

# Issues Paper: Food Regulatory Framework Considerations for Cell-based Human Milk Products

Food Regulation Standing Committee, March 2024

## Executive Summary

Cell culture and precision fermentation science is advancing rapidly, and it is expected that a range of foods produced using these technologies will be commercialised in the coming years. This includes products which aim to replicate human breastmilk components or whole breastmilk as an alternative to infant formula for caregivers that cannot or choose not to breastfeed. These products are collectively referred to in this paper as cell-based human milk products. While Food Ministers have advised that existing regulatory arrangements are equipped to deal with foods produced by cell culture and precision fermentation, cell-based human milk products present a number of complexities that require specific consideration, including the vulnerability of the intended end consumers (i.e., infants) and the unique production inputs (i.e., human breast tissue cells). As a first step in examining these complexities, this issues paper considers the applicability of current food regulation frameworks to cell-based human milk products targeted at infants, in order to identify potential regulatory gaps or matters that may require Ministerial consideration.

The review of food regulatory frameworks found that:

- cell-based human milk products are unlikely to truly replicate the composition and health benefits of human milk, and are comparable from a function and regulatory perspective to infant formula products;
- existing food regulation frameworks are appropriate for cell-based human milk products, although some specific provisions will be required within these frameworks to address unique characteristics of cell-based human milk products;
- while the principles of the Policy Guideline on the Regulation of Infant Formula are highly relevant for cell-based human milk products, it is not clear whether cell-based human milk products would be captured within the scope; and
- there are outstanding matters that require more thorough examination to understand food regulatory gaps.

On this basis and to ensure regulatory parity, it is recommended that:

- 1) ministerial policy guidance is developed to articulate the expectation that cell-based human milk products are regulated in a manner consistent with 'traditional' infant formula products; and
- 2) a further separate analysis is undertaken to consider outstanding food regulatory issues. This should be progressed separately to the development of policy guidance to ensure the guidance is delivered promptly in advance of applications seeking regulatory approval for cell-based human milk products.

## Introduction

In November 2019, the Food Regulation Standing Committee (FRSC) agreed that existing regulatory arrangements in Australia and New Zealand are sufficient for foods produced by emerging cell culture and precision fermentation technologies. Subsequently in November 2022, the Food Ministers Meeting affirmed Food Standards Australia New Zealand's (FSANZ) view that such foods would be captured by existing standards within the Code and would require pre-market assessment under Standard 1.5.1 Novel foods and Standard 1.5.2 Foods produced using gene technology.

Despite agreement on the sufficiency of overarching regulatory controls, it is recognised that cell-based human milk products are likely to present unique complexities due to the vulnerable infant population they will serve and the novel production inputs (i.e., human breast tissue cells). It is understood that both domestic and international companies intending to manufacture cell-based human milk are nearing a point of commercialisation and have begun enquiring about regulatory approvals. For these reasons, it is important that current regulatory arrangements are further reviewed with a specific focus on the unique complexities related to breastmilk substitutes and cell-based human milk products.

The purpose of this issues paper is to explore and provide advice on regulatory framework considerations for cell-based human milk within the context of the existing food regulatory system. As per the Terms of Reference, matters related to social and ethical issues, changes to novel foods regulation, and broader definition changes such as 'human tissue' and 'nutritive substance' are not considered within the scope of this paper.

## Background

### Human milk and breastmilk substitutes

Infant feeding guidelines in Australia and New Zealand recognise exclusive breastfeeding is the preferred way to feed an infant until around 6 months of age when complementary foods are introduced. It is also recommended that breastfeeding continues up to 12 months (Australia) or two years (NZ) and beyond (National Health and Medical Research Council, 2012; Ministry of Health, 2021).

When breastfeeding is not possible, commercial infant formula products are the only recommended substitute until 12 months of age. There are a range of commercially available infant formula products for infants of different age and nutrient requirements, including infant formula, follow-on formula, pre-term formula and specialised products for infants with specific nutritional needs. These products may be based on a range of animal and plant protein sources including bovine (cow), goat, sheep and soy. These products are regulated under Standard 2.9.1 and Schedule 29 of the Code.

Pre-term and low birthweight infants may also be fed commercial human milk fortifier. These products are mixed with expressed breastmilk (mother's own milk or donated human breastmilk) to meet the increased nutritional needs of these infants. Human milk fortifier has historically been manufactured from bovine sources. However, since August 2023, following agreement to new certification arrangements between the US Government and Australian Government, a human-derived human milk fortifier has been imported and distributed in Australia for use in specialised hospital neonatal intensive care units. Regardless of source, human milk fortifier is not captured as an infant formula product under the Code as these products do not provide a sole or principal source of nourishment. Human milk fortifiers are instead typically regulated as foods for special medical purposes under Standard 2.9.5 of the Code.

Donated expressed human breastmilk may also serve as an alternative or supplementary source of nourishment for infants. Expressed human breastmilk may be obtained through established breastmilk banks which collect, process and distribute excess breastmilk from non-enumerated donors. The regulation of breastmilk banks and their products varies according to state and national (NZ) human tissue and food legislation. Expressed human milk may also be obtained through informal sharing networks. These informal practices do not involve a sale and are therefore not subject to food and human tissue regulation requirements.

