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Tēnā koe,

Proposal P1028 – Infant Formula

New Zealand Food Safety (NZFS) welcomes the opportunity to comment on the 2nd Call for Submissions (CFS) for Proposal P1028 – Infant Formula.

NZFS acknowledges that breastfeeding is the recommended way to feed infants. For infants who are not breastfed, a safe and nutritious substitute for breast milk is needed. Infant formula products are the only safe and suitable alternative to breast milk.

NZFS continues to support the regulatory objectives and principles that FSANZ has applied to its assessment to clarify and revise the standards for the composition, labelling and representation of infant formula products – with the primary consideration to protect the health and safety of formula-fed infants. We support approaches to align with international regulations as appropriate for our infant population, particularly to minimise barriers to trade and to enable New Zealand businesses to compete in the global infant formula market.

We are pleased that many issues raised by NZFS in the 1st CFS are appropriately resolved in the 2nd CFS. In particular, the positive changes to the regulatory framework, recognising sheep's milk as a safe and suitable protein source for infant formula products, and addressing inconsistencies in the conversion of kcal to kJ to achieve alignment with relevant Codex standards. We also acknowledge the progress on many labelling and representation matters, including those that better enact the provisions of the World Health Organization International Code of Marketing of Breast-milk Substitutes.

This submission outlines outstanding matters for NZFS in relation to P1028.

1. REGULATORY FRAMEWORK

NZFS supports the revised regulatory framework for infant formula products presented in the 2nd CFS. The simplified framework provides three clear subcategories for infant formula products – infant formula, follow-on formula and special medical purpose product for infants (SMPPi) suitable as the sole or principal liquid source of nourishment for the infant – to be regulated under Standard 2.9.1 of the Australia New Zealand Food Standards Code (the Code). Specialised supplementary products and human milk fortifiers for infants will continue to be regulated as food for special medical purposes under Standard 2.9.5 of the Code.

The proposed regulatory framework positions infant formula and follow-on formula as products for use by healthy formula-fed infants, and SMPPi for use by those infants with a medically diagnosed

[redacted]

disease, disorder or condition. We support the proposed definition for SMPPi as it clearly demonstrates the nature of the products that may be positioned in this regulatory category – specifically those that are specially formulated for the dietary management of infants who have medically determined nutrient requirements, where dietary management cannot medically be achieved without use of the product, and that are intended to be used under medical supervision. The principles captured in the definition alongside the specific labelling requirements and restriction on sale for these products clearly demonstrate the intended special medical purpose of these products.

Low lactose and lactose free products are proposed to be regulated in the infant formula subcategory. NZFS understands these products may be used in the management of lactose intolerance in infants. We consider low lactose products designed for the management of lactose intolerance may be best regulated as SMPPi to reduce the risk of a caregiver selecting an unsuitable product. We understand that many dairy-based low lactose products contain negligible amounts of lactose compared to the upper level of 0.3 g lactose/100 mL to represent infant formula as low lactose. As a SMPPi these products could state the medical purpose on label as suitable for lactose intolerance. We also consider it important to retain ability for soy-based formula, which may be represented as lactose free, to be positioned as infant formula and therefore readily accessible for purchase by caregivers who wish to provide their infant with a plant-based formula.

2. DEFINITIONS

NZFS support the proposed definitions for infant, infant formula product, infant formula, follow-on formula and SMPPi.

However, we note that the drafting should be amended to:

- Provide the agreed revised definition for ‘infant formula’ that refers to ‘under the age of 6 months’ (and not ‘under the age of 4 to 6 months’).
- Remove, as agreed, the definition for ‘soy-based infant formula’.

3. NOVEL FOODS AND NUTRITIVE SUBSTANCES

NZFS continues to support the approach to exclude the substantial consideration of novel foods and nutritive substances for use in infant formula products from P1028, and to instead consider the issue as part of the broader review under P1024 to prevent inconsistencies and regulatory ambiguity in the Code. However, the regulation of substances added to infant formula products remains an important issue, and we encourage FSANZ to prioritise its work on P1024 once the FSANZ Act Review is complete.

As part of P1028, we support the proposed amendment to section 1.5.1—3 to state that novel foods must not be added to infant formula products unless an express permission is stated in the table to S25—2. This provides greater regulatory certainty about permissions for use of novel foods in infant formula products.

We also support the approach to permit use of trehalose as a novel food in infant formula products as a cryo-preservative for L(+) lactic acid producing microorganisms. The acceptable daily intake of trehalose established by JEFCA is “not specified” and the estimated trehalose exposure used as a cryo-preservative in infant formula products is low.

4. L(+) LACTIC ACID PRODUCING MICROORGANISMS (LAM)

NZFS supports the proposal by FSANZ to retain the current permission for L(+) lactic acid producing microorganisms (LAM) but to restrict any claims for the specific L(+) LAM strain in the nutrition information statement (NIS). If a company wants to reference a specific L(+) LAM strain in the NIS to indicate that L(+) LAM was added for a nutritive purpose, then this would require a pre-market assessment by FSANZ. We note the divergent stakeholder views that have led FSANZ to their proposed approach.

