140-6736(22)01931-6.

Romero-Bachiller, C., & Santoro, P. (2023). The cryopolitics of human milk: Thermal assemblages of breast milk in donation, banking, and bioindustrial research. *Science, Technology, & Human Values*, *48*(4), 805–831. https://doi.org/10.1177/01622439221100868.

Ross, F. C., & Waltz, M. (2016). Milk, meaning, and morality: following the trajectory of donated breast milk from donor to baby. *Medicine Anthropology Theory*, *3*(3), 22-33.

Rusi, H. C., Grummer-Strawn, L., Perrin, M. T., Risling, T., & Brockway, M. L. (2024). Conceptualizing the commercialization of human milk: A concept analysis. *Journal of Human Lactation*, *40*(3), 392–404. https://doi.org/10.1177/08903344241254345.

Sánchez, C., Franco, L., Regal, P., Lamas, A., Cepeda, A., & Fente, C. (2021). Breast milk: A source of functional compounds with potential application in nutrition and therapy. *Nutrients*, *13*(3), 10-26. https://doi.org/10.3390/nu13031026.

Shenker, N., Linden, J., Wang, B., et al. (2024). Comparison between the for-profit human milk industry and nonprofit human milk banking: Time for regulation? *Maternal & Child Nutrition*, *20*(1), 35-70. https://doi.org/10.1111/mcn.13570.

Sproat, T. D. R. (2023). Lyophilized (freeze-dried) human milk for preterm infants: A scoping review. *Journal of Perinatology*, *9*(4), 12-23. https://doi.org/10.1038/s41372-023-01861-8.

Steele, S. L., Cooke, N. C., Stuckler, D., & Kamradt-Scott, A. (2025). The commodification of human milk: Analysing corporate practices and policy implications using the UCSF Industry Documents Library. *Social Science & Medicine*, *7*(4), 118-125. https://doi.org/10.1016/j.socscimed.2025.118875.

Unger, S. L., & O'Connor, D. L. (2024). Review of current best practices for human milk banking. *Maternal & Child Nutrition*, *20*(4), 136-147. https://doi.org/10.1111/mcn.13657.

Wiley, L. F. (2015). *From patient rights to health justice: securing the public's interest in affordable, high-quality health care.* Cardozo Law Review. Retrieved on January 20, 2026, from https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2676336.

World Health Organization. (2023). *Donor human milk for low-birth-weight infants*. Retrieved March 17, 2026, from https://www.who.int/tools/elena/interventions/donormilk-infants.
Wu, S. (2024). *Effect of drying methods on the physicochemical and bioactivities of bovine colostrum and lactoferrin*. Massey: Massey University (Master's thesis).

Acknowledgment
We gratefully acknowledge the contributions of individuals who supported the completion of this article.

Funding Information
This research did not receive any funding.

Conflict of Interest Statement
The authors declare that there is no conflict of interest.

Ethical Approval and Originality Statement
Ethical approval was obtained for this study. The manuscript represents original work and has not been previously published, nor is it under consideration by another journal.

Data Disclosure Statement
The data that support the findings of this study are available from the corresponding author upon reasonable request.