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HUMAN TISSUE AND TRANSPLANT ACT 1982

SUPPLY OF PROCESSED DONOR HUMAN MILK IN WESTERN AUSTRALIA CODE OF PRACTICE 2024

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The Code of Practice (Code) is approved by the Minister and issued by the Chief Health Officer under section 32A of the *Human Tissue and Transplant Act 1982*.

PART 1—PRELIMINARY

1. Citation

The Code may be cited as the Supply of Processed Donor Human Milk in Western Australia—Code of Practice 2024.

2. Commencement

The Code comes into operation on 19 August 2024.

3. Application

Donor Human Milk Banks that supply, and Treating Hospitals that receive and dispense, processed donor human milk in Western Australia under a contract or arrangement authorised under Part 5 of the *Human Tissue and Transplant Act 1982* must comply with the Code, unless an exemption under clause 8 applies.

4. Review

A review of the operation and effectiveness of the Code will be carried out as soon as practicable—

(a) after the expiry of 2 years from commencement of the Code and thereafter every 5 years, and;

(b) after an update to the *Operational Guidelines for Milk Banks in Australia and New Zealand* published in July 2022, is endorsed by Health Ministers.

5. Terms used

In the Code, the following words have the following meanings—

batch means a discrete volume of donor human milk for processing under the same conditions at the same point in time.

cold-chain means the maintenance of appropriate storage and transport conditions under which donor human milk is handled within the safe temperature range guaranteeing suitability for clinical use.

collection centre means an outreach facility located in a hospital or in the community which provides temporary storage of raw donor human milk before transport to a Donor Human Milk Bank.

discard means for disposal or other use, such as quality assurance purposes, after being deemed unsuitable for human consumption.

dispensing means the process of allocating processed donor human milk to a recipient.

donor means a person who donates or has donated their own donor human milk.

donor human milk means human milk from a lactating person donated for use by a non-biologically related infant.

Donor Human Milk Bank means a facility established for the purposes of collection, evaluation, processing, storage and distribution of donor human milk, or any of those purposes.

Donor Human Milk Bank Operations means all steps in the collection, evaluation, processing, storage and distribution of donor human milk by a Donor Human Milk Bank.

eligible recipient means an infant meeting the criteria set out in clause 9(2).

excess milk means residual human milk from a lactating person after the feeding needs of their own infant are satisfied.

Holder Pasteurisation method means the treatment process, used for the reduction or destruction of undesirable microbiological loads, where milk is heated to 62.5^{o}C for 30 minutes and then subsequently cooled to 5^{o}C or below.

Human Tissue Advisory Body means the Human Tissue Advisory Body established under the *Human Tissue and Transplant Act 1982* section 29F(1).

National Health and Medical Research Council means the National Health and Medical Research Council established by the *National Health and Medical Research Council Act 1992* (Commonwealth) section 5B.

pasteurisation means the Holder Pasteurisation method or an equivalent method approved by the Chief Health Officer under clause 31(2).

processed donor human milk means donor human milk that has been subjected to pasteurisation.

quarantine means isolation, physically or by other effective means, of raw donor human milk or processed donor human milk, during which it is assessed against acceptance criteria requirements of the Code.

raw donor human milk means donor human milk that has not been subjected to pasteurisation.

recipient means an infant who receives processed donor human milk.

traceable or traceability means capacity to accurately link a specific donor, raw donor human milk, processed donor human milk, and any recipient.

Treating Hospital means a hospital or hospital-based unit (for example, a neonatal intensive care unit or milk room) that transports, receives, stores and dispenses processed donor human milk for the purpose of treating eligible recipients.

Treating Hospital Operations means all steps in the transport, receipt, storage and dispensing of processed donor human milk by a Treating Hospital.

unique identifier means a numeric or alpha-numeric sequence that provides for the unique identification of an individual or thing.

PART 2—GENERAL GOVERNANCE

6. Objectives and guiding principles

(1) The objective of the Code is to set out minimum standards for the safe and ethical processing and supply of donor human milk in Western Australia.

(2) The Code must be read having regard to the following guiding principles—

(a) Human milk is the optimal nutrition for infants, and breastfeeding by the mother is recognised as the optimal feeding method for infants.

(b) Donation of donor human milk does not interrupt or impact the successful feeding of the donor's infant.

(c) Where responsible for the collection of raw donor human milk and/or supply of processed donor human milk, Donor Human Milk Banks and Treating Hospitals work with the community to best meet the needs of donors, recipients, and their families.

(d) The protection of donors, potential donors and recipients against physical and psychosocial harm is the primary concern in the supply of processed donor human milk. Where self-determination conflicts with the safety of a donor, potential donor or recipient, safety considerations are paramount.