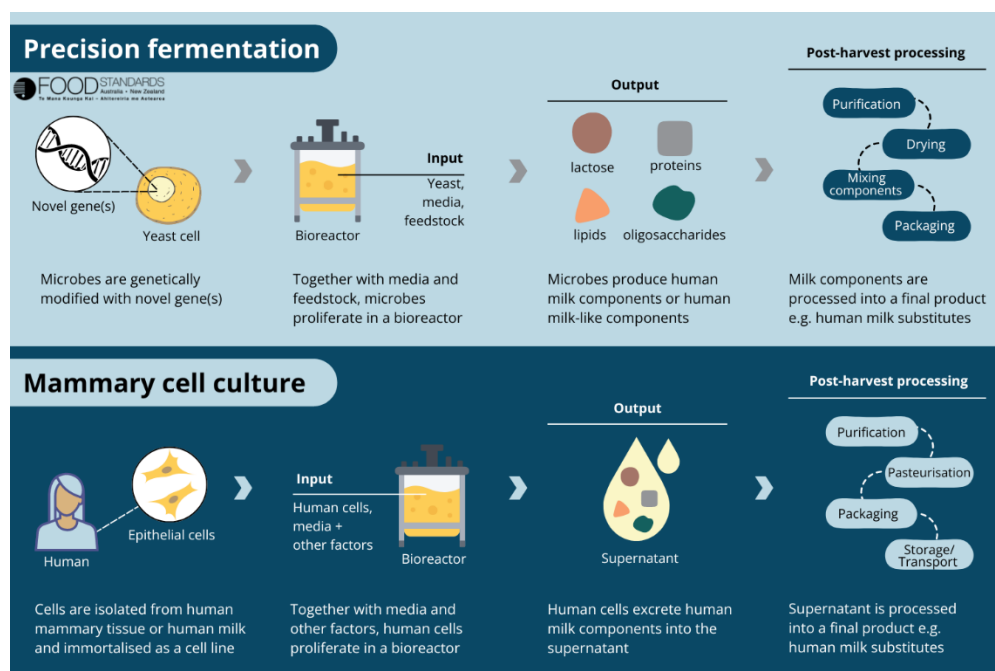
## Cell-based human milk

Cell-based human milk is a novel breastmilk substitute product which is expected to be sold commercially as an alternative to infant formula products in the coming years. The term broadly encompasses a range of products intended to closely match human breastmilk and its components, that are produced through cell culture and precision fermentation technologies.

**Precision fermentation** – This technology uses genetically modified microorganisms to produce human milk components.

**Mammary cell culture** – This technology involves isolating, growing and treating human tissue cells to produce human milk components or human milk analogue products. However, production of human milk is different from other cell-based foods such as meat because the harvested end product for consumption is not the cell tissue itself, but a substance produced and excreted by the tissue cells.

See Figure 1 for a process overview of precision fermentation and mammary cell culture.



**Figure 1:** Production methods for producing cell-based human milk and its components.

It is expected that these technologies will be used to produce whole foods (e.g. cell-cultured human milk), as well as various components and subcomponents found within human milk (e.g. oligosaccharides) that may undergo further processes to produce a product suitable as a breastmilk substitute. This may include processes to adjust composition through combining multiple cell-based ingredients or adding substances such as processing aids and/or additives, and processing technologies such as pasteurisation, drying and freezing. It is anticipated that the range of commercialised end products produced by cell culture and precision fermentation will be broad and likely include nutrient sub-components of human milk, human milk fortifier and products designed as a complete source of nourishment (i.e., as an alternative to infant formula) for pre-term, term and older infants. Subcomponents produced through precision fermentation or cell culture could also potentially be added to standard infant formula products, similar to recent approval for various human-identical milk oligosaccharides.

Cell-based human milk, should it be presented as a complete source of nutrition, would be expected to more closely match the composition of breastmilk compared to current infant formula products. However, there are likely to be a number of differences including the absence of certain components not produced by breast tissue such as immune-protective antibodies, or substances that are ingested through maternal microbial transfer that occur during breastfeeding (Atyeo & Alter, 2021). Breastmilk composition is also subject to large variations, including across individuals due to biological and dietary factors, throughout an infant's life course to meet stage-related nutrition demands, and even within a singular feeding occurrence (Bravi, et al., 2016). Given the complex composition of human breastmilk which contains a multitude of bioactive components, presumably many of which are still unknown, and advanced feedback loops that modify composition according to an infant's growth and nutritional needs, it is reasonable to assume that cell-based products will never truly replicate breastmilk.

## Application of the current food regulation framework to cell-based human milk

This section considers how the current food regulation framework applies to cell-based human milk in order to understand sufficiency and to identify gaps in regulatory controls.

