World Breastfeeding Trends Initiative (WBTi)
AUSTRALIA

World Breastfeeding Trends Australia (WBTi-AUS) response regarding human milk

to the Australian Law Reform Commission Review of Human Tissue Laws Discussion Paper

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Who we are

Thank you for the opportunity to respond to the Australian Law Reform Commission Issues Paper: Review of Human Tissue Laws.

Authors

Submission prepared by:

- Dr Libby Salmon, PhD, Australian National University
- Assoc Prof. Julie Smith, PhD, Australian National University, University of Canberra

On behalf of WBTi-AUS team members:

- Ms Naomi Hull (chair), (University of Sydney)
- Assoc Prof. Julie Smith (Australian National University, University of Canberra)
- Dr Libby Salmon (Australian National University)
- Dr Karleen Gribble (Western Sydney University)
- Ms Heather Gale (Lactation Consultants of Australia and New Zealand)
- Ms Decalie Brown (Independent)
- Dr Susan Tawia (Independent)
- Prof. Elaine Burns (Western Sydney University)
- Dr Bindi Borg
- Dr Simone Sherriff
- Dr Kaitlyn Brunacci
- Dr Jennifer Hocking (Australian Breastfeeding Association)

WBTi Australia

The World Breastfeeding Trends initiative – Australia Incorporated (WBTiAUS) is a team of academics, clinicians, and advocates who undertake national assessments of Australian policies and programs intended to support and protect breastfeeding (Box 1). This is achieved by using a globally validated tool utilised by over one hundred countries. The last report was published in 2023, Australia scored 31/100 over ten indicators. This places Australia third from the bottom globally.

Box 1. WBTi Assessment tool indicators

1. National Policy, Governance and Funding
2. Baby Friendly Hospital Initiative / Ten Steps to Successful Breastfeeding
3. Implementation of the International Code of Marketing of Breastmilk Substitutes (WHO Code) and all subsequent World Health Assembly (WHA) Resolutions
4. Maternity protection
5. Health and Nutrition Care Systems (in support of breastfeeding & IYCF)
6. Counselling Services for Pregnant and Breastfeeding Mothers
7. Accurate and Unbiased Information Support
8. Infant Feeding and HIV
9. Infant and young child feeding during emergencies (IYCF-E)
10. Monitoring and evaluation

Further information about WBTi Assessment- Australia
https://www.worldbreastfeedingtrends.org/wbti-country-report.php?country_code=AU

Summary

We are a collective of academics, health professionals, and other experts in breastfeeding and human milk, and human milk sharing practices in Australia and internationally. Human milk sharing is a broad term that includes human milk banking as well as a range of informal arrangements for providing milk to another mother's child (such as through wet nursing or providing expressed milk) which reflect diverse historical and cultural traditions around the breastfeeding of infants and young children (Table 1). These milk sharing practices are now being shaped by modern technologies and contexts which generate concerns and calls for new regulation. (see Background).

Our submission is focused on whether the regulatory scope of human tissue (HT) laws in Australia should exclude "human milk", as proposed in Question 7 of the Discussion Paper.

This is a complex issue that encompasses the human rights of new mothers, infants and young children regarding breastfeeding. There are diverse views within the Australian community on how, if at all, human milk should be regulated by HT laws. As concerned experts who are approaching this question from the viewpoint of ensuring that milk sharing is used safely to expand women's and infants' opportunities to breastfeed, we have significant concerns about how consent and "commercialisation" of human milk – and legal reforms intended to regulate transactions in human milk – may negatively impact women's breastfeeding and milk sharing practices, the availability of breastfeeding and lactation support, and equity of access to breastfeeding and human milk.

Introduction

Human milk is scarce and valuable (1-4). Despite health recommendations for 6 months of exclusive breastfeeding, one third of infants have been fed commercial milk formula (CMF) before leaving hospital, and only one in three is breastfed to 12 months (5, 6). Policies and practices in medical facilities do not meet adequate quality standards for successful breastfeeding (7-9), and in this environment expanding the supply of donor milk risks displacing mothers' own milk and breastfeeding (10). Human milk should be supplied through breastfeeding and the use of expressed milk prioritised for nutrition of infants and young children, and not other purposes. Other purposes include research by CMF companies, treatment of adult cancer patients, performance enhancement for athletes and sexual fetishes (11, 12).

There is a need to consider carefully whether including human milk in HT law is the best approach to improving equitable access to human milk, including the wider implications for breastfeeding women and their children, and unintended consequences. This includes the question of how to regulate transactions such as in "human milk products" (HMP) in a way which strengthens, rather than weakens, the current regulation of commercial milk formulas (CMFs) under Australian food laws (Table 1) (13, 14).

The safety of CMFs consumed by 60% of infants during their first year of life is currently far less scrutinised than the safety of shared human milk despite the comparative risks of CMFs, demonstrated by regular episodes of mass contamination of these products in China, the US and most recently, globally (15-17). Likewise, restrictions on marketing and requirements for consent are far stricter for human milk than CMF, with regard to marketing to the public or health professionals or compliance with ethical standards in medical facilities.

Competition with breastfeeding

A key issue for regulators is the triangulated competition between human milk products, breastfeeding and commercial milk formulas (CMFs) and other breastmilk substitutes[1] (Fig.1). This competition is shaped by the regulation of products as food or human tissues and the extent to which they permit selling and marketing (18-22).[2] Research on donor human milk may promote the dairy and CMF industries, whose marketing and political influence undermine breastfeeding (23), without the consent of the milk donor.

In addressing these issues, we encourage the ALRC to consider how human milk is regulated through Australian food regulatory frameworks, including their strengths and weaknesses. For example, the Australian government intends to mandate current self-regulatory restraints on the marketing of infant formula products, presenting an opportunity for regulation that is world-leading and fit-for-purpose by optimising breastfeeding and access to human milk (24).

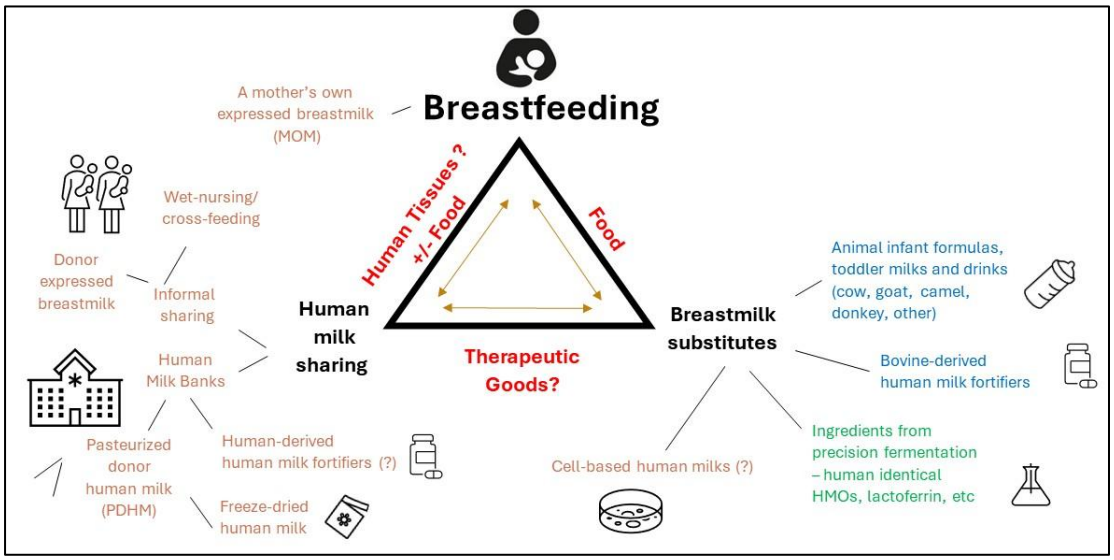

Figure 1. The competition and interdependencies between breastfeeding, human milk sharing (practices and products) and breastmilk substitutes and their alignment with regulatory frameworks for food, human tissue and therapeutic goods. Source: (25).