(e) Donor Human Milk Banks and Treating Hospitals uphold the World Health Organization's 'Principles on the donation and management of blood, blood components and other medical products of human origin' in relation to donor human milk banking activity, including—

(i) recognition of donor human milk as a medical product of human origin;

(ii) maintenance of confidentiality of donor information; and

(iii) equitable access to processed donor human milk.

(f) Donors are to be protected from exploitation. The use of processed donor human milk derived from raw donor human milk that is altruistically donated within Australia is strongly supported.

(g) Donor Human Milk Banks and Treating Hospitals are encouraged to comply with the Operational Guidelines for Milk Banks in Australia and New Zealand, endorsed by the Health Chief Executives Forum, so far as they do not conflict with the Code.

7. Purpose of supply

In WA, the supply of processed donor human milk by a Donor Human Milk Bank may only be—

(a) to a Treating Hospital for—

(i) use for therapeutic or medical purposes; or

(ii) use for the purposes of training, education or quality assurance relating to a use referred to in subparagraph (i);

or

(b) to a Treating Hospital or to another entity, under a research proposal approved by a Human Research Ethics Committee registered with the National Health and Medical Research Council for—

(i) scientific purposes; or

(ii) use for the purposes of training, education or quality assurance relating to a use referred to in subparagraph (i).

8. Exemptions to requirements of the Code

(1) The Chief Health Officer may exempt a Donor Human Milk Bank or Treating Hospital from all or some requirements under the Code, including eligibility criteria under clause 9, in relation to a contract or arrangement for the sale or supply of processed donor human milk authorised under Part 5 of the *Human Tissue and Transplant Act 1982* if—

(a) the Chief Health Officer is satisfied that special circumstances exist; or

(b) the requirements in subclause (2) are met.

(2) The requirements for the purposes of an exemption under subclause (1)(b) are as follows—

(a) the Donor Human Milk Bank will be supplying processed donor human milk to a Treating Hospital or another entity for a purpose referred to in clause 7(b); and

(b) the proposed exemption has been reviewed and approved in writing by the Human Research Ethics Committee that approved the research proposal; and

(c) the Treating Hospital or other entity provides a copy of the approval of the proposed exemption to the Chief Health Officer as soon as practicable and no later than 14 days after the proposed exemption is approved.

(3) An exemption under subclause (1) must—

(a) be in writing; and

(b) specify the provisions of the Code from which the Donor Human Milk Bank or Treating Hospital is exempt; and

(c) specify the contract or arrangement to which the exemption applies; and

(d) specify the period for which the exemption applies.

9. Eligible recipient for processed donor human milk

(1) Processed donor human milk must only be dispensed to an eligible recipient.

(2) Where suitable mother's own milk is not available or sufficient, an infant meeting the following criteria is an eligible recipient for processed donor human milk—

(a) a preterm infant <33 weeks gestational age; or

(b) <1500g birth weight; or

(c) an infant with a medical condition which poses a higher risk of necrotising enterocolitis (NEC), as determined by a neonatologist.

PART 3—DONOR HUMAN MILK BANKS

Division 1—General

10. Donor Human Milk Bank Operations—general

(1) A Donor Human Milk Bank will assign a person or persons as administratively responsible for all Donor Human Milk Bank Operations.

(2) A Donor Human Milk Bank will ensure the premises used for Donor Human Milk Bank Operations are suitable for the intended purpose.

(3) A Donor Human Milk Bank will develop, and implement, standard operating procedures for all Donor Human Milk Bank Operations including requirements for equipment, materials and processes.

(4) A Donor Human Milk Bank will provide a copy of any standard operating procedure relating to Donor Human Milk Bank Operations to the Chief Health Officer upon request.

11. Safety and quality control

(1) A Donor Human Milk Bank will ensure all—

(a) Donor Human Milk Bank Operations; and

(b) premises, equipment and materials used in the processing of donor human milk,

are subject to an effective safety and quality management system and surveillance program.

(2) The safety and quality management system and surveillance program will—

(a) include management of hazards using a Food Safety Program in accordance with Australia New Zealand Food Standards Code—Standard 3.2.1—Food Safety Programs; and

(b) implement Hazard and Critical Control Points principles (HACCP) against quality assurance processes to minimise potential hazards to donors and recipients; and

(c) include—

(i) good hygiene practices; and

(ii) risk identification and management; and

(iii) record-keeping and documentation; and

(iv) training and competence of personnel; and

(v) performance, maintenance and cleaning of premises, equipment and materials; and

(vi) management of outsourced activities and provision of service; and

(vii) processing safety and quality controls; and

(viii) quarantine and distribution; and

(ix) validations and verifications; and

(x) management of complaints, product and process non-conformances, adverse events and reactions; and

(xi) investigations (including traceability) and reporting of deviations; and

(xii) product recall; and

(xiii) internal and external auditing; and

(xiv) strategies for continuous improvement.