### Ministerial Policy Guideline on the Regulation of Infant Formula Products

The Policy Guideline on the Regulation of Infant Formula Products (the Infant Formula Policy Guideline) outlines Food Ministers' expectations for the composition, labelling, advertising and promotion of infant formula products. The policy guideline sets out various principles which FSANZ must have regard to when developing or amending relevant standards. This includes high order principles that underlie all work of FSANZ, and specific policy principles that recognise overarching matters such as the protection of breastfeeding and vulnerability of infants as well as requirements for composition, labelling and products for special dietary use. Each section of the Infant Formula Policy Guideline and how it might apply to cell-based human milk is reviewed and discussed below.

#### **Purpose**

The stated purpose of the Infant Formula Policy Guideline is to provide guidance on the expectations of the Australia New Zealand Food Regulation Ministerial Council (now the Food Ministers' Meeting) for the composition, labelling, advertising and promotion of infant formula products. This section also provides the context for the guidance related to the importance and health implications of

breastfeeding, the vulnerability of infants, particularly where infant formula products may be the sole or principal source of nutrition, and the need for a regulatory framework that is commensurate with this level of risk for the composition, labelling, advertising and promotion of infant formula products.

Cell-based human milk is intended for the same population as infant formula products and Ministers are likely to hold similar expectations for cell-based human milk. Accordingly, ministerial policy guidance is likely to be desired in relation to the regulation of cell-based human milk products.

## Scope

The scope of the Infant Formula Policy Guideline is stated to cover infant formula, follow-on formula and infant formula for special dietary uses for infants from 0 to 12 months of age, with the following definitions provided for the purpose of the policy guideline:

***follow-on formula** means an infant formula product represented as either a breastmilk substitute or replacement for infant formula and which can constitute the principal liquid source of nourishment in a progressively diversified diet for infants aged from six to 12 months of age*

***infant** means a person under the age of 12 months*

***infant formula** means an infant formula product represented as a breastmilk substitute for infants and which satisfies, as the sole source of nourishment, the nutritional requirements of infants up to six months of age*

***infant formula product** means a manufactured product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve as the principal liquid source of nourishment for infants.*

It is not clear whether cell-based human milk is captured within these definitions as it could be argued that products produced through cell culture and precision fermentation are an 'edible food constituent of animal origin'. At the time the policy guideline was developed and endorsed, cell culture food technology was in its infancy and cell-based human milk would not have been considered or intended to be included within the definitions. There may be advantages of including cell-based human milk products within the scope of the Infant Formula Policy Guideline given they are also intended to be consumed as a breast milk substitute. Although this will depend on applicability of the policy guideline in its entirety, which is explored throughout the following section.

## High Order Policy Principles

The high order policy principles recognise the objectives for FSANZ in developing or reviewing standards under the *Food Standards Australia New Zealand Act 1991* to ensure that food regulatory measures protect public health and safety, provide adequate information relating to food to enable consumers to make informed choices, and prevent misleading or deceptive conduct. Other matters that FSANZ must have regard to when amending standards, include but are not limited to, the need for evidence-based risk assessment, the promotion of harmonisation with national and international food standards and promotion of fair trading. These principles apply to the development or

amendment of all food standards and thus would be applicable to any regulatory amendments relevant to cell-based human milk.

### **Specific Policy Principles – Overarching Principles**

The overarching specific policy principles that apply to all infant formula products state that:

- a) The regulation of infant formula products should recognise that breastfeeding is the normal and recommended way to feed an infant.
- b) The regulation of infant formula products should not be inconsistent with the national nutrition policies and guidelines of Australia and New Zealand that are relevant to infant feeding.
- c) The regulation of infant formula products should be based on risk analysis, taking into account the vulnerability of the population for whom they are intended and the importance of these products in the diets of formula fed infants.

Despite the purported increased compositional alignment of cell-based human milk with human breastmilk, there will continue to be additional benefits to both mother and baby from breastfeeding. There is also not yet evidence to demonstrate whether the suggested increased compositional alignment will translate into improved health outcomes consistent with breastfed infants. It therefore is appropriate for the regulation of cell-based human milk to also recognise that breastfeeding is the recommended feeding method for infants. As infants are also the intended population for cell-based human milk, consideration of infant feeding policies and the need for risk-based regulation are also applicable.

### **Specific Policy Principles – Composition**

Specific policy principles d), e) and h) recognise the need for the composition of infant formula and follow-on formula to be safe, suitable and to replicate human breastmilk as closely as possible. Specific policy principles f) and g) set out the regulatory requirements for the composition of infant formula products, stating that the essential composition of infant formula and follow-on formula should be prescribed in regulation where necessary to ensure infant nutritional requirements are satisfied, and that compositional requirements should only be mandated where there is evidence to demonstrate it is safe and essential for normal growth and development. Specific policy principles concerning composition in infant formula products are given legal effect through specific clauses in Standard 2.9.1 and Schedule 29 listings.

As already noted, cell-based human milk products are expected to serve as an alternative to current infant formula products, meaning they will be consumed by the same infant population in which precise nutrient intake is critical for safety and to support healthy development. Accordingly, these principles, which provide for regulations that ensure products that are the sole or principal source of nutrition for infants are safe and suitable, are also applicable to cell-based human milk products.