Many of the terms related to breastfeeding and milk sharing practices (Table 1) are inadequately defined in Australian law and the published literature. The main legal definitions are found in food law, which define "infant formula products" and "food businesses". Common terms such as "breastmilk substitutes" and "commercial milk formula" products (CMFs), which are relevant to the national implementation of the World Health Organization's *International Code of Marketing of Breast-milk Substitutes*,[2] are not legally defined, yet must be consistent with any regulation of human milk through tissues law because these products compete with breastfeeding and human milk for infant "meal share" (26).

[1] Breastmilk substitutes include commercial milk formula (CMFs): infant formula, follow-on formula, toddler milks and growing up milks, which are typically based on cow's milk.

[2] CMFs have been marketed since the 1930s for mothers unable to breastfeed. CMF manufacture and marketing are regulated by national and international food standards, including national implementation of the WHO *International Code of Marketing of Breast-milk Substitutes* and subsequent World Health Assembly Resolutions (the WHO Code) Available at: https://www.who.int/teams/nutrition-and-food-safety/food-and-nutrition-actions-in-health-systems/code-and-subsequent-resolutions

Table 1. Terms used this submission and the literature on human milk

Term	Definition
Breastfeeding	The production and feeding of breastmilk by suckling a child directly at the breast.
Breastfeeding system	Breastfeeding and the sociocultural practices that support it, including some milk sharing practices, and which include factors that operate at individual, community, institutional and societal levels.
Breastmilk	Milk produced by a human mother
Breastfeeding substitute	Any product or practice that displaces breastfeeding (at the breast)
Breastmilk substitute (BMS)	Any product that displaces breastmilk, including commercial milk formulas and cell-based human milks
Cell-based human milk	A collective term for food products made using cell culture and precision fermentation science "which aim to replicate human breastmilk components or whole breastmilk as an alternative to infant formula" (27)
Cell-cultured human milk	Laboratory-produced human milk developed from mammary epithelia cells (28).
Commercial milk formula (CMF)	Includes infant formula products and toddler milks, typically dairy or soy-based
Commercialized human milk	The packaging and sale of human milk and human milk components for financial gain (28).
Directed donation	The use of milk from a known donor under medical supervision in a health facility.
Donor human milk	Milk provided by someone who is not the child's mother
Expressed breastmilk (EBM)	Milk that has been expressed from the breast by hand or a breast pump
Freeze dried human milk	Human milk freeze dried and ready to be reconstituted with water (28).
Human-derived human milk fortifier	Pasteurised human milk-based products administered in addition to human milk, designed to meet the specific needs of premature and low birth weight infants (28).
Human donor milk products	An umbrella term that includes all processed human milks and their derivatives that include: PDHM, commercially sterile human milk stored at room temperature ("shelf-stable"), freeze-dried human milk, human-derived human milk fortifiers, cell-based human milks, ingredients derived from human mammary cells or DNA using cell-culture or precision fermentation technologies, some of which may be added as ingredients to CMFs
Human milk fortifier	Extracts, typically from cow's milk, added to a mother's own milk or PDHM to increase the caloric intake of extremely premature infants in NICUs.
Infant formula products	CMFs regulated by ANZ Food Code Standard 2.9.1 for use by infants from birth to 12 months.
Informal milk sharing	Milk sharing in the community that does not involve a milk bank. These practices include the provision of expressed milk or wet nursing through private arrangements between relatives, friends, acquaintances or strangers. In Australia, donors are typically unpaid and meet face to face with the recipient parents. These practices may be facilitated by social media or health professionals, but do not typically involve donor blood testing or treating milk with heat. Donors typically volunteer information to recipient mothers about their routine antenatal blood testing, health and lifestyle.
Lactation	The normal physiological processes of human milk production as a consequence of pregnancy and birth. Lactation may be stimulated hormonally without pregnancy ("induced lactation")
Maternal breastfeeding	Breastfeeding by an infant's birth mother.
Milk banking	Organizations that collect, store, process and distribute human milk. Most milk banks screen and test milk donors, pasteurise and test milk and supply hospitals. Milk processing may also involve other forms of heat, pressure or freeze drying.
Milk donation	A general term for the provision of human milk for the purpose of feeding another mother's child or other uses
Milk sharing	A broad term that includes "human milk banking" ("milk banking") as well as a range of informal arrangements for providing milk to another mother's child (such as through wet nursing or providing expressed breastmilk)
Mother	Biological or birth mother
Mother's own milk (MOM)	Expressed milk produced by an infant's own mother
Pasteurised donor human milk (PDHM)	Human milk that is pasteurised and frozen by a milk bank.
Toddler milks	CMFs regulated by ANZ Food Code Standard 2.9.3 for use by infants 13-36 months.
Unpaid/altruistic donation	Provision of human milk without payment or reimbursement to the donor
Wet nursing	Breastfeeding another mother's child.

Defining the problem

There is confusion and incoherence on how current laws apply to 'human milk' – is it a food, a tissue, or a uniquely human milk for human babies? And how are CMFs regulated in comparison?

Australia scores poorly on policies for protection, promotion and support for breastfeeding.[3] This has profound implications for women, infants and young children. Breastfeeding is recognised as a human rights issue for women, infants and young children, in relation to maternal employment, and to the health of both mother and child.

In the context of the ALRC review, there is confusion and lack of consistency in how current food and HT laws apply to human milk. For clarity, we recognise that human milk may be included in HT laws through interpretation of the current definition of human tissue or by adding human milk to the definition or subsidiary regulations (as in Victoria and Western Australia). We understand that the ALRC Discussion Paper proposes that HT laws explicitly exclude human milk, (as has occurred in Queensland and Tasmania).

There is a risk that if human milk is included in HT laws, that it will be too broadly interpreted and suppress human milk sharing practices in the community which assist breastfeeding, but will not adequately constrain the use of human milk in the unethical research and development or marketing of CMFs and milk products that function as breastmilk substitutes (29).

Including human milk in HT laws may provide some benefits of limiting potential harms and undesirable practices arising from its commodification and commercialisation, but there is a crucial need to avoid overreach of the law that may cause unintended harms to women, to breastfeeding and to maternal and child health.

Accordingly, **if human milk is included in HT laws, it should only apply to human milk which is collected and distributed as part of formal milk banking systems to vulnerable infants in formal clinical settings such as neonatal intensive care units (NICUs).**
Care needs to be taken to ensure that:

- This does not disrupt non-commercial medically supervised milk donation in health facilities (e.g. "directed donation" in maternity wards), and
- Expanded access to human milk in these settings does not displace breastfeeding i.e. effective lactation support is resourced and provided and donor milk (and CMFs) are not marketed.

One of the unintended harms to breastfeeding is the way various laws frame risk differently for human milk and CMFs, in ways that benefit CMFs (30). Commonwealth law relevant to infant and young child feeding is mainly food law. Food law is applied in regulating the safety and product labelling of CMF products,[4] and in regulating imports of CMFs and human milk products.[5] In the application of these laws, the Commonwealth regulates the safety and sale of human milk products much more tightly than it regulates the safety and sale of CMF. **In combination with HT laws applied by some**

[3] WBTi Assessment- Australia https://www.worldbreastfeedingtrends.org/wbti-country-report.php?country_code=AU
[4] Through the ANZ Food Standards Code under the FSANZ Act 1991 (Cth) administered by Food Standards Australia New Zealand (FSANZ)
[5] Through the Imported Food Control Act 1992 (Cth)

jurisdictions to human milk, Australian legal frameworks currently create an environment in which human milk and practices related to breastfeeding are wrongly seen as more risky than commercial substitutes for breastfeeding, including infant formula. This inconsistency is despite ample evidence that CMF products are high risk for contamination and for aggressive advertising, promotion and marketing (including online and via social media) (31-34).