12. Donor Human Milk Banks within a Treating Hospital

Where a Donor Human Milk Bank is part of a Treating Hospital, separate Donor Human Milk Bank Operations and Treating Hospital Operations requirements or processes set out in the Code may be fully or partly integrated. In this case, the integrated requirements or processes must—

(a) meet the purpose of the relevant requirement/s or processes in the Code; and

(b) be documented in the Donor Human Milk Bank's and Treating Hospital's standard operating procedures.

Division 2—Donation practices

13. Recruitment

A Donor Human Milk Bank will ensure that information intended for the recruitment of donors is directed at lactating persons already expressing excess milk.

14. Promotion of breastfeeding

A Donor Human Milk Bank will develop and implement standard operating procedures for collection of raw donor human milk which—

(a) promote breastfeeding, in accordance with the Australian National Breastfeeding Strategy: 2019 and Beyond, published by the COAG Health Council; and

(b) ensure that raw donor human milk is only collected for donation where the milk is excess milk; and

(c) provide donors access to ongoing expert lactation support; and

(d) ensure that cultural values, beliefs and personal circumstances of the donor are explored and respected in the context of donating.

15. Donor eligibility assessment

(1) A Donor Human Milk Bank will develop and implement standard operating procedures for assessing donor eligibility which include—

(a) donor consent processes in accordance with clause 16; and

(b) donor medico-social screening in accordance with clause 17; and

(c) donor infectious disease blood screening in accordance with clause 18; and

(d) donor exclusion criteria in accordance with clause 19; and

(e) donor ongoing eligibility in accordance with clause 20; and

(f) donor education in raw donor milk handling in accordance with clause 21.

(2) A Donor Human Milk Bank will support disclosure of medico-social and infectious disease blood screening results to donors and potential donors and provide—

(a) support for the continuation or interruption of breastfeeding if the donor/potential donor or their milk is not found to be eligible; and

(b) where applicable, referral of the donor/potential donor (and their infant) for further support and clinical care.

(3) A Donor Human Milk Bank will ensure donor and potential donor privacy and confidentiality of information is upheld at all times.

(4) A Donor Human Milk Bank will ensure that donors and potential donors make a declaration that the information they provide, for initial and continued donor eligibility assessments, is given honestly and to the best of their knowledge.

16. Donor consent processes

Donor consent processes will include a verbal explanation on donation practices, supported by relevant written material. This must include information about—

(a) the donor screening processes; and

(b) raw donor human milk and processed donor human milk testing; and

(c) handling and processing of raw donor human milk; and

(d) the intended use of processed donor human milk; and

(e) the need to communicate with the Donor Human Milk Bank where a change in medico-social status or lifestyle may preclude ongoing donation of raw donor human milk; and

(f) the ability to cease donation of raw donor human milk at any time.

17. Donor medico-social screening

(1) A Donor Human Milk Bank will screen all potential donors by conducting a donor medico-social interview.

(2) Donor medico-social interviews can be conducted in person or via telehealth.

(3) Initial donor medico-social interviews will include questions to explore medical and lifestyle risk factors, and establish—

(a) age and health status of the donor's infant; and

(b) donor general health status; and

(c) medical and surgical history; and

(d) medications, including over the counter and alternative/complementary therapies; and

(e) infectious disease history and risk factors; and

(f) recent potential exposure to blood-borne viruses (such as blood transfusion, tattoo, piercing or needle-stick injury); and

(g) relevant travel history; and

(h) cigarette smoking history (active and passive), including use of other nicotine products; and

(i) caffeine consumption; and

(j) alcohol consumption; and

(k) recreational drug use; and

(l) any clinically relevant dietary restrictions or preferences.

18. Donor infectious disease blood screening

(1) A Donor Human Milk Bank will conduct infectious disease blood screening of all potential donors.

(2) A Donor Human Milk Bank will conduct infectious disease blood screening by serological and nucleic acid amplification technique (NAT) testing as close as possible to the first milk expression for donation, for each lactation cycle.

(3) A Donor Human Milk Bank will not use antenatal serology and/or NAT testing results as the initial donor infectious disease blood screening.

(4) Infectious disease blood screening conducted by a Donor Human Milk Bank will include testing for—

(a) Human Immunodeficiency viruses (HIV type 1 and type 2 antibodies and RNA); and

(b) Hepatitis B viruses (surface antigen and DNA); and

(c) Hepatitis C virus (antibody and RNA); and

(d) Human T–Lymphotropic viruses types 1 and 2 (HTLV 1 and 2 antibodies), and

(e) Syphilis (antibodies).

19. Donor exclusion criteria

(1) A Donor Human Milk Bank will develop, and implement, donor permanent or temporary exclusion criteria.

(2) Potential donors will be deemed ineligible to donate donor human milk, either temporarily or permanently, if risk factors known to impact on the safety and/or quality of human milk are present.