Specific policy principle i) specifies a requirement for pre-market assessment of substances without a history of safe use in infant formula products in Australia and New Zealand, having regard to the proposed levels, source, form/structure and production technique/technology. Specific policy principle j) established that such substances subject to pre-market assessment should have a substantiated beneficial role or technical role.

It is appropriate that cell-based human milk is subject to the same pre-market assessment requirements given such products do not have a history of safe use in relation to the source and production technology and is intended to be consumed by the same vulnerable infant population. It is possible that as cell technologies advance, the range of subcomponents present in breastmilk that can be produced within cell-based human milk products will also increase. This extended composition may be considered equivalent to the addition of substances to infant formula products and therefore subject to the same pre-market assessment requirements.

### **Specific Policy Principles – Labelling and Advertising**

Specific policy principle k) states that the labelling and advertising of infant formula products should be consistent with the World Health Organization (WHO) International Code of Marketing of Breastmilk Substitutes as implemented in Australia and New Zealand. In Australia, the Marketing in Australia of Infant Formulas (MAIF) is Australia's response to the WHO Code. In New Zealand, the response to the WHO Code is The Infant Nutrition Council Code of Practice for the Marketing of Infant Formula in New Zealand. The aim of the WHO Code and the tools which give effect to the WHO Code in Australia and New Zealand is to protect and promote breastfeeding by ensuring proper use of breastmilk substitutes.

As already noted, there will likely be compositional differences between cell-produced and maternal human milk. Cell-based human milk will also be unable to provide non-nutritive benefits such as the reduced risk of maternal ovarian and breast cancer, and type 2 diabetes (Chowdhury, et al., 2015). Given these limitations, breastfeeding is likely to continue to be the preferred and recommended way to feed a baby. It is therefore appropriate to ensure the labelling and advertising of cell-based human milk protects and supports breastfeeding, and does not permit cell-cultured human milk products to be marketed as potentially superior to maternal human breast milk.

### **Specific Policy Principles – Infant Formula Products for Special Dietary Uses**

The Infant Formula Policy Guideline notes that infants with specialised dietary or medical needs are a small and diverse group with varying needs, and as such, policy principles d) – h) (related to composition) do not apply, and principles i) – j) may apply at the discretion of FSANZ. The policy guideline instead states that the composition of infant formula products for special dietary use must be safe, suitable, and meet the nutritional requirements of the infants for whom they are intended. Further, the composition should be based on appropriate scientific evidence. Specific policy principle q) states that the labelling and advertising of such products should clearly specify the dietary or medical uses for which the product is intended.

As an alternative to traditional infant formula products, it is anticipated that cell-based human milk products are likely to expand into products for special medical or dietary use. The infant population that requires such products would be similarly small and diverse, and as such, the specific policy principles would continue to apply to cell-based human milk products for special dietary use.

The key consideration for cell-cultured human milk is the need for an appropriate scientific evidence base for the claimed medical purpose given the novelty of the technology. It is not clear whether the cell-cultured human milk industry has established this evidence base yet, but it will be critical given the regulatory flexibility permitted for these special purpose products.

### **Additional policy guidance – Expert Group**

The Infant Formula Policy Guideline states that FSANZ should consider establishing an independent scientific expert group that may provide advice on whether a substance that may be subject to pre-market assessment:

- i) has a history of safe use in infant formula or follow-on formula in Australia and New Zealand; and
- ii) has a substantiated beneficial role in the normal growth and development of infants or children as supported by evidence.

Independent expert scientific advice is important given the complexities in conducting and interpreting scientific evidence to demonstrate safety and benefits in infant populations. This is likely to also be relevant to the pre-market assessment of cell-based human milk given the similar infant population and associated evidence challenges.

#### **Additional policy guidance – Relevant International Agreements**

The policy guideline provides that the regulation of infant formula products in Australia and New Zealand should be consistent to the greatest extent possible with:

- relevant World Health Organization agreements; and
- relevant World Trade Organization agreements, Codex standards and guidelines.

Currently there are no WHO agreements, Codex standards or guidelines specifically related to cell-based human milk. As already discussed, the WHO International Code of Marketing of Breastmilk Substitutes is likely to be relevant to cell-based human milk.

#### **Additional policy guidance – Definitions**

As discussed above, it is not clear whether the definitions within the Infant Formula Policy Guideline would include cell-based human milk products. The term ‘infant formula’ is generally understood to describe infant formula products currently on the market based on traditional animal and plant protein sources. Further, cell-based human milk products are expected to be distinct in some ways from traditional infant formula products in relation to composition. For these reasons and to provide regulatory clarity, it would be beneficial to utilise distinct definitions to differentiate between ‘traditional’ and novel cell-based human milk products that are breastmilk substitutes.

If timing aligns, the revised definitions proposed under P1028 relating to infant formula products could also be incorporated in the Policy Guideline.

#### [Other Policy Guidelines and Statements](#)

Other Ministerial policy guidance that may be relevant are summarised below. The applications of these documents to cell-based human milk are reviewed in brief, acknowledging that they are not specifically related to breastmilk substitutes and will likely be considered as part of broader cell-based food approvals.