Other Commonwealth laws may be relevant. The Commonwealth also regulates to protect breastfeeding through sex discrimination laws.[6] In addition, Commonwealth or State/Territory labour and OHS laws, which include protections for breastfeeding, may have relevance for women employed formally as wetnurses (which is rare in Australia).

Human milk banking is mainly regulated through State/Territory food regulation and the policies and practices of their health services and voluntary compliance with 2022 *Operational Guidelines for Milk Banks in Australia and New Zealand* (35). This mix of regulations incorporate elements of HT law, medical ethics and food safety practices in order to meet the unique characteristics of human milk and the health settings which milk banks service. In most jurisdictions, State/Territory health and food authorities typically licence milk banks, consistent with requirements for food businesses. We note that food licencing enables exemptions for less risky and non-businesslike activities by individuals, including community-based activities such as fetes.

For informal milk sharing practices, which do not typically involve selling or other commercial transactions in human milk, any risky practices may fall under common law if identifiable harm results to individuals, but we are not aware of such incidents in Australia.

In some jurisdictions, such as Western Australia which pioneered human milk banking in Australia, HT law has been applied to milk banking.[7] This ensured its successful establishment and acceptability to health professionals, with high standards of safety and ethics, and enabled the human milk bank to recover costs. In other jurisdictions, human milk banking is unregulated, or is regulated by food laws (e.g. NSW). As stated earlier, Queensland and Tasmania HT laws exclude human milk.[8]

A Commonwealth issues paper in 2014 did not take a strong position on the best way to regulate donor milk (36), but subsequent guidelines for milk banks underpin their operation– whether they are in hospitals or independent (35). These guidelines regulate matters such as safe collection and use, consent, privacy, cost reimbursement and advertising by milk banks. Notably, consent is specific, and this is desirable for women who intend their altruistic donations to benefit other mothers and infants, not CMF companies or commercial human milk products. Adverse events in milk banking are recorded and very rare (37). Adverse events associated with human milk in hospitals typically involve very small health risks arising from accidentally giving another mothers milk to a baby.

In contrast, the comparative risks of non-human milk feeding, lack of consent for CMF use, or CMF marketing in health systems are poorly documented, largely unenforced and rarely considered in health policymaking or regulation.

[6] Sex Discrimination Act 1984 (Cth) - S7AA.
7 Human Tissue and Transplant Act 1982, Human Tissue and Transplant Regulations 2024 (WA)
[8] Transplantation and Anatomy Act 1979 and Health and Other Legislation Amendment Act 2022,(Qld); Human Tissue Act 1985 and Human Tissue Amendment Act 2024 (TAS).

There are some problems in current milk banking regulatory arrangements which it may be beneficial to address, but not without a wider comparative perspective and consideration of whether they create further barriers to breastfeeding.

Human milk – what is it?

Human milk is primarily **a food** providing species-specific milk for human babies, with hormonal and immunological components for their normal growth, development and protection. It includes **human cells**, including forms of stem cells, and is produced by glands in **an organ** – the breast of a lactating **body** of a woman, who has given birth to an infant, in a relationship described as the **breastfeeding dyad**, and influenced by sociocultural and political economic determinants, described as the **breastfeeding system**.

These features are **unique to human milk**, and justify an approach to its regulation which fully reflects its medical, nutrition, commercial and social complexities.

Regulation of human milk as a human tissue in Australia – expedient but narrow

There is no uniform regulatory framework for human milk internationally (28, 38-41). The WHO considers human milk as a 'substance' in its consideration of principles for regulation of Medical Products of Human Origin (MPHO) which are intended for clinical application (42, 43). Such products include organs, blood, human tissue, eggs and sperm – hence applying strong principles of ethics and safety in such treatments (these also exclude payment, including for blood products) (44). The European Union counts human milk in its regulatory framework for tissues, blood and cells (45), but excludes human milk collected or used outside of formalised settings: cost reimbursement is allowed and reward is permitted for both non-profit and commercial providers but with strict safety and ethical standards including on marketing activities. Program for Appropriate Technology in Health (PATH)[9] has advocated for human milk to be regulated in its own right – as human milk, with an integrated approach across health and community settings to ensure human milk banks operate as a bridge to breastfeeding not a substitute for it (40, 46, 47). In northern European countries and the UK, milk banking is integrated into newborn care - with milk donor costs reimbursable (38). By contrast in the US and Canada, not for profit milk banks set standards requiring altruistic donation (to keep their costs down) while selling milk to hospitals at high prices.[10]

Medical associations provide limited guidance on informal milk sharing, with varying positions on its safety (48-54). It is well accepted across these diverse governance and policy approaches, that purchasing shipped human milk from strangers located online is unsafe (55-60), while on the other hand informal milk sharing is outside the practical scope of regulations addressing human milk banking.

It is also accepted that breastfeeding is the optimal way to feed infants and young children, and mothers' own milk (MOM) is preferable for infants that cannot be breastfed, even if donated human milk (DHM) from a milk bank is available (61, 62). Successful establishment of breastfeeding requires being fully supported by policies and practices in maternal and newborn care facilities: just as CMF can displace breastfeeding or mothers' own milk (MOM), so too can donor human milk (10, 63, 64).

[9] https://www.path.org/
[10] Human Milk Banking Association of North America

Regulation of human milk through HT laws could benefit mothers, children and breastfeeding if the reforms introduced requirements to help prevent donor human milk prevent displacement of breastfeeding/MOM.

Consent and human milk products in medical settings

Human milk provided to vulnerable infants in medical settings is regulated in some global and national contexts as a 'human tissue' rather than a food (38, 39, 43, 65-69). This is primarily to ensure its ethical and safe use as a clinical intervention in **formal clinical settings** treating **premature infants**. In those settings, CMFs are pervasive and consent for their use is often perceived as unnecessary, yet consent requirements for collecting and using human milk is strict.

One area of consent requirements that are not strict in current HT laws is the use of donated human milk for research purposes. Women who donate their milk intending to help other mothers and their vulnerable infants may not give specific consent for its use in research or other uses (even if designated 'waste' or 'discarded' milk)[11]. This may include research by companies on components of human milk to manufacture or market CMFs or other novel food and biopharma products claiming to replicate components and benefits of human milk (e.g. synthetic arachidonic acid (ARA), human milk oligosaccharides (HMOs) and lactoferrin)[12] (Fig 2).

Figure 2. International Milk Genomics Consortium research partners include companies that manufacture CMF and commercial human milk products and industry and research organisations, including those in Australia. Source: https://www.milkgenomics.org/partners/ (Accessed 12 February 2026)

[11] For example, donated milk that does not meet the testing standards or storage times for feeding vulnerable premature infants.
[12] Companies include: Helaina; TurtleTree; Wilk; Checkerspot; Conagen (accessed 11 February 2026)

In Australia, human milk may fit the definition of State/Territory human tissue laws as a "substance extracted from the human body," but it is unclear how the objects of the law for consent for **removal** of human milk and its **transplantation** apply to a breastfeeding/lactating female[13] producing or donating human milk through breastfeeding and milk sharing (70-72). It is also unclear how HT law's protection of those who "remove" tissue apply to breastfeeding women as "donors" or "recipients" through offence provisions for "unauthorised removal" of human tissue, or its "transplantation," and requirements for medical certification.

Furthermore, breastfeeding is recognised as a human rights issue for infants (recipients of human milk) as well as mothers (donors of human milk), and the relationship between the mother and child in the breastfeeding dyad must be accounted for (73-76).

Accordingly, including human milk in HT laws adds confusion about consent, prohibitions on commercialisation, advertising and non-disclosure when applied to human milk donation in health or medical settings and informal milk sharing in the community between individual mothers.

