

Breast milk substitutes – update on regulation and emerging products

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I acknowledge the Traditional Owners of the land on which we are meeting. I pay my respects to their Elders, past and present, and the Aboriginal Elders of other communities who may be here today

Breast milk substitute regulation

- The sale of food is regulated to ensure the food supply is safe and consumers are appropriately informed.
- In Victoria, two main regulatory tools:
 - Australia New Zealand Food Standards Code
 - *Food Act 1984*
- Food means *‘any substance or thing of a kind used, or represented as being for use, for human consumption’*
 - >>breast milk and substitutes are a food!

Review of the infant formula standard

- Food Standards Australia New Zealand (FSANZ) is the independent statutory authority responsible for drafting and amending food standards.
- Standard 2.9.1 of the Australia New Zealand Food Standards Code (the Code) was established in 2002 and outlines composition and labelling requirements for infant formula.



Review of the Infant Formula Standard – anticipated changes

Regulatory framework

Two broad infant formula categories:

- ‘general purpose’ infant formula
- special medical purpose products for infants (SMPPi)
 - exempt from some labelling and compositional requirements
 - restrictions on places of sale.

Note: Stage 3 (toddler milk) excluded from scope of the review.

Review of the infant formula standard – anticipated changes

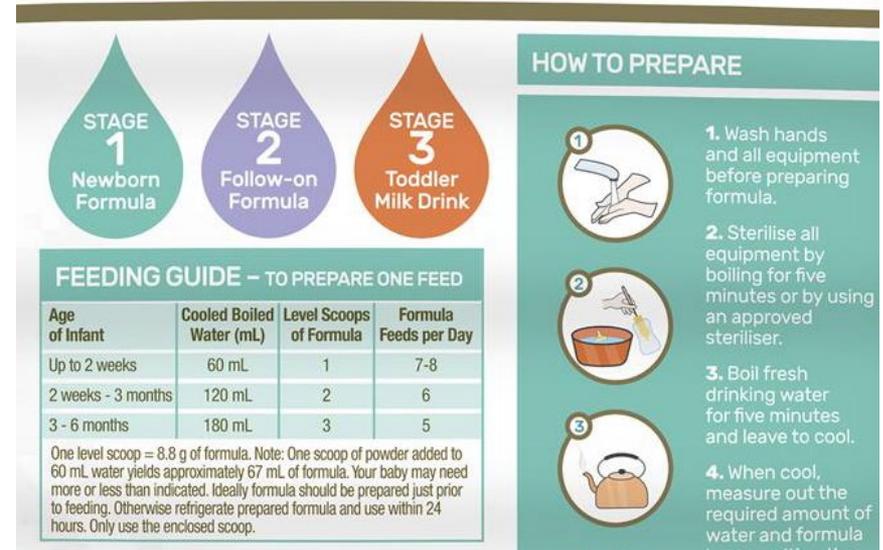
Composition

- Small changes to several nutrient composition requirements to align with international regulations.
- Choline, L-carnitine and myo-inositol mandatory in infant formula (but not follow-on formula).
- Limit protein sources to cow's milk, goat's milk, sheep's milk and soy.

Review of the infant formula standard – anticipated changes

Labelling:

- updated preparation instructions to improve clarity
- prescribed format for the nutrition information statement
- restrictions on stage labelling on infant formula.



The infographic is titled 'HOW TO PREPARE' and is divided into three stages of infant formula preparation. Stage 1 is 'Newborn Formula' (teal drop), Stage 2 is 'Follow-on Formula' (purple drop), and Stage 3 is 'Toddler Milk Drink' (orange drop). Below the stages is a 'FEEDING GUIDE – TO PREPARE ONE FEED' table. To the right of the table are three numbered steps with icons: 1. Wash hands and all equipment before preparing formula. 2. Sterilise all equipment by boiling for five minutes or by using an approved steriliser. 3. Boil fresh drinking water for five minutes and leave to cool. 4. When cool, measure out the required amount of water and formula.

Age of Infant	Cooled Boiled Water (mL)	Level Scoops of Formula	Formula Feeds per Day
Up to 2 weeks	60 mL	1	7-8
2 weeks - 3 months	120 mL	2	6
3 - 6 months	180 mL	3	5

One level scoop = 8.8 g of formula. Note: One scoop of powder added to 60 mL water yields approximately 67 mL of formula. Your baby may need more or less than indicated. Ideally formula should be prepared just prior to feeding. Otherwise refrigerate prepared formula and use within 24 hours. Only use the enclosed scoop.

1. Wash hands and all equipment before preparing formula.
2. Sterilise all equipment by boiling for five minutes or by using an approved steriliser.
3. Boil fresh drinking water for five minutes and leave to cool.
4. When cool, measure out the required amount of water and formula.