#### **Ministerial Policy Guideline on the Labelling of foods produced or processed using new technology**

This policy guideline outlines ministerial expectation on labelling of foods produced or processed using a new technology following pre-market assessment. The policy guideline acknowledges that following pre-market safety assessment, labelling in relation to new technologies is not a public health or safety issue, but a consumer interest matter. The specific policy principles recognise that



the provision of information in relation to new technologies should be cost effective, comply with international obligations while not being more trade restrictive than necessary and ensure parity between domestic and imported foods.

Cell-based human milk products are likely to attract consumer interest because of the novel production methodologies, particularly related to product naming to ensure appropriate pre-purchase disclosure. The principles of this policy guideline are therefore likely to be relevant to cell-based human milk.

### **Policy Statement on the Interpretation of public health and safety in developing, reviewing and varying food regulatory measures**

This policy statement clarifies how public health and safety should be interpreted by FSANZ when developing or varying food standards, emphasising the need to consider both immediate health risks and longer-term health impacts.

Approval for the sale of cell-based human milk products will require consideration of health and safety risks, and if necessary, development or amendment of food regulatory measures by FSANZ. Accordingly, the policy statement will apply and there will need to be consideration of both short- and long-term health implications. It is likely these issues would be considered as part of the mandatory pre-market safety assessment process that FSANZ must undertake on all novel food applications.

### **Ministerial Policy Guidelines on Novel foods**

In November 2022, the Food Ministers' Meeting noted the expectation that foods produced by cell culture and precision fermentation would be subject to pre-market assessment as a novel food. Accordingly, this the policy guideline will be applicable to cell-based human milk products as they are a food that may be produced by cell culture and/or precision fermentation. While some aspects of the novel foods policy guideline relate specifically to the review of Standard 1.5.1 Novel foods and are not relevant to cell-based human milk, there are several other points that are highly relevant. This includes the need to protect commercially sensitive intellectual property as well as ensuring consumers are not misled by novel foods or ingredients that appear similar to existing foods but differ in nutrition or function.

### [Australia New Zealand Food Standards Code](#)

*Note: FSANZ is currently finalising its review of infant formula product regulations however the consideration of the below high-level context remains applicable to the potential regulatory options for cell-based human milk and related products.*

Cell-based human milk as a food for sale will be required to comply with the Food Standards Code, as is the case for all foods. To date, manufacturers have stated that cell-based human milk is not designed as a replacement for breastfeeding an infant but as a more suitable alternative to current infant formula products, suggesting that manufacturers are intending to market these foods as complete sources of infant nutrition.

Given this context, many of the existing standards within the Code will be applicable to cell-based human milk products e.g. Standard 1.2.1 – Requirements to have labels or otherwise provide information; Standard 1.5.1 – Novel foods; Standard 1.5.2 – Foods produced using gene technology;

Standard 2.9.1 – Infant formula products. However, some aspects will require specific consideration, and can only be determined once details of a product are provided.

Cell-based human milk products will require express permission in the Code as a food for sale or as an ingredient in a food for sale. In November 2022, Food Ministers affirmed FSANZ’s view that food produced by cell culture and precision fermentation would require pre-market assessment under Standard 1.5.1 Novel foods and Standard 1.5.2 Foods produced using gene technology. However, it should be noted that in the Code, food must be regulated as either a novel food or as a food produced using gene technology. It is expected that precision fermentation products will also be captured as food produced using gene technology, whereas cell cultured tissue cells may be produced without the use of genetic modification techniques.

Rapid innovation has led to the development of a number of ingredients that do not clearly fit as either a novel food or a nutritive substance. In some instances, an ingredient may meet the definitions of both. This can occur when an ingredient is developed using a novel process but is used as a nutritive substance in the final food. For regulatory clarity, from both an implementation and enforcement purpose, the Code stipulates that a food cannot be regulated as both a novel food and a nutritive substance.

Typically, if an ingredient is a novel food used as a nutritive substance as defined in paragraph 1.1.2—12 of the Code, it will be regulated as a nutritive substance. Regardless of whether a food is assessed as a novel food, food produced using gene technology or nutritive substance, cell-based human milk products will be subject to pre-market assessment as specified by Food Ministers. However, given the vast array of possible products (nutritive substances, partial and complete sources of nutrition) and production methodologies (with or without the use of gene technology), there is a need to consider how best to ensure appropriate, coherent and consistent regulatory placement of substances and foods across successive regulatory approvals.

There is also a need to consider the possibility of a purpose built Standard for foods produced by cell culture and precision fermentation. While Food Ministers previously noted that these novel products would be captured within existing standards in the Code, the suitability of this approach may need to be revisited as the category expands.

The following section outlines existing standards in the Code and identifies where specific considerations for cell-based human milk may be required.

## Part 2.9 Special Purpose Foods

### Standard 2.9.1 – Infant Formula Products

Although breastfeeding is the recommended way to feed infants, a safe and nutritious substitute for breastmilk is needed for infants who are not breastfed. Infant formula products are currently the only safe and suitable alternative to breastmilk.