Human milk is unique and requires a unique regulatory approach

In general, human milk and breastfeeding are not well-suited to the current structure of HT laws. However, if human milk is included in HT laws, there is potential value in targeted law reform to address policy and public concerns about:

- The importance of requiring specific donor consent for uses such as research.
- Prohibitions on commercialisation that prevent milk donors receiving reasonable compensation for costs – permitted in some other countries – yet enable corporate entities to benefit from procuring human milk at zero cost and selling it for reward, financial gain or profit to health, medical or research facilities.[14]

Other concerns with including human milk in HT laws are:

- Prohibitions on 'advertising', which may have restrict willing donors and recipients finding each other in informal arrangements, or in disasters and emergency situations.
- Non-disclosure requirements, which could prevent donors and recipients sharing information about their health status or other relevant information that is necessary for informed and safe informal milk sharing, or adherence to religious or cultural rules about "milk kinship".

On the other hand, if HT laws exclude human milk, a consequence may be inadequate protections around consent, commercialisation and advertising in health settings.

[13] Henceforth described as mother or woman, acknowledging that some women who give birth identify their gender as "man" or a "woman." Breastfeeding is conceptualized as "sexed" care work (70), while lactation and milk sharing can cross gender boundaries and diverse family structures (71-72).

[14] Here it is worth comparing the business models of two milk banks, Lifeblood and Prolacta. The former is an Australian non-commercial entity that benefits from obtaining donated human milk at zero cost and selling it to facilities at high prices. The latter is a US commercial entity that benefits from obtaining donated human milk from women in the US by a reimbursement of costs of around $1 an ounce (comparable with the cost reimbursement paid to milk bank donors in northern Europe) and selling it to facilities for even higher prices after more intense processing of larger quantities of human milk. Should donation be altruistic or cover donor costs when milk is provided to commercial not for profit or for profit entities? Furthermore, in the case of for-profits, should donors receive a more proportionate share of those profits (akin to a co-op model)?

- We note that Australian guidelines require milk banks to obtain specific donor consent for research on their milk. These guidelines are mandatory but not statutory and compliance is not enforced (35). However, consent requirements for donors of human milk are not part of Australian food regulations. The lack of clarity around these issues is especially problematic for vulnerable mothers and newborns who are patients in health care settings, including premature infants and mothers experiencing difficulties in establishing breastfeeding.[15]
- In practice, some protections take effect through medical ethical requirements for consent in some state/territory health policies, hospital protocols and health professional guidelines. However, these protections may not apply outside medical settings or in informal arrangements.
- Potential risks associated with paying donors depend on many factors, including the form and rate of payment e.g. in kind, a fixed amount per litre to cover costs or market rates that enable reward/gain/profit). While financial transactions may incentivise some women to produce surplus milk and enable poor women to breastfeed (77), the risk of exploitation and potential harms include: inadequate human milk feeding of the donor's infant, adulteration of milk, the donor not disclosing her health status, coercion of women and encouraging "middle men." In addition, health professionals and mothers with experience of informal milk sharing express a concern that financial transactions would erode the trust necessary for these systems to function safely and be contrary to social norms for volunteering and altruistic tissue donation, which are strong in Australia (78).

If human milk is included in HT laws, the ALRC might like to consider how to constrain the reach of these laws, and their objects, to ensure consistency across other areas. Further considerations include:

- If HT laws are applied, human milk needs to be treated separately because it is uniquely and primarily a food for infants.
    - Like the provisions for blood and oocytes (egg donation), human milk needs special treatment if it is to be regulated as part of HT laws (without needing to cover the high risk activities of organ donation and transplant) (66, 79).
- Safety risks are greatest for premature or sick, and newborn infants receiving medical treatment, and systematic ethical risks are heightened by organisational incentives for financial gain through exploitation of donors, advertising and marketing, and unethical research.
- The use of human milk for adult patients with specific diseases or conditions, but which diverts milk supplies away from infants and young children.
- There are also issues of gender bias in bodily autonomy if women's informal milk sharing activities are to be covered by the strict requirements of HT laws but informal sharing of semen is not (80).
- The human rights of mothers and children to health and breastfeeding remain unaddressed in surrogacy laws.

In raising these matters, we ask the ALRC to consider:

[15] Mothers who have given birth under surrogacy arrangements may be coerced either to breastfeed or prevented from breastfeeding the newborn, depending on the preferences of the other parties to the surrogacy agreement. Similarly, milk sharing by the surrogate mother may be coerced or through consent. In this submission we do not give further consideration to the situation of surrogate mothers, who have the same rights as other birthing women. Surrogacy law is currently under consideration by the ALRC, and it is important that it include full investigation of issues regarding breastfeeding/breastmilk, human milk, or milk sharing in surrogacy arrangements, in the context of human rights to breastfeeding for both maternal and child health.

1. Our concerns that there is not overregulation of informal milk sharing
2. How to strengthen regulation against inappropriate or non-medically indicated commodification or commercial uses in formal health or medical settings, including for purposes other than infant nutrition; and
3. The regulation of human milk using a comparative perspective, with regulation of consent, food risk and safety, and advertising, promotion and marketing of CMF products.[16]

Implications and unintended consequences of applying human tissue laws to human milk

We raise the following issues concerning proposals in the ALRC Discussion Paper, should human milk be included in HT laws.

Legal definitions and purposes

HT laws risk capturing maternal breastfeeding and provision of a mother's own milk to her child, and informal milk sharing between parents (mothers). Informal milk sharing arrangements contribute to resilient breastfeeding systems and are valued by mothers unable to access milk banks. Accordingly, HT laws should not cover human milk donation that is not medicalised (i.e. is outside medical supervision or a medical setting), for example informal milk sharing between mothers in the community.

In addition, HT laws currently fail to properly address the *purposes* of human milk use for infant nutrition. This depends on the definition of "medical purposes" and whether it includes breastfeeding and the provision of expressed human milk.

Legal frameworks

The value of a uniform Commonwealth law and regulatory structure, including a National Regulator, for human milk as a human tissue is not clear in relation to human milk donation and breastfeeding.

- Current variation in the application of HT laws to human milk between jurisdictions has added regulatory costs and restricts access to human milk banking. Consistent laws and federal oversight may provide more equitable access. However, applying HT laws to milk risks regulating human milk more strictly than CMFs, which would misrepresent their relative health risks (30, 81).
- Development of regulatory structures affecting breastfeeding and breastmilk, including in relation to the use of human milk outside the breastfeeding dyad should be through processes and institutions which facilitate consultation with experts in breastfeeding, human milk sharing and human milk products. We have concerns that a National Regulator – especially with wide powers and flexibility to redefine the scope of the term "human milk" – would simply give greater access and influence to CMF companies in policymaking at the expense of health professionals, public health and community-based breastfeeding advocates.
- There is also a need to consider controls on trade in human milk, including the importation and marketing of donor human milk products (29, 39, 77, 82). These are currently more strictly regulated than imported CMF products, which is inappropriate.

[16] WBTIAus assesses policies on breastfeeding, including regulation of marketing in health facilities as well as to the public. It also assesses policies and practices related to informed consent, milk banking, and infection risk in this wider context, and concludes on the need for human rights, evidence based and coherent policies and their implementation to better enable breastfeeding in Australia.

- Currently, Australia lacks a national framework for the governance of human milk banks that is coherent with national breastfeeding policy. In this context a human tissues framework applied to milk banking may raise awareness of the value of donor human milk. In other jurisdictions, such as in Brazil, a strong national framework for the governance of milk banking helps protect, promote and support breastfeeding, including from marketing of human milk products and CMFs (83-85). The ethics and safety of these products are not adequately addressed by food regulation in Australia, which offers no restraints on competition with breastfeeding and breastmilk/MOM in community or healthcare settings.
- Commonwealth oversight risks centralising power over women's bodily autonomy and human and reproductive rights to breastfeed and share milk. At present, diverse approaches in different jurisdictions provides some protection against overreach.