(3) Risk factors precluding a potential donor from donating human milk include—

(a) use of prescription medications, over-the-counter medications, or alternative/complementary therapies, contraindicated during breastfeeding; and

(b) history of infection with HIV, HTLV and/or hepatitis C; and

(c) current infection with hepatitis B and/or syphilis; and

(d) activity associated with risk of HIV, HTLV, hepatitis B, hepatitis C and/or syphilis; and

(e) recent potential exposure to blood-borne viruses (such as blood transfusion, tattoo, piercing or needle-stick injury); and

(f) cigarette smoking or use of other nicotine products (e.g. nicotine patches); and

(g) consumption of more than three caffeine-containing beverages/products (or >400mg caffeine) per day; and

(h) consumption of more than one standard alcoholic drink per day; and

(i) use of recreational drugs within the past 12 months; and

(j) other medical history or recent travel history where a risk assessment by a medical practitioner deems donation of human milk is not suitable.

20. Donor ongoing eligibility

(1) A Donor Human Milk Bank will ensure that donor eligibility is routinely reassessed by—

(a) conducting a donor medico-social interview (in person or via telehealth) at each deposit of raw donor human milk; or

(b) repeating infectious disease blood screening every three months.

(2) A Donor Human Milk Bank will ensure that infectious disease blood screening of a donor is conducted where a new donor medico-social risk is identified.

(3) A Donor Human Milk Bank will suspend or stop raw donor human milk donation by a donor where a change in medico-social status or lifestyle precludes ongoing raw donor human milk donation.

21. Donor education in handling of raw donor human milk

A Donor Human Milk Bank will provide education for donors about raw donor human milk handling, including:

(a) good personal hygiene practices, including handwashing and breast care; and

(b) milk expression and collection technique, including;

(i) that raw donor human milk may be hand or pump expressed (manual or electric); and

(ii) that expressed raw donor human milk must be collected in containers provided or approved by the Donor Human Milk Bank;

(c) cleaning, sterilising and use of breast pumps and containers; and

(d) cold-chain principles; and

(e) storage of raw donor human milk; and

(f) processes for transporting raw donor human milk; and

(g) when change of medico-social status or lifestyle may affect or preclude ongoing raw donor human milk donation.

22. Labelling—general

A Donor Human Milk Bank will develop and implement standard operating procedures for labelling to ensure—

(a) accurate and standardised raw donor human milk and processed donor human milk labelling in accordance with clause 23 or 35 respectively; and

(b) traceability of donor human milk; and

(c) that labels remain adherent and inscriptions withstand all processes and environments that containers are exposed to throughout the product life cycle.

23. Labelling—raw donor human milk

Information on raw donor human milk container labels will include the date of expression and—

(a) the donor's name and date of birth; or

(b) the donor unique identifier.

24. Handling and storage of raw donor human milk collected in a Treating Hospital or collection centre

Where raw donor human milk is collected for a Donor Human Milk Bank in a Treating Hospital or collection centre—

(a) the Donor Human Milk Bank will retain responsibility for donation practices and other Donor Human Milk Bank Operations relevant to Treating Hospital or collection centre activities; and

(b) standard operating procedures for raw donor human milk handling will be developed in consultation between the Donor Human Milk Bank and the Treating Hospital or collection centre; and

(c) the Treating Hospital or collection centre will provide donors with a suitable space for milk expression; and

(d) raw donor human milk will be collected in containers provided or approved by the Donor Human Milk Bank; and

(e) containers of expressed raw donor human milk will be immediately labelled in accordance with clause 23; and

(f) labelled containers of expressed raw donor human milk will be—

(i) immediately frozen in a dedicated area for raw donor human milk within a temperature monitored freezer; or

(ii) in an emergency situation, stored in a temperature monitored refrigerator, then transferred for freezing as per subparagraph (i) within 24 hours.

25. Storage of raw donor human milk collected in the home

A Donor Human Milk Bank will provide education for donors to ensure a donor collecting donor human milk in the home will—

(a) store expressed raw donor human milk in containers provided or approved by the Donor Human Milk Bank; and

(b) immediately label containers of expressed raw donor human milk in accordance with clause 23; and

(c) ensure that labelled containers of expressed raw donor human milk—

(i) are frozen as soon as possible or, where immediate freezing is not possible, are placed immediately in the coldest part of the refrigerator then transferred to a freezer within 24 hours; and

(ii) are stored in the coldest part of the freezer until it is time to transport; and

(iii) are checked regularly to ensure raw donor human milk remains hard frozen.

26. Transport of raw donor human milk

(1) Standard operating procedures for transport of raw donor human milk to the Donor Human Milk Bank will include—

(a) that raw donor human milk is transported to the Donor Human Milk Bank within 10 weeks of expression; and

(b) procedures to ensure cold-chain maintenance so that raw donor human milk is hard frozen at all times; and

(c) transport container specifications; and

(d) transport container identification.