Infant formula products are specifically regulated through Standard 2.9.1 and Schedule 29 of the Code and have the most prescriptive requirements of any food category in the Code. Other standards in the Code also contain provisions for infant formula products, such as those relating to definitions, food additives, contaminants, labelling, novel foods and microbiological limits.

Standard 2.9.1 sets out the specific compositional, labelling and packaging requirements, and any exemptions, for infant formula products.

Infant formula product is defined similarly as in the Infant Formula Policy Guideline, stating:

***infant formula product*** means a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants, depending on the age of the infant.

In addition to the definitions for ‘infant formula products’, definitions for ‘infant formula’, ‘follow-on formula’, ‘pre-term formula’ and ‘protein substitute’ are provided in sections 1.1.2—2 and 1.1.2—3 of the Code.

Like in the Infant Formula Policy Guideline, it is somewhat unclear whether the current definitions for ‘infant formula’, ‘infant formula product’, and ‘follow-on formula’ would include cell-based human milk products. As already discussed, it is desirable that definitions provide clear distinction between current infant formula products and cell-based human milk products given the expected differences in these products. This is important for definitions within the Code given implications not only for the framework of Standard 2.9.1, but also linkages with prescribed names and labelling requirements, which in turn provide information to consumers about the nature and intended use of the product. The term ‘infant formula product’ is defined under the Code, standardising the product category name of all infant formula products. It will be necessary to examine whether this term is appropriate for use for cell-based human milk products with the current structure of Standard 2.9.1 in combination with appropriate specified naming conventions (e.g., cell-cultured infant formula) or whether a standalone definition that clearly differentiates cell-based human milk is required (e.g., cell cultured human milk formula).

Compositional specifications laid out in Standard 2.9.1 and Schedule 29 include both mandatory essential composition for a range of macronutrients, micronutrients and nutritive substances, and substances that may voluntarily be added to infant formula products. For cell-based human milk products that intend to act as alternative to infant formula and follow-on formula (i.e., as a complete or principal source of nourishment), some existing specifications, such as energy and protein content, are likely to be relevant. However, for other nutrients, such as iron where bioavailability differs between synthetic forms added to infant formula and that naturally present in breastmilk, current specifications may not be appropriate for human identical products produced through precision fermentation or cell culturing. Establishment of an appropriate nutritional and compositional baseline for cell-cultured human milk products will likely be necessary and would be considered as part of the standards development process once an application is submitted to FSANZ. This could take the form of a Schedule 3 identity and purity specification for these foods. The presence of micronutrients in these foods (vitamins, minerals etc) will also require consideration of Schedule 29 permissions.

Division 5 of Standard 2.9.1 outlines labelling and packaging requirements as follows:

- 2.9.1 – 16 Representations about food as an infant formula product
- 2.9.1 – 17 Prescribed names
- 2.9.1 – 18 Requirement for measuring scoop
- 2.9.1 – 19 Requirement for warning statements and directions
- 2.9.1 – 20 Print size
- 2.9.1 – 21 Declaration of nutrition information
- 2.9.1 – 22 Storage instructions
- 2.9.1 – 23 Statement of protein source and dental fluorosis
- 2.9.1 – 24 Prohibited representations

The current labelling and packaging provisions outlined in Division 5 will mostly be relevant to cell-based human milk. For example, as already noted, breastfeeding is expected to continue to be the preferred and recommended way to feed an infant and thus prohibited representations under section 2.9.1 – 24 that prevent promotion of breastmilk substitutes as equivalent or better than breastfeeding (e.g., prohibition on the words ‘humanised’ or ‘maternalised’ or words having the same or similar effect) would be appropriate. However, applicability of other provisions will be dependent of the type and format of the product. For example, Section 2.9.1 – 18 Requirement for a measuring scoop will depend on whether the product is sold as concentrated/multi-serve product or ready-to-drink, and whether it is in a powdered or liquid format. Additionally specific descriptors may also be necessary in Division 5 to enable truthful description of cell-cultured human milk, or ingredients/components derived from cell-cultured human milk similar to those used to assist in accurately describing human identical milk oligosaccharides (HiMO’s).

#### Standard 2.9.5 – Food for Special Medical Purposes

While Standard 2.9.1 sets out regulations for infant formula products (which serves as sole or principal liquid source of nourishment) formulated for a medically diagnosed disease, disorder or condition of an infant, Standard 2.9.5 sets out regulations for supplementary products not intended as breast milk substitutes, such as human milk fortifiers. Similarly, cell-based human milk product not intended as a sole or principal source of nourishment are likely to fall within the regulatory scope of Standard 2.9.5. However, the ‘medical condition’ these products would be developed to assist would need to be established to permit capture as a food for special medical purposes (FSMP). The additional risk associated with capture as a FSMP is that offence provisions concerning use as un-approved novel foods and nutritive substance do not apply to FSMP (refer Standard 2.9.5-3(a)). Consideration would need to be given to define this specific category of FSMPs and the related application of Standard 2.9.5.