Equitable access

While nearly all Australian women initiate breastfeeding, many wean sooner than they intended; around one third of infants are discharged from hospital having received CMF, which reduces the likelihood of breastfeeding as recommended. Mothers and babies who are socially or economically disadvantaged, or have specific medical conditions or birth complications, are more likely to lack support and be deprived of access to breastfeeding and breastmilk, and to donated human milk in healthcare settings.

Proposed provisions for equitable access to human milk in HT law are therefore consistent with human rights to breastfeeding, wider use of donor human milk in healthcare settings, and principles of health equity, particularly if they progress implementation of improved quality standards for breastfeeding support in maternal and newborn care facilities (86).

- Our WBTIAus Assessment reports note the persistent deficiencies in Australia's implementation of the Baby Friendly Hospital Initiative, which extends to breastfeeding and lactation support in NICU settings and use of donor human milk.[17] We note specific barriers regarding donor access to milk banks and recipient access to donor milk in hospitals, and outdated protocols for protecting breastfeeding and access to human milk in the case of specific medical conditions or in disasters and emergencies.

Consent

Explicit consent should be required for use of both CMF and donor human milk in medical facilities.

Specific consent should also be required for the use of donor milk in research (35, 87, 88). This includes the use of human milk provided to tissue collections, for example milk biobanks, which develop or manufacture commercial human milk products that function as CMF and undermine breastfeeding (27, 89, 90).

Consent between donors and recipients in informal milk sharing arrangements is implied and sufficient; it should remain in the private sphere and regulated by contract law and the principles of common-law tort. NHMRC guidelines provide information on safe milk expression and storage of breastmilk, but no information on safe practices related to informal milk sharing (62). Guidance on

[17] https://www.worldbreastfeedingtrends.org/wbti-country-report.php?country_code=AU

safety is available from several sources, but some of these are obscure, out of date or do not provide advice on emerging human milk products.[18]

Informal milk sharing typically occurs between those known to each other such as friends or relatives, and where the donor's own baby is still breastfed providing greater assurance for recipients about safety, and on the wellbeing of the donor's infant. Facebook groups facilitate connections between mothers needing human milk and those willing to donate, and typically involve face to face engagement and sharing relevant information about their health status. In cultures in which wet-nursing is normal, consent may be implied, noting however that occasionally, these cultural expectations may feel coercive to some individuals.

Directed donation of milk (with a known donor under medical supervision in health facilities) can assist mothers having difficulties breastfeeding but not wanting to use CMF. Regulatory reform on human milk in health and medical contexts should take account of such arrangements and ensure that breastfeeding/MOM is prioritised.

Commodification and commercialisation of human milk

The increasing extent of commodification and commercial human milk has potential effects on breastfeeding at the level of individuals and healthcare settings, as well as in wider society. Applying concepts of commodification and commercialisation to human milk reveal the complexity of the issues involved in regulating it through the narrow lens of HT law.

Valuing breastfeeding and human milk

Commodification of women's breastfeeding and lactation in various contexts highlights how the labour of women is undervalued and regulated by law as well as social and institutional norms in Australian society (77). Proposals to include human milk in HT laws imply prohibition of the exchange of human milk for reward, should consider principles which allow reasonable cost reimbursement of donors, as in in European regulation, in ways that do not weaken informal milk sharing systems (39, 45, 91, 92). Similarly, advertising for donors or to promote use of human milk would not be permitted. These aspects need detailed consideration to ensure women's autonomy and human rights on breastfeeding are protected, and the protection, promotion and support for breastfeeding in healthcare and in the community is not undermined.

There is an argument that the value of breastfeeding and human milk for infants and young children and to population health should be recognised by permitting cost reimbursement of donors, while the exchange of human milk for reward (whether by a not for profit or for profit entity) should be limited to medical settings. Prohibiting remuneration for providing human milk could remove a form of paid care work historically available to women, raising concerns about economic rights and reproductive justice (77, 82, 93-98).

[18] The Australian Breastfeeding Association Position statement on donor milk (2021); The Australian College of Midwives Position statement on the use of human donor milk. (2014, revised 2017); The Academy of Breastfeeding Medicine Position statement on informal breast milk sharing for the term healthy infant (2017); Australian Government Pregnancy, Birth and Baby webpage Donor breast milk and milk banks (updated 2025); The altruistic informal milk sharing groups Human Milk For Human Babies and Eats on Feets refer to The Four Pillars of Safe Milk Sharing (Walker and Armstrong 2012).

Arguments against payment of milk donors may overlook cost reimbursement and the political economic context of infant feeding (23), to focus on financial incentives more generally and potential risks, including: less equitable access to donor milk and public trust in its safety (especially informal arrangements); exploitation; diversion of the supply of milk from the donor's baby or community; violation of maternal identity, cultural values of altruism and volunteering or displacement of maternal breastfeeding (28, 43, 78, 79, 88, 99-104). However, such arguments need to distinguish donor reimbursement from rewards and consider regulatory options to address specific risks (82).

The selling and purchase of milk is rare in Australia, and typically occurs online. USA websites like, Craigs List or Only the Breast, are also the pathway for less accepted uses of commodified lactation or human milk sharing (12, 105). These avenues appear to be limited in Australia and reports of their use are rare (Fig. 3).

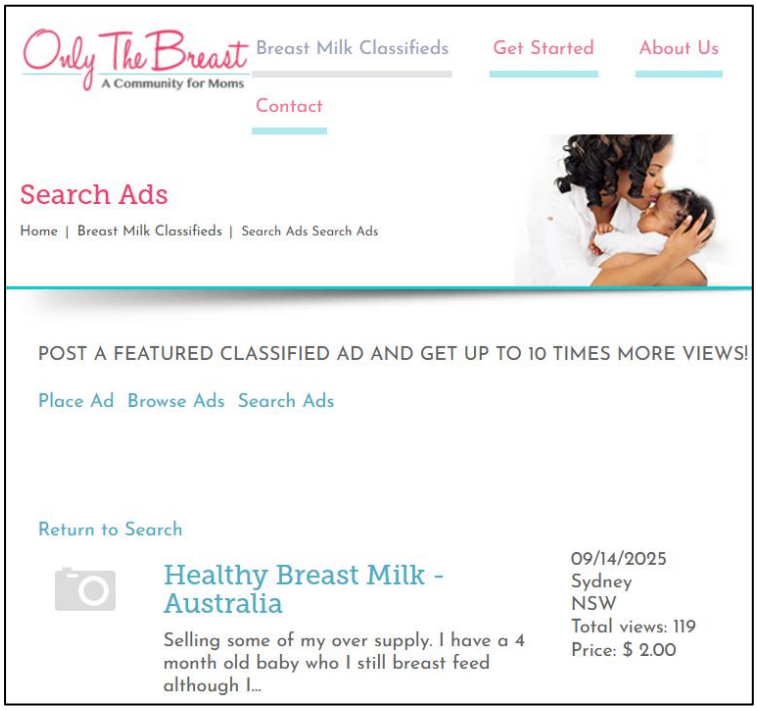

Figure 3. An advertisement from the website Only the Breast from a mother in Sydney NSW, wanting to sell her breastmilk for USD$2.00 per ounce, dated 14 September 2025.
https://www.onlythebreast.com/breast-milk-classifieds/show-ad/144962/healthy-breast-milk-australia/sydney/nsw/australia/selling-locally/ (Accessed 9 February 2026)

Markets in milk for babies

We note that prohibitions on donor payment do not preclude commercialisation and profit-taking by others, including after processing (28, 39, 94, 106-108).[19] We also note that exemptions to the prohibition on rewards for products regulated by the TGA could include human milk products.[20] Such exemptions require consideration and public consultation about potential harms to breastfeeding, diversion of human milk from infants and the viability of milk banking and informal milk sharing.

[19] The meaning of "processing" with regard to human milk is problematic, as it is routine for breastfeeding mothers to refrigerate and freeze their expressed milk, and donation typically involves sharing frozen milk. Human milk banks receive frozen milk, which is then thawed, tested, pasteurized or treated in some other way, re-tested and refrozen or freeze-dried and re-packaged.
[20] i.e. if they meet TGA criteria for therapeutic products or "biologicals."