(2) If a courier or transport service is used for the transport of raw donor human milk, the Donor Human Milk Bank will have a documented agreement with the courier or service setting out agreed transportation requirements.

Division 3—Processing

27. Receipt and storage of raw donor human milk

(1) A Donor Human Milk Bank will develop, and implement, acceptance criteria for the purpose of rejecting, or accepting, raw donor human milk for further processing.

(2) A Donor Human Milk Bank will ensure raw donor human milk on delivery, is—

(a) labelled in accordance with clause 23; and

(b) hard frozen; and

(c) collected in an approved container that is not damaged or tampered with in any way.

(3) A Donor Human Milk Bank will ensure that received raw donor human milk is—

(a) stored in a dedicated pre-processing freezer area, under temperature monitored conditions, so that it is hard frozen at or below -18°C at all times before undergoing pasteurisation; and

(b) quarantined from raw donor human milk accepted for further processing until compliance with acceptance criteria is confirmed; and

(c) pasteurised within three months of expression.

28. Thawing and pooling of raw donor human milk

(1) A Donor Human Milk Bank will ensure raw donor human milk is processed in containers that can be hermetically closed and withstand handling and storage.

(2) A Donor Human Milk Bank will ensure that once the raw donor human milk is ready for pre-pasteurisation testing, it will be thoroughly thawed, at or below +5 °C; and

(a) kept in a refrigerator for up to (no longer than) 24 hours; or

(b) if storage of thawed milk at or below +5°C is beyond 24 hours, this requires the Donor Human Milk Bank to validate that that microbial contamination load remains within safe levels and comply with food safety requirements.

(3) A Donor Human Milk Bank will ensure a batch is not pooled using raw donor human milk from different donors.

(4) Raw donor human milk from the same donor can be pooled to make a batch.

29. Endorsed microbial thresholds—before pasteurisation sample testing

(1) A Donor Human Milk Bank will ensure each batch of raw donor human milk is sampled for microbial contamination before pasteurisation.

(2) Batches can be accepted for further processing if microorganism growth is—

(a) $\leq 10^4$ colony-forming units/mL (cfu/mL) for Staphylococcus aureus; and

(b) $\leq 10^4$ cfu/mL for Enterobacteriaceae; and

(c) $\leq 10^5$ cfu/mL for total viable microorganisms.

30. Discard process for raw donor human milk

A Donor Human Milk Bank will ensure raw donor human milk that has not been pasteurised within 3 months of expression, or does not meet criteria for further processing, is disposed of immediately, or labelled and clearly segregated for discard.

31. Pathogen reduction or elimination process (pasteurisation)

(1) A Donor Human Milk Bank will subject raw donor human milk accepted for further processing to pasteurisation.

(2) The Chief Health Officer may approve an equivalent method for the reduction or destruction of undesirable microbiological loads if the Chief Health Officer is satisfied that the method provides equivalent or greater microbiological decontamination to that achieved by the Holder Pasteurisation method, as assessed against evidence-based process design, risk analysis and process validation.

32. Endorsed microbial thresholds—after pasteurisation sample testing

(1) A Donor Human Milk Bank will develop, and implement, acceptance criteria for the purpose of rejecting, or accepting, processed donor human milk for release.

(2) A Donor Human Milk Bank will ensure all processed donor human milk is quarantined, and a sample set aside from each batch for testing after pasteurisation.

(3) The post-pasteurisation microbial acceptance criteria threshold is a total viable microbial count of ≤ 1 cfu/mL.

(4) A Donor Human Milk Bank will ensure any microorganisms grown from post-pasteurisation samples are identified and evaluated for quality assurance purposes.

33. Storage and expiry of processed donor human milk

(1) A Donor Human Milk Bank will ensure that—

(a) processed donor human milk is stored in a dedicated post-processing freezer area, under temperature monitored conditions, so that it is hard frozen at or below -18°C at all times; and

(b) quarantined processed donor human milk is clearly segregated from processed donor human milk accepted for distribution.

(2) The processed donor human milk expiry date (total shelf life) is—

(a) three months from the date of pasteurisation; or

(b) six months from the earliest date the raw donor human milk within the processing batch was expressed, if the Donor Human Milk Bank has validated that microbial contamination load remains within safe levels and complies with food safety requirements.

34. Discard process for processed donor human milk

A Donor Human Milk Bank will ensure processed donor human milk that has expired, or is not accepted for release, is disposed of immediately, or labelled and clearly segregated for discard.

35. Labelling—processed donor human milk

Information on processed donor human milk container labels will include—

(a) the product name (e.g. Pasteurised Donor Human Milk); and

(b) the product unique identifier; and

(c) the volume in container (in ml); and

(d) the expiry date; and

(e) a sterility claim (if applicable); and

(f) the name of the supplying Donor Human Milk Bank.