#### Other relevant Standards and Code definitions

##### Standard 1.5.2 Food produced using gene technology

Section 1.1.2—2 of the Code defines **food produced using gene technology** as a *food which has been derived or developed from an organism which has been modified by gene technology*. **Gene technology** is defined as *recombinant DNA techniques used to alter the heritable genetic material of living cells or organisms*.

FSANZ is in the process of reviewing the definitions for food produced using gene technology and gene technology under Proposal P1055 – Definitions for gene technology and new breeding techniques. In the meantime, the current Code provisions for food produced using gene technology apply.

Unless expressly permitted, food is prohibited from sale if it is a food produced using gene technology or contains food produced using gene technology as an ingredient or component (Paragraph 1.1.1—10(5)(c) and 1.1.1—10(6)(g) of the Code). Permitted foods produced using gene technology are listed in Schedule 26 of the Code, unless they are used as a processing aid or food additive, in which case they are listed in the relevant schedules related to those substances. Nutritive substances permitted for use in infant formula products that are food produced using gene technology are listed in Schedule 26. Standard 1.5.2 also sets out the labelling provisions for permitted food produced using gene technology.

For example, a number of human identical milk oligosaccharides produced by precision fermentation are already permitted in the Code to be used as a nutritive substance and as food produced using

gene technology. It is important to highlight that permission for these substances under Schedule 26 are subject to conditions of use, which includes that they may only be added to infant formula products. . As precision fermentation technology is likely to advance and expand into other human milk subcomponents, it will be important to consider whether such conditions of use remain appropriate.

### Standard 1.5.1 Novel foods

Paragraphs 1.1.1—10(5)(b) and 1.1.1—10(6)(f) of the Code provide that, unless expressly permitted by the Code, a food offered for retail sale must not be a novel food or have a novel food as an ingredient.

Section 1.1.2—8 of the Code defines **novel food** as a *non-traditional food that requires an assessment of the public health and safety considerations* having regard to any of the following (see subsection 1.1.2—8(1)):

- the potential for adverse effects in humans
- the composition or structure of the food
- the process by which the food has been prepared
- the source from which it is derived
- patterns and levels of consumption of the food
- any other relevant matters.

*Non-traditional food* is defined as any of the following (see also subsection 1.1.2—8(1)):

- a food that does not have a history of human consumption in Australia or New Zealand, or
- a substance derived from a food, where that substance does not have a history of human consumption in Australia or New Zealand other than as a component of that food, or
- any other substance, where that substance, or the source from which it is derived, does not have a history of human consumption as a food in Australia or New Zealand.

For the purposes of the definition of *novel food*, neither of the following constitutes a history of human consumption in Australia or New Zealand (see subsection 1.1.2—8(2)):

- the presence of a food in a food for special medical purposes
- the use of a food as a food for special medical purposes.

Section 1.5.1—3 of Standard 1.5.1 – Novel foods, permits a food offered for retail sale to consist of, or have as an ingredient, a novel food that:

- is listed in the table to section S25—2 of Schedule 25 – Permitted novel foods; and
- complies with any conditions of use specified in the corresponding row of that table.

Schedule 25 currently allows for the following novel foods to be added to infant formula products:

1. Dried marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA)
2. Oil derived from marine micro-algae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695)
3. Oil derived from marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA)
4. Oil derived from marine micro-algae (*Ulkenia* sp.) rich in docosahexaenoic acid (DHA)
5. Trehalose.

Cell-based food is not currently permitted for sale in Australia and New Zealand and there is no specific standard in the Code for this category of food. FSANZ received its first application for a cell-

cultured product in 2023 ([Application A1269 – Cultured Quail as a Novel Food](#)) which is being assessed as a novel food. Outcomes of this assessment may be relevant to the regulation of cell-based human milk products.

A further consideration for cell-based human milk products is whether regulation as a novel food should be subject to conditions of use that limit end point commercialisation. For example, a restriction to infant products (<12 months) which would in effect prevent age-based stage progression practices used in the standard infant formula industry, as well as being marketed towards other population sub-groups (e.g., as a formulated supplementary sports foods).

### Nutritive substances

Paragraph 1.1.1—10(6)(b) of Standard 1.1.1 requires that, unless expressly permitted, a food for sale must not have as an ingredient or component a substance that was *used as a nutritive substance*. A substance that is *used as a nutritive substance* is defined in section 1.1.2—12 of the Code as a substance that has been concentrated, refined or synthesised and added to food to achieve a nutritional purpose.

The Code already permits the voluntary addition of substances to be *used as a nutritive substance* in infant formula products. Permitted nutritive substances are listed in Schedules 29-5, 5A, 6 and 7 , along with permitted forms and amounts. Depending on the scope of use, cell-based human milk products may be regulated as nutritive substances if they are intended to be added to infant formula products for a nutritional purpose.

### Labelling Requirements

In addition to the specific labelling requirements outlined in Standard 2.9.1, the Code sets out general labelling requirements, including the type of food products that are required to bear a label and the information that must be provided. Public health and safety is the overarching policy principle that guides mandatory food labelling in the Code. Labelling requirements are also intended to provide consumers with adequate information to enable informed choice. Australian Consumer Law prohibits businesses from making false or misleading representations about goods or services (Competition and Consumer Act 2010 (Cth) Schedule 2, s29). In New Zealand, Section 13 of the Fair Trading Act 1986 prohibits false or misleading representations.