Advertising

Advertising of CMF products is weakly regulated and competes with breastfeeding and human milk. There needs to be more integrated regulatory approaches so there is a comparative and proportionate approach to their relative risks and to promotion in healthcare and public settings of products that displace breastfeeding, including CMFs, donor milk and human milk products.

We also note that if human milk is included in HT laws, prohibition of advertising, if interpreted broadly, could have unintended effects of discouraging informal milk sharing and encouraging less safe practices. For example, the proposal to prohibit the public dissemination of information that invites, promotes, or seeks to induce a person to engage in a prohibited exchange of human tissue may:

- Stop donors and recipient families from finding each other to share milk informally, including via social media and the internet, through sites dedicated to unpaid milk donation.
- Prevent milk banks from using the internet and social and traditional media to increase awareness of human milk donation, screen prospective donors and alert donors when milk supplies are running low.

Background

International and National Policy context for breastfeeding and human milk in Australia

1. The WHO/UNICEF *Global Strategy for Infant and Young Child Feeding* establishes the international framework for protecting, promoting, and supporting breastfeeding . The *World Breastfeeding Trends Initiative (WBTI)* provides the monitoring system that assesses how well countries implement this framework across ten key indicators, including governance, BFHI implementation, Code compliance, maternity protection, health-system support, counselling, information quality, HIV-related feeding guidance, emergency preparedness, and monitoring and evaluation. The *Australian National Breastfeeding Strategy: 2019 and Beyond* (ANBS)[21] aligns closely with these indicators, setting national priorities for leadership, coordinated governance, BFHI implementation, maternity protection, skilled workforce development, community support, and improved data systems.[22] Together, WBTI and ANBS provide a coherent structure for assessing and strengthening Australia's breastfeeding environment.
2. The ALRC's proposed reforms to HT law—if human milk is included—intersect with several WBTI and ANBS domains but do so in a limited and sometimes misaligned way. While the reforms may enhance regulatory coherence for milk banking, they do not integrate with national breastfeeding governance structures or ANBS priorities. They do not strengthen BFHI implementation, health-system lactation support, or health-worker training, nor do they improve public access to accurate breastfeeding information.
3. The proposals also risk unintended consequences. Including human milk in HT law may discourage informal milk sharing and cross-nursing, practices some families use to avoid CMF. The reforms do not address the need for mandatory lactation support when donor milk is used, nor do they improve safety information for families engaging in informal sharing.
4. Critically, the proposals do not strengthen monitoring and evaluation systems. Australia lacks systematic data on donor milk use, breastfeeding outcomes, and supplemental feeding practices in

[21] https://www.health.gov.au/resources/publications/australian-national-breastfeeding-strategy-2019-and-beyond?language=en
[22] https://www.worldbreastfeedingtrends.org/wbti-country-report.php?country_code=AU

health facilities. Without improved data collection, donor milk programs may inadvertently displace breastfeeding rather than support it.

5. Overall, while the ALRC reforms may modernise aspects of HT regulation, they do not advance the core policy and public-health priorities articulated in the ANBS or measured through WBTI. Ensuring alignment with national breastfeeding goals will require complementary policy action beyond the scope of HT law. Table 2 summarizes how the proposed HT law reforms align with WBTI Indicators and policy priorities identified in the ANBS. **The overall object for tissue law reforms in relation to human milk must be to increase access to human milk through creating an institutional environment, along with health systems and community settings, which better enable women and infants to breastfeed.**
6. We conclude that the appropriate regulatory framework for human milk will recognise its unique characteristics and social context, rather than characterising it narrowly and inappropriately within food, tissue or other regulatory frameworks

Breastfeeding and milk sharing practices

In Australia, about 96% of mothers initiate breastfeeding after birth, but about one third of newborn infants are fed CMF before they leave hospital. Only 15% of infants are exclusively breastfed to 5 months (109).[23] When a mother is unable to breastfeed or her expressed milk is not available, infants are typically supplemented with CMF, but there are also options to use donor milk obtained through various milk sharing practices. In Australia, the prevalence of these practices is not known, because they are not included in statistics on infant feeding. Studies in Belgium and the USA –high income countries comparable to Australia – suggests that around 5% of mothers engage in informal milk sharing as part of their practice of breastfeeding (110-112).

Women have donated milk to other mothers throughout human history, through wet-nursing or cross-nursing. Milk sharing practices occur in a range of medical and community settings and situations in Australia, including emergencies. These practices include milk banking, which supplies pasteurised donor human milk (PDHM) to hospitalised infants and informal arrangements in the community. Both may be facilitated by social media or medical supervision. An extensive literature documents wet-nursing and milk sharing practices in Australia – and the evolution of milk banking - over the past century and a half (71, 113-118) (78, 119-124) and New Zealand (125). Employment as a wetnurse is currently rare in Australia and most such arrangements are informal, leaving the health and safety of women or infants covered through private law and public health systems concerning infectious diseases.

Some Indigenous groups, cultures and religions (including Islam) recognise milk kinship between the child of the donor and the recipient child. Milk kinship may restrict access to PDHM through milk banks if donation is anonymised or privacy laws prevent donor and recipient families from knowing each other, and require considered local interpretation and approaches (124, 126-129).

Table 2: WBTI Indicators, ANBS Priorities, and ALRC Human Tissue Law Reform Proposals, if applied to human milk

WBTI Indicator	Relevant ANBS Priorities	Commentary on ALRC Human Tissue Law Reform Proposals
1. National Policy, Governance and Funding	National leadership; coordinated governance; alignment with global	Including human milk in HT law may improve regulatory coherence for milk banking, but the proposals are not aligned with broader infant feeding strategies or ANBS governance priorities. There is no

[23] ABS National Health Survey breastfeeding data is weak, inconsistent with other infant feeding surveys, and not sufficient to make the claim that Australian breastfeeding rates are increasing. The WBTiAUS team do not consider these statistics as valid and therefore do not report on them.