Human breast milk import regulations

- Several enquiries to import human milk into Australia in recent years.
- FSANZ conducted a risk assessment of imported human milk and identified numerous potential risks, including microbiological hazards and risks associated with maternal use of medicines and/or illicit substances.
- As a result, human milk can only be imported from countries where a government to government agreement has been established.
 - US agreement signed in April 2023
 - first product imported in August 2023 for distribution to hospitals in NSW.
- Human breast milk is considered a tissue in Victoria and requires a permit for trade under the *Human Tissue Act 1982*.

Non-regulatory initiatives

Marketing in Australia of Infant Formulas: Manufacturers and Importers (MAIF) Agreement:

- voluntary self-regulated code of conduct to promote responsible marketing and protect breastfeeding
- acts at Australia's implementation of the WHO International Code of Marketing Breast-milk Substitutes
- review of the agreement currently underway.

Non-regulatory initiatives

MAIF Agreement:

- Opportunities to strengthen the agreement and alignment with WHO code
 - legislate/mandate
 - increase scope of signatories (distributors, retailers)
 - increase scope of products (toddler milk)
 - modernise to recognise modern marketing techniques (social media)
 - effective penalties and enforcement tools.

Emerging ingredients and products

Human identical milk oligosaccharides (HMOs/HiMOs)

- Over 200 HMOs identified in human milk.
- Four applications to permit HiMOs to infant formula since 2018.
- Evidence base limited for beneficial effect in formula-fed infants.
- Restrictions on labelling in Australia and New Zealand (HMO and references to human-identical not permitted).



Source: similac.com

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Emerging ingredients and products

- claims
- plant-based formula



Source: <https://happihealth.com.au/products/stage-2-night-follow-on-formula/>



Source: <https://sproutorganic.com.au/products/infant-formula>

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Emerging ingredients and products

Cell-based ('synthetic') human milk

BIOMILQ AND THE NEW
SCIENCE OF ARTIFICIAL
BREAST MILK

The biotech industry takes on infant nutrition.

By Molly Fischer

March 6, 2023



Lab-grown 'human milk' may be just three years away

By Milly Chan, CNN Business

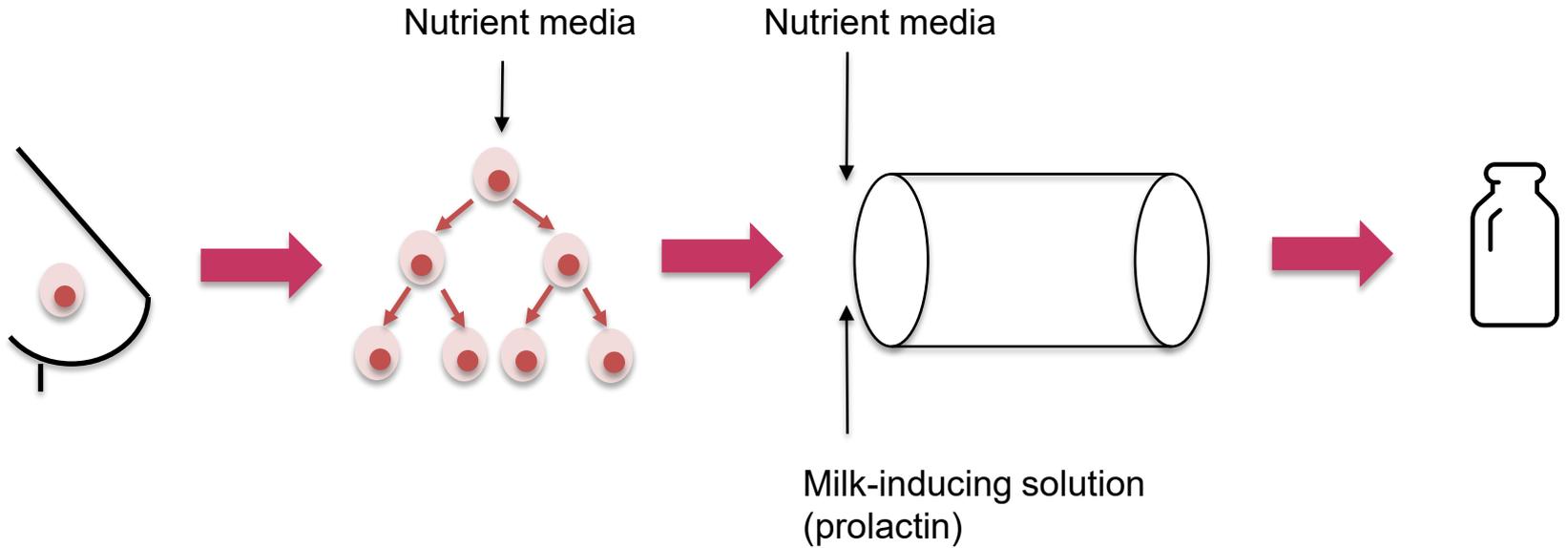
Updated 12:52 PM EDT, Tue May 3, 2022

Australia's first cell-based milk startup, Me&, says it is developing cell-based breast milk just like a human mother would.

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Emerging ingredients and products

Cell-based ('synthetic') human milk



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