Subsection 1.1.1—10(8) requires that food for sale must comply with all relevant labelling requirements in the Code for that food. Currently, the Code does not include specific labelling requirements for a cell-cultured food. However, at the first Call for Submissions for Application A1269, FSANZ proposed specified naming to identify cultured quail, suggesting there will likely be consideration of naming conventions for these foods produced using similar technology.

Subsection 1.1.1—13(4) states if a food name is used in connection with the sale of a food (for example in the labelling), the sale is taken to be a sale of the food as the named food unless the context makes it clear that this is not the intention. This provision is supplemented with examples that include:

*‘The context within which foods such as soy milk or soy ice cream are sold is indicated by use of the name soy; indicating that the product is not a dairy product to which a dairy standard applies.’*

Cell-based human milk is a breastmilk substitute and likely to act as an alternative to currently available infant formula product or food for special medical purpose intended for use by infants. However, the identity of cell-based human milk is neither of breastmilk, milk, plant-based milk, infant formula or follow-on formula. Consideration will need to be given so that the name of cell-based human milk for sale and its representation (including pictorial images on the package) will indicate that the product is neither human breastmilk, milk, plant-based milk, infant formula or follow-on formula. Decisions concerning naming conventions for these foods will also need to be influenced by what consumers understand 'cell-cultured' to mean as it is highly likely there is little familiarity with use of this technology with regard to infant food production.

Standard 1.2.2 sets information requirements for food identification, including requirements for the name of a food. Specifically, paragraph 1.2.2—2(1)(a) requires packaged food to be labelled with a prescribed name if one is prescribed. Food names are prescribed for public health and safety reasons relating to the food for sale, for example the names 'Infant formula' and 'Follow-on formula' are prescribed to ensure caregivers can identify the appropriate formula for their infant. Cell-based products are not currently defined in the Code. Infant formula is a prescribed name in the Code, resulting in products labelled as 'infant formula' required to meet requirements of Standard 2.9.1 of the Code. Ramifications of the use of a prescribed name along with a descriptor to indicate the true nature of the food (e.g. cell-cultured infant formula product) will need to be carefully explored through the standards development process to ensure impacts on broader Code interpretation are considered once applications for this technology are submitted to FSANZ.

If the name of a food has not been prescribed, the food is required to have a name or description sufficient to indicate the true nature of the food (subparagraph 1.2.2—2(1)(b)(i) and include any additional words the Code requires to be included in the name of the food (subparagraph 1.2.2—2(1)(b)(ii)).

The need for specific labelling requirements in the Code to distinguish cell-based human milk products will need to be considered.

### Food Safety Standards

Food businesses in Australia must comply with the Food Safety Standards in Chapter 3 of the Code. These include general food safety requirements for people, premises, equipment and processes. A food business may also be required to develop and implement a documented food safety program to demonstrate how they will manage food safety risks (see Standard 3.2.1).

New Zealand enforces similar requirements through the Food Act 2014. Food businesses manufacturing and/or selling high-risk foods, such as foods for vulnerable populations, are required to register a custom food control plan which identifies food safety hazards and how they will be managed. The custom food control plan needs to be independently evaluated before the business can begin operating.

The risk categorisation of cell-based milk products as potentially hazardous or high-risk foods, and the required risk-based measures will need to be considered.

## Other food regulatory considerations

The scope of this paper is limited to regulatory framework matters related to cell-based human milk products and there remain other considerations that require examination to ensure consistent and appropriate food regulatory controls are in place. This includes interface with other regulatory frameworks such as human tissue and gene technology legislation, cell line sourcing and safety considerations, and implications for imported food control.

## Key findings and Recommendations

The key findings of the regulatory framework review presented in this issues paper are:

- cell-based human milk products are unlikely to truly replicate the composition and health benefits of human milk, and are comparable from a function and regulatory perspective to infant formula products;
- existing food regulation frameworks, including the Infant Formula Policy Guideline and Standard 2.9.1 of the Code, are appropriate for cell-based human milk products, although some specific provisions will be required within these frameworks to address unique characteristics of cell-based products;
- while the principles of the Infant Formula Policy Guideline are highly relevant for cell-based human milk products, it is not clear whether cell-based human milk products would be captured within the scope;
- there are outstanding food regulatory matters that require more thorough examination to understand regulatory gaps, including regulatory design questions related to some areas of the Code, interface with human tissue and gene technology legislation, cell line sourcing and safety considerations, and implications for imported food control.

Based on the above findings, it is recommended that:

- 1) ministerial policy guidance is developed to articulate the expectation that cell-based human milk products are regulated in a manner consistent with infant formula products. This will provide regulatory parity between the two products, and ensure cell-based human milk products are subject to appropriate controls to protect infant health and safety; and
- 2) further analysis is undertaken to consider outstanding food regulatory issues. This should be progressed separately to the development of policy guidance to ensure the guidance is delivered promptly in advance of applications seeking regulatory approval for cell-based human milk products.



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