	strategies; investment in breastfeeding	mechanism to connect HT law objectives with ANBS goals, including increasing exclusive breastfeeding to 50%.
2. Baby Friendly Hospital Initiative / Ten Steps to Successful Breastfeeding	BFHI implementation; support for mothers' own milk (MOM); safe donor milk use; NICU support	Reforms relating to milk banking are relevant but do not integrate with BFHI systems. Existing guidelines already support donor milk for vulnerable infants. The ALRC proposals do not advance ANBS goals beyond current frameworks. Including human milk in HT law may discourage informal sharing and could reduce breastfeeding or MOM use if lactation support is not mandated where donor milk is used.
3. Implementation of the WHO International Code of Marketing of Breast-milk Substitutes	Strengthened Code implementation; protection from commercial influence	Food law is currently the only mechanism implementing the WHO Code in Australia, which is applied inadequately to CMFs. The ALRC proposal to prohibit advertising related to human milk imposes stricter limits on human milk supply than those applied to CMF, despite the potential benefits of donor or shared milk. Expanding HT law may discourage informal sharing and negatively affect breastfeeding and infant health.
4. Maternity Protection	Adequate paid leave; workplace breastfeeding support; childcare support	Inadequate maternity protection drives CMF use and informal sharing. Applying HT law may interfere with consensual practices such as informal sharing and cross-nursing. Prohibiting remuneration for providing human milk could remove a form of paid care work historically available to women, with implications for economic rights. Labour law—not tissue law—is the appropriate mechanism to prevent exploitation and ensure safe, fair working conditions.
5. Health and Nutrition Care Systems	Integration of breastfeeding support into health services; support for MOM and donor milk	Applying HT law does not strengthen breastfeeding information or support within health systems. It does not improve mothers' access to guidance on breastfeeding or safe use of human milk as an alternative to CMF.
6. Counselling Services for Pregnant and Breastfeeding Mothers	Universal access to skilled lactation support; funded counselling services	Reforms aimed at expanding access to human milk do not include requirements for implementing or funding breastfeeding and lactation support. Without skilled counselling, mothers may not receive the support needed to use MOM effectively or transition to breastfeeding when donor milk is used.
7. Accurate and Unbiased Information Support	Health worker training; unbiased breastfeeding information; culturally safe support	The proposals do not require improved education or training for health workers on breastfeeding and lactation. They do not ensure mothers receive accurate, unbiased information about using MOM, donor milk, or transitioning to breastfeeding.
8. Infant Feeding and HIV	Safe feeding guidance; risk-appropriate counselling; informed decision-making	Applying HT law does not improve safety in the use of donor milk from milk banks, which is already addressed through Operational Guidelines. Nor does it enhance information for mothers involved in informal sharing about comparative risks, safe practices, or informed consent.
9. Infant and Young Child Feeding in Emergencies (IYCF-E)	Emergency preparedness; protection from CMF exploitation; support for wet-nursing and donor milk	Human milk sharing is recognised by WHO/UNICEF as appropriate in emergencies. The ALRC proposals do not improve public information on safe milk sharing and may discourage cultural norms that support informal sharing, potentially undermining breastfeeding. Increased access to donor milk could also reduce breastfeeding or MOM use if lactation support is not mandatory in facilities using donor milk.
10. Monitoring and Evaluation	National breastfeeding data; monitoring of feeding practices; evaluation of donor milk use	Australia lacks systematic monitoring of human milk use in healthcare settings and breastfeeding outcomes associated with donor milk. Broader infant feeding data is outdated. The ALRC proposals do not address these gaps. Monitoring systems—such as registers of infants receiving donor milk versus MOM, and tracking breastfeeding exclusivity and duration—are essential to ensure donor milk supports breastfeeding rather than replacing it and to promote equitable access.

All milk sharing practices, including use of donor human milk products, may support or displace breastfeeding. Milk sharing may displace breastfeeding if recipient mothers cannot access skilled breastfeeding and lactation support or breastfeeding-friendly workplaces and communities.

Milk banking

Proposed HT law reforms appear to be of most relevance to human milk exchanged in organised healthcare settings, especially in neonatal intensive care units (NICU), and specifically through formal milk sharing, that is, milk banking.

In Australia, PDHM is used under medical supervision in NICUs to supplement vulnerable very premature or low birth weight infants.[24] PDHM is supplied by three milk banks:

i. **Lifeblood Milk**[25] collects milk from donors in Sydney, Brisbane, Melbourne and Adelaide, processes it in Sydney and Brisbane and distributes it to 40 NICUs and special care nurseries in NSW, ACT, Qld, SA, TAS, WA and VIC.[26] In 2024-25, Lifeblood Milk processed milk from 478 donors and supplied 4,448 litres of PDHM nationally (130).
ii. The Perron Rotary Express Milk (PREM) Bank in Perth supplies the King Edward Memorial Hospital in Perth, WA.[27]
iii. Mothers Milk Bank Charity is located in SE Queensland and supplies PDHM and freeze dried human milk to hospitals and the public.[28]

Australian milk banks are not governed by an association, but by health and food authorities in the jurisdictions in which they are located. At the Commonwealth level, the Australian Health Minister's Advisory Council (AHMAC) Clinical Principal Committee (CPC) Human Milk Regulation Working Group, with representatives from jurisdictions, milk banks and the public, developed 2022 *Operational Guidelines for Milk Banks in Australia and New Zealand*. The guidelines require:

- Milk banks to comply with "relevant laws" in the jurisdiction/s in which they operate and service, but treat human milk as food, for example through references to food grade containers and food testing laboratories.
- Unpaid donation of human milk, but allow for the milk bank to commercialise donated milk, with donor consent.[29]
- Milk bank donation campaigns to meet advertising requirements, as regulated by the relevant jurisdictional Act.

Emergencies and other special circumstances

Breastfeeding provides crucial resilience in disasters and emergencies (131, 132), and UNICEF recently published operational guidelines for wet nursing and milk sharing (133-136). In these guidelines, considerations of equity and obtaining supply have included the appropriate forms of reward for women willing to provide wet-nursing or donate milk for orphaned or separated infants.

[24] Studies are also being conducted on the use of PDHM in older premature infants.
[25] Australian Red Cross Lifeblood LifeBlood Milk (https://www.lifeblood.com.au/donors/milk)
[26] Lifeblood Milk replaced the Queensland Milk Bank in Brisbane and the Mercy Health Breastmilk Bank in Melbourne (https://health-services.mercyhealth.com.au/our-health-services/mercy-health-breastmilk-bank/)
[27] PREM Bank: https://cahs.health.wa.gov.au/Our-services/Neonatology/The-Perron-Rotary-Express-Milk-Bank
[28] Mothers Milk Bank Charity: https://mothersmilkbank.com.au/
[29] *Operational Guidelines for Milk Banks in Australia and New Zealand* require milk banks to obtain specific consent for:

i. Use of discarded milk in research projects approved by a Human Research Ethics Committee; and/or
ii. Use of discarded milk in HMB internal product development and/or process validations; and/or
iii. Donated milk to be commercialised by the HMB or by a contracted distributor (where applicable and if allowed under jurisdiction-specific legislation).

Other circumstances also raise concerns about human rights and equitable access to breastfeeding and human milk, for example, adoptive or incarcerated mothers, in which donor human milk has a potential role.

Commodification and commercialisation: past and present

Remuneration (financial gain) or cost compensation (which can include for time, transportation, storage bags, etc) of milk donors has historical precedents and modern iterations:

- Women have historically been employed as wet nurses across a wide range of cultural and geographic contexts. In some historical and geographic contexts wet-nursing was a respected occupation, but in other contexts it was exploitative of poor women, and included associations with colonisation and slavery.
- Historically, women have also been remunerated for providing human milk, including in modern times to hospitals or milk banks. In the UK and US, remuneration of milk donors was an official practice prior to WWII that was displaced by commercial infant formula use. Payments to milk bank donors continue in parts of Europe and are considered as a form of cost reimbursement.
- In the USA human milk is mostly unregulated and is both sold or donated, including to commercial milk banks. Human milk exchange (sale or donation) can also be arranged via internet sites such as 'Only the Breast'. Some state laws in combination with milk banking standards set by the HMBANA encourage milk to be donated altruistically to not for profit milk banks, which is then sold to hospitals. In the USA, equity of access is a significant issue as a largely private healthcare system allocates supplies according to ability to pay or private health insurance coverage.
- Wet-nursing may also be part of unpaid or paid private baby-sitting or childcare arrangements, with consent. In France, historically the state systematically regulated wet-nursing across the country in response to high infant mortality and concerns about exploitation and unsafe practices. This evolved into a nationally coordinated, state-regulated system of human milk banks in which donors are not paid, but may receive reimbursement for reasonable costs (e.g., equipment, transport); milk is prioritised for premature and medically vulnerable infants; and distribution is based on clinical need.

The commercial structure of milk banks and suppliers of human milk products in Australia varies. Australian milk banks are not-for-profit entities with various methods of cost recovery. Recipient families are not charged for PDHM provided in public hospitals, and milk banks recover their costs through the public health system. Milk bank donors are not remunerated, nor are their costs reimbursed. Milk bank operations may also be funded through philanthropic donations, partnerships and government grants (130, 137).

- For products supplied to the public, the Mothers Milk Bank Charity charges processing fees of $115/litre for frozen PDHM, and $175/litre (reconstituted) for freeze dried PDHM.[30] The charge for freeze dried milk covers contractual arrangements with Nourishy[31], a for-profit company that freeze dries milk in Australia, in collaboration with Milkify,[32] a private company in the USA. Milk donors are not remunerated, nor are their costs reimbursed.