Division 4—Training

36. Training

(1) A Donor Human Milk Bank will provide relevant staff education and training to ensure each staff member—

(a) is competent to undertake assigned tasks; and

(b) understands, and is able to comply with, the requirements for Donor Human Milk Banks; and

(c) understands quality control; and

(d) understands the regulatory and ethical concepts related to donor human milk banking.

(2) Staff education and training includes—

(a) the promotion of breastfeeding; and

(b) the promotion of culturally appropriate services.

Division 5—Record Keeping and Audit Requirements

37. Record keeping—Donor Human Milk Bank records

A Donor Human Milk Bank will keep adequate records to ensure traceability, including—

(a) donation records in accordance with clause 38; and

(b) processing records in accordance with clause 39; and

(c) distribution records in accordance with clause 40; and

(d) discard records in accordance with clause 41; and

(e) quality assurance records in accordance with clause 42; and

(f) a register of staff training and achieved relevant competencies.

38. Donation records

Donation records include—

(a) the donor identification details and contact address; and

(b) the donor unique identifier; and

(c) informed consent for donation and intended uses; and

(d) the initial eligibility assessment (medic-social interview and blood screening results); and

(e) on-going eligibility assessments (updates and re-testing where applicable); and

(f) raw donor human milk record information, including—

(i) raw donor human milk collection dates and volumes; and

(ii) condition of milk on delivery to the Donor Human Milk Bank; and

(iii) storage at the Donor Human Milk Bank; and

(iv) assigned raw donor human milk unique identifier; and

(v) details of any relevant transportation issues.

39. Processing records

Processing records include—

(a) identification of the raw donor human milk pooled for each processing batch; and

(b) the assigned batch unique identifier; and

(c) the batch volume; and

(d) the number of processed donor human milk containers originating from the batch; and

(e) the assigned product unique identifier for each container of processed donor human milk aliquoted from the batch; and

(f) the pre-pasteurisation testing log: tests undertaken and the results; and

(g) details of the pasteurisation process and other processing steps; and

(h) processing quality controls and risk management; and

(i) the post-pasteurisation testing log (tests undertaken and the results); and

(j) the process to approve distribution or discard.

40. Distribution records

Distribution records include—

(a) the product unique identifier; and

(b) the Treating Hospital receiving the processed donor human milk; and

(c) the date and time of delivery; and

(d) records of complaints, withdrawal and/or product recall use.

41. Discard records

Discard records include—

(a) the name of the person authorising discard; and

(b) the date of discard; and

(c) the volume discarded; and

(d) the circumstances for discard.

42. Quality assurance records

Quality assurance records include—

(a) premise cleaning and maintenance; and

(b) environment controls; and

(c) calibration records; and

(d) testing (platforms with specificity, sensitivity and acceptance thresholds, microbial speciation); and

(e) equipment performance, cleaning and maintenance; and

(f) critical materials (tracking and expiry); and

(g) process validations and verifications; and

(h) process and HACCP critical control point monitoring; and

(i) audits (outcomes and response to findings).

43. Audit and notification requirements

(1) A Donor Human Milk Bank will provide the Chief Health Officer contact details of any Treating Hospital with which the Donor Human Milk Bank has a service agreement for processed donor human milk.

(2) A Donor Human Milk Bank will undertake an annual audit to assess Donor Human Milk Bank Operations and outcomes including—

(a) compliance with donation practices required under clauses 13—26; and

(b) compliance with safety and quality management system, processing, training and record keeping requirements required under clauses 11 and 27—42; and

(c) breaches in product safety and quality.

(3) A Donor Human Milk Bank will ensure annual external food safety program audits are undertaken by an independent certified auditor.

(4) A Donor Human Milk Bank will take reasonable steps to address non-compliance with the Code or other risks identified in the annual audit.

(5) A Donor Human Milk Bank will provide the Chief Health Officer as soon as practicable and no later than 14 days after occurrence, notice of any—

(a) adverse event where supply of processed donor human milk has posed a serious clinical risk to donors or recipients; or

(b) recall of processed donor human milk due to clinical safety concerns; or

(c) event that poses a serious risk of disrupting the supply of processed donor human milk to eligible recipients in WA; or

(d) failed audit results; or

(e) steps or actions to address or mitigate risks identified from an adverse event notified under paragraph (a).

(6) Every three years on or before the 1st day of September, or at any time upon request in writing by the Chief Health Officer, a Donor Human Milk Bank will provide to the Chief Health Officer an audit report summarising findings from audits completed in accordance with this clause, including—

(a) whether the Donor Human Milk Bank has passed or failed an audit; and

(b) significant shortcomings or risks identified within the audit process for addressing by the Donor Human Milk Bank; and

(c) the steps taken, or to be taken, to address these shortcomings or risks.