[30] Mothers Milk Bank Charity
[31] Nourishy
[32] Milkify

International trade in human milk since 2015 has generated concerns about exploitation of women:

- In 2017 in Cambodia, a low income country, a charitable organisation paid mothers of healthy older infants (> 6 months) about US$0.50/ounce (around US$15 a litre) to provide their milk, which was then exported to the USA for processing by Ambrosia Labs into PDHM for sale to the public. Advocacy by UNICEF resulted in the Cambodian government banning the export of human milk but deprived poor women of income that enabled them to continue to breastfeed in a country with no paid maternity leave (138, 139).
- An Indian company, Neolacta Lifesciences,[33] recruited poor women giving birth to premature infants in a charity hospital to donate their surplus milk in return for cash or food (94, 140). This company was granted a permit by the Australian Government to import human milk into Australia for processing into human milk products. However, importation did not proceed, partly because of uncertainty about the application of HT laws to commercial human milk products at the time.

Other human milk products

Human-derived human milk fortifiers are concentrates of pasteurised human milk that are added to a mother's own milk or pasteurised donor milk for extremely premature and low birthweight infants in NICUs.

- Products imported into Australia are manufactured by a US for-profit company Prolacta Bioscience,[34] which compensates donors USD $1.20 per ounce (about AUD $62 per litre). Prolacta sells the final product to medical facilities for approximately USD $193 per 15 ml or USD $257 per 40ml (about AUD $12,875-$19,699 per litre). Despite their price, these products are used in very small amounts to support an exclusive human milk diet and are cost-effective for hospitals (141), due to reduced medical complications such as NEC in some studies (142-145), but not others (146-148).
- The commercial value of human-derived fortifiers has prompted their development in other countries.[35] In Australia, Lifeblood Milk has developed but not yet commercialised a powdered human-derived fortifier in response to demand for a locally sourced product that complies with Australian ethical guidelines for altruistic donation (149). In India, Neolacta Lifesciences, commercialised donor human milk products and fortifiers from paid donors, which Indian authorities struggled to regulate under food laws in that country (150). An affiliated company in the United Kingdom (NeoKare),[36] has been criticised for marketing these products in British hospitals (29, 39, 140).

Cell-based human milk products are classified by FSANZ as a novel foods and are manufactured either using precision fermentation or mammary cell culture (27).

- Precision fermentation uses genetically modified microorganisms to produce human milk components. These components may be used as ingredients in traditional CMFs, and regulated under relevant ANZ Food Standards, which include restrictions on the use of terms like "human identical" in their labelling and advertising.
- Mammary cell culture uses human tissue cell culture to produce human milk components or human milk analogue products. These analogue or "lab" milks lack the immunological

[33] Neolacta (India)
[34] Prolacta Bioscience (USA)
[35] Medolac (USA); NeoKare (UK)

components of human milk, but are likely to be used and marketed as breastmilk substitutes. Individual components may have potential as therapeutic products. These products are likely to be commercialised in the next few years, with companies seeking guidance on their regulation in Australia (see below) (27).

Human milk regulation

Human milk may be imported into Australia under the Imported Food Control Act 1992 (Cth) and subject to post-border restrictions on sale and advertising in States/Territories that apply HT laws to human milk. With regard to the application of laws to human milk sharing, a 2024 Issues Paper by the Food Regulation Standing Committee stated that "informal practices do not involve a sale and are therefore not subject to food and human tissue regulation requirements." (27).

WHO and UNICEF recommendations on infant feeding state that when mother is unable to breastfeed or provide her own milk, options are to use a wet-nurse, or use donated human milk or CMF (61, 151). Nutrition guidelines recommend safe donor human milk from a human milk bank when the mother's own milk is not available (152). In Australia, 2013 NHMRC Infant Feeding Guidelines state that hospitalised preterm infants may be supplemented with donor milk, preferably from a milk bank (62).

Emerging cell-based human milk products raise new challenges to regulators. ANZ Food Ministers recently agreed to ensure that regulation of these analogue or "lab" milks "is consistent with 'traditional' infant formula products" in regard to marketing (153).

All milk sharing practices and donor human milk products raise ethical concerns about potential exploitation of donors (of milk, cells or genetic material), and recipient families and communities. In Australia, social norms in informal milk sharing networks and milk banks support altruistic donation but are also open to consideration of some recompense or reward in some contexts.

- The regulatory systems for food and therapeutic goods do not address human ethics or social values. In health settings, many aspects of donor human milk fall under medical ethical frameworks for informed consent and privacy.
- Informed consent is not always required for use of commercial milk formulas in health settings, yet required, paradoxically, for the use of donor human milk. These differences may restrict access to donor milk or decrease confidence in the safety of breastfeeding and human milk compared to CMFs, which also carry risks (30).
- Other ethical and economic questions arise around the commercialisation of human milk and trade in human milk products, that include how the costs of donating milk and breastfeeding are valued and remunerated in the country of origin.

Key principles to guide any regulation of human milk

1. Human milk is a unique substance provided by breastfeeding mothers to their own and other women's children across a range of settings, including informal arrangements. Its properties, functions, and uses intersect with multiple regulatory domains—such as food law, human tissue and cell regulation, and MPHO frameworks—yet no existing regulatory approach is fully appropriate or sufficiently integrated with the strategies and policies needed to enable and support breastfeeding.
2. Any inclusion of human milk in HT law should respect and protect the rights of women and children in relation to breastfeeding and the use of mothers' own milk (MOM), and should

enhance equitable access to both. It should not interfere with or discourage social norms that enable milk sharing in situations such as emergencies and disasters.

3. Donated human milk should be used primarily as a bridge to breastfeeding, not as a substitute that displaces it.
4. Milk-sharing arrangements—including altruistic donation to milk banks for premature infants—must not exploit the generosity or vulnerability of women or their children, whether donating or receiving human milk.
5. Milk sharing arrangements must be grounded in informed consent and appropriate privacy safeguards, tailored to the specific context and proportionate to the comparative risks of feeding infants with human milk versus CMF. Consent should be specific so that women can limit donation or disposal of their unused human milk for purposes they may not agree with (e.g. research, adult recipients).
6. Public health policy recognises breastfeeding as essential to infant and maternal health and relevant regulation should acknowledge that expressing human milk, milk sharing, and wet-nursing or cross-nursing are historically and culturally normal breastfeeding practices.
7. Donor human milk is inseparable from the broader breastfeeding system, which includes sociocultural norms and public policies designed to promote, protect, and support breastfeeding. Understanding breastfeeding as a complex biosocial system highlights how regulation can either support or destabilise breastfeeding through the incentives it creates and the ways it interacts with informal milk sharing and CMF markets.
8. Prohibitions in tissue law on remuneration or payments that generate "financial gain" for supplying human milk should:
    - clearly distinguish reasonable cost reimbursement from prohibited profit;
    - exclude informal milk sharing; and
    - ensure that requirements for altruistic donation do not reduce the quality or availability of donor milk. This includes addressing risks that prohibitions on payment, lack of cost reimbursement, and perceptions of donor exploitation may reduce supply, compromise safety, or weaken donor commitment to required standards.
9. Tissue law restrictions on advertising should not restrict donors and recipients from find each other in informal milk sharing arrangements, and should encourage public education and development of guidelines on practices enabling safe milk sharing in community settings.

Conclusions

a) Existing HT laws risk capturing breastfeeding and informal milk sharing practices.
b) A unique legal classification (*suis generis*) rather than expanding the scope of HT law is preferable for donor human milk.
c) Existing HT laws offer some protections from exploitation of individual human milk donors but risk perpetuating exploitation of breastfeeding women by the current political economic system.
d) HT laws may have value in regulating commercial donor human milk products, especially in medical settings.
e) Any benefits from including donor human milk in HT laws can only be fully realised if other regulatory gaps are closed to protect and support the production of human milk, by legislating the WHO Code in full and implementing the *Australian National Breastfeeding Strategy: 2019 and Beyond*.

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