Division 6—Distribution

44. Service Agreement

(1) Where a Donor Human Milk Bank supplies processed donor human milk to a Treating Hospital, the Donor Human Milk Bank and the Treating Hospital will enter into a Service Agreement.

(2) The Service Agreement will set out agreed arrangements for supply, including—

(a) the roles and responsibilities of all parties in maintaining quality and safety requirements for processed donor human milk; and

(b) delivery arrangements, including whether as frozen or thawed product; and

(c) supply for inventory (stock) or for named-patient supply (where applicable); and

(d) transport arrangements; and

(e) stock levels and resupply periods; and

(f) traceability arrangements; and

(g) reporting arrangements such as usage and discard reports, non-compliance and adverse events, relevant audit results and risk mitigation strategies.

(3) The Treating Hospital is responsible for storage and dispensing on receipt of processed donor human milk from the Donor Human Milk Bank.

45. Transport of processed donor human milk to a Treating Hospital

(1) Standard operating procedures for transport of processed donor human milk to a Treating Hospital will include—

(a) procedures to ensure cold-chain maintenance; and

(b) transport container specifications; and

(c) transport container identification; and

(d) recording of inventory in the transport load.

(2) If a courier or transport service is used for the transport of processed donor human milk to a Treating Hospital, the Donor Human Milk Bank will have a documented agreement with the courier or service setting out agreed transportation requirements.

PART 4—TREATING HOSPITALS

Division 1—General

46. Treating Hospital Operations—general

(1) A Treating Hospital will assign a person or persons as administratively responsible for all Treating Hospital Operations.

(2) A Treating Hospital will ensure the premises used for Treating Hospital Operations are suitable for the intended purpose.

(3) A Treating Hospital will develop, and implement, standard operating procedures for all Treating Hospital Operations, including requirements for equipment, materials and processes.

(4) A Treating Hospital will provide a copy of any standard operating procedure relating to Treating Hospital Operations to the Chief Health Officer upon request.

47. Safety and quality control

(1) A Treating Hospital will ensure all—

(a) Treating Hospital Operations; and

(b) premises, equipment and materials used in the receipt, storage and dispensing of processed donor human milk,

are subject to an effective safety and quality management system and surveillance program.

(2) The safety and quality management system and surveillance program will include—

(a) management of hazards using a Food Safety Program in accordance with Australia New Zealand Food Standards Code—Standard 3.2.1—Food Safety Programs; and

(b) good hygiene practices; and

(c) risk identification and management; and

(d) record-keeping and documentation; and

(e) training and competence of personnel; and

(f) performance, maintenance and cleaning of premises, equipment and materials; and

(g) management of complaints, product and process non-conformances, adverse events and reactions; and

(h) investigations (including traceability) and reporting of deviations; and

(i) product recall; and

(j) internal and external auditing; and

(k) strategies for continuous improvement.

Division 2—Receipt and storage

48. Receipt of processed donor human milk

(1) A Treating Hospital will develop, and implement, acceptance criteria for the purpose of rejecting, or accepting, processed donor human milk for release for dispensing.

(2) A Treating Hospital will ensure that processed donor human milk on delivery is—

(a) labelled in accordance with clause 35; and

(b) not expired; and

(c) for frozen processed donor human milk, hard frozen; and

(d) for thawed processed donor human milk, at an appropriate temperature (below +5°C); and

(e) not damaged or tampered with in any way; and

(f) consistent with despatch inventory details; which, if applicable, may include specific recipient details; and

(g) signed-off at delivery in the processed donor human milk inventory register.

49. Storage of processed donor human milk

A Treating Hospital will ensure that—

(a) frozen processed donor human milk is maintained frozen at or below -18°C; and

(b) thawed processed donor human milk is stored refrigerated and is used within 24 hours; and

(c) processed donor human milk is not refrozen once thawed.

50. Discard process for processed donor human milk

A Treating Hospital will ensure processed donor human milk that is expired, or is not accepted for release, or is thawed but not used within 24 hours, will be disposed of immediately, or labelled and clearly segregated for discard.

51. Labelling

A Treating Hospital will develop and implement standard operating procedures for labelling to ensure—

(a) accurate and standardised processed donor human milk labelling; and

(b) traceability of donor human milk.

Division 3—Dispensing practices

52. Promotion of breastfeeding

A Treating Hospital will develop and implement standard operating procedures for dispensing processed donor human milk which—

(a) promote breastfeeding, in accordance with the Australian National Breastfeeding Strategy: 2019 and Beyond, published by the COAG Health Council; and

(b) provide the recipient's family access to ongoing expert lactation support; and

(c) promote culturally appropriate services.

53. Processed donor human milk dispensed to eligible recipients

(1) A Treating Hospital will ensure that, when a potential eligible recipient is identified—

(a) consent is obtained from the infant's parent/guardian before processed donor human milk is dispensed; and

(b) consent processes include a verbal explanation of the risks and benefits of processed donor human milk, supported by relevant written material.

(2) A Treating Hospital will ensure that—

(a) processed donor human milk is dispensed in accordance with clause 9; and

(b) there is a plan for appropriate cessation of dispensing.

Division 4—Training

54. Training

(1) A Treating Hospital will provide relevant staff education and training to ensure each staff member—

(a) is competent in performing their work; and

(b) understands, and is able to comply with, Treating Hospital Operations; and

(c) understands quality control; and

(d) understands the regulatory and ethical concepts related to donor human milk banking.

(2) Staff education and training includes—

(a) the promotion of breastfeeding; and

(b) the provision of culturally appropriate services.

Division 5—Record Keeping and Audit Requirements

55. Record keeping

A Treating Hospital will keep adequate records to ensure traceability, including—

(a) a processed donor human milk inventory register in accordance with clause 56; and
(b) processed donor human milk stock requests in accordance with clause 57; and
(c) a processed donor human milk dispensing register in accordance with clause 58; and
(d) recipient hospital medical records in accordance with clause 59; and
(e) discard records in accordance with clause 60; and
(f) quality assurance records in accordance with clause 61; and
(g) a register of staff training and achieved relevant competencies.

56. Processed donor human milk inventory register

A processed donor human milk inventory register includes—

(a) the date and time of delivery; and
(b) the form of processed donor human milk received (frozen or thawed); and
(c) the product unique identifier; and
(d) the volume of processed donor human milk; and
(e) the expiry date on the label; and
(f) the condition of processed donor human milk on delivery; and
(g) the name and signature of responsible staff members.

57. Processed donor human milk stock request

A processed donor human milk stock request includes—

(a) the requested amount of stock; and
(b) the name of the supplying Donor Human Milk Bank; and
(c) the arrival date and time at the Treating Hospital; and
(d) any ad hoc requests made in addition to the requested amount.

58. Processed donor human milk dispensing register

A processed donor human milk dispensing register includes—

(a) the name of the dispensing facility (e.g. milk room); and
(b) the storage conditions; and
(c) the recipient name and date of birth, gestational age, medical record number and parent/guardian name; and
(d) the eligibility of the recipient; and
(e) the name of the authorised prescriber; and
(f) the processed donor human milk record: batch/product unique identifier, expiry date, volume and date dispensed; and
(g) the identification of the responsible staff member/s (processed donor human milk preparing/dispensing); and
(h) the signed (parent/guardian) consent form (copy).

59. Recipient hospital medical record

A recipient's hospital medical record includes—

(a) the recipient's name and date of birth; and
(b) medical record number; and
(c) parent/guardian name; and
(d) the signed (parent/guardian) consent form; and
(e) the dates and times of dispensing of processed donor human milk; and
(f) the product unique identifiers; and
(g) identification of responsible staff member/s.

60. Discard records

Discard records include—

(a) the name of person authorising discard; and
(b) the date of discard; and
(c) the volume discarded; and
(d) the circumstances for discard.

61. Quality assurance records

Quality assurance records include—

(a) premise cleaning and maintenance; and
(b) environment controls; and

(c) calibration records; and

(d) equipment performance, cleaning and maintenance process monitoring; and

(e) audits—outcomes and response.

62. Audit and notification requirements

(1) A Treating Hospital will undertake an annual audit to assess Treating Hospital Operations and outcomes including—

(a) compliance with dispensing practices required under clauses 52—53; and

(b) review of breastfeeding rates at infant discharge from the Treating Hospital; and

(c) compliance with safety and quality management system, receipt and storage, training, and record keeping requirements under clauses 47—51 and 54—61; and

(d) breaches in product safety and quality.

(2) A Treating Hospital will ensure an annual external food safety program audit is undertaken by an independent certified auditor.

(3) A Treating Hospital will take reasonable steps to address non-compliance with this Code or other risks identified in the annual audit.

(4) A Treating Hospital will provide the Chief Health Officer as soon as practicable and no later than 14 days after occurrence, notice of any—

(a) adverse event where dispensing of processed donor human milk at the Treating Hospital has posed a serious clinical risk to recipients; or

(b) recall of processed donor human milk at the Treating Hospital due to clinical safety concerns; or

(c) failed audit results; or

(d) evidence the Treating Hospital is undertaking a review process, for example, Clinical Incident Management, where appropriate for the matter reported.

(5) Every three years on or before the 1st day of September, or at any time upon request in writing by the Chief Health Officer, a Treating Hospital will provide to the Chief Health Officer an audit report summarising findings from audits completed in accordance with this clause, including—

(a) whether the Treating Hospital has passed or failed an audit; and

(b) significant shortcomings or risks identified within the audit process for addressing by the Treating Hospital; and

(c) the steps taken, or to be taken, to address these shortcomings or risks.

Dr ANDREW ROBERTSON, Chief Health Officer.