NZFS agrees with FSANZ that:

1. There are no safety concerns for a range of non-pathogenic L(+) LAM – including species of Bifidobacterium, Propionibacterium and Lactobacillus, as evidenced through the 2021 P1028 Consultation Paper 1 risk assessment.
2. There is a long history of safe use and use of L(+) LAM is ubiquitous in products currently on the market due to differing interpretations of the Code.
3. The proposed approach aligns with Codex and other international regulations – noting Codex CXS 72-1981 for infant formula contains a similar permission to add L(+) LAM. Also, the draft Follow-up Formula Standard for Older Infants Codex CXS 156-1987 (draft Codex FuFOI) clarifies the dual purpose for addition of LAM and the conditions if LAM is added for a beneficial physiological effect. In the European Union, while non-pathogenic L(+) lactic acid producing cultures may be used for the provision of acidified formula, there is also the ability to add LAM if the ingredients have been shown to be suitable for infants through a review of available data, and complemented by the QPS list for microorganisms which is regularly maintained and identifies if further pre-market safety assessment is required.
4. The impact of removal of permission would require reformulation of many products and may result in loss of product from the market. The removal of the permission to add L(+) LAM would be unjustified when there is no safety concerns or precedent in other international regulations.

Furthermore, NZFS considers that enforcement agencies may have difficulty in determining the purpose of addition for L(+) LAM if the Code was to limit addition to acidification purposes only, or to require specific conditions to be met for other purposes.

As part of the P1028 review some stakeholders have suggested the need for a permitted list of LAM to provide regulatory clarity. NZFS notes the rationale to not include a list of permitted LAM is based on the FSANZ view that assessment of novel foods is not a part of P1028. While we acknowledge that Standard 1.5.1 includes microorganisms as a potential novel food, the Advisory Committee on Novel Foods' record of views lists several LAM that are deemed to be either traditional or not novel. In some instances, the rationale is that it is found in human milk.

As some stakeholders may have ongoing concerns about retaining the current permission for L(+) LAM, NZFS is open to exploring potential options which could provide regulatory certainty while retaining the general permission for addition of L(+) LAM to infant formula products.

5. SAFETY AND FOOD TECHNOLOGY

Food additives

NZFS agrees with the technological justification provided by FSANZ for the proposed food additives for use in infant formula products. We support removing the current permission of

diacyltartaric and fatty acid esters of glycerol (INS 472e) in the Code. We also support all food additive permissions proposed except for sucrose esters of fatty acids (INS 473) and pectin (INS 440), which we consider require further evaluation before a final decision is made.

Sucrose esters of fatty acids (INS 473):

The 2nd CFS restates the proposed approach to permit the addition of sucrose esters of fatty acids at 120 mg/L to align with EU regulations for SMPPI with a condition of use statement. NZFS supports the intent of the proposed approach to ensure the continued importation of such products from the EU for infants with specific medical conditions. However, we note that from the EFSA re-evaluation[1], INS 473 is not in fact used in infant formula and special medical purpose formulas for infants in European Union countries. Furthermore, no data was provided to address the safety of the uses of INS 473 in food for infants below 16 weeks of age. We note that FSANZ did not undertake any further safety assessment between the 1st and 2nd CFS to determine whether there is a history of safe use of this additive at the proposed level, and in particular, for infants aged less than 12 weeks there is no substantial evidence for safety. Therefore, NZFS requests that FSANZ reconsiders the need to permit INS 473 in SMPPi as part of the preparation of the approval report, particularly as the EFSA re-evaluation was published within days of the release of the 2nd CFS.

Pectin (INS 440):

FSANZ proposes to permit addition of pectin as a food additive in:

- follow-on formula at a MPL of 10,000 mg/L;
- SMPPi liquid product containing hydrolysed protein at 2,000 mg/L; and
- SMPPi for the management of gastrointestinal disorders at 5,000 mg/L.

The key change at 2nd CFS is to permit the use of pectin in follow-on formula to align with the draft Codex FuFOI at 10,000 mg/L (which we note is not a new permission but carried over from the existing Codex STAN 156-1987).

While NZFS supports the principle to align with international standards wherever appropriate in the Australia/New Zealand context, we have identified a need to re-assess the safety of pectin at the proposed levels in follow-on (10,000 mg/L) and SMPPi (5,000 mg/L). We note that JECFA[2] raised concerns about pectin exposures from a formula containing ≥ 5,000 mg/L in their 2016 evaluation. Furthermore, EFSA[3] concluded in their 2021 re-evaluation of pectin that the current EU MPL for pectin (10,000 mg/L) should be reduced, and that the reported industry use level of pectin in SMPPi equivalent products is at a maximum of 4,170 mg/L.

Carry-over of food additives

NZFS continues to support FSANZ's approach that carry-over of food additives should not be permitted in infant formula products unless specific permission exists in the Code for that food

[1] Re-evaluation of sucrose esters of fatty acids (E 473) as a food additive in foods for infants below 16 weeks of age and follow-up of its previous evaluations as food additive for uses in foods for all population groups - - 2023 - EFSA Journal - Wiley Online Library
[2] Joint, F. A. O., World Health Organization, and WHO Expert Committee on Food Additives. Evaluation of certain food additives: eighty-second report of the Joint FAO. World Health Organization, 2016.
[3] Opinion on the re-evaluation of pectin (E 440i) and amidated pectin (E 440ii) as food additives in foods for infants below 16 weeks of age and follow-up of their re-evaluation as food additives for uses in foods for all population groups - - 2021 - EFSA Journal - Wiley Online Library

additive to be used in the final infant formula product. This approach ensures that food additive use is minimised in products for infants, and achieves consistency with Codex and EU Regulations.

Nutrient preparations

We note that some food additives carried over from nutrient preparations used in existing infant formula products are not listed or proposed to be listed in S15—5 food categories 13.1 and 13.1.1. For example, the antioxidant dl-alpha-tocopherol (INS 307c). These carried-over additives perform technological purposes in nutrient preparations and hence would not be permitted for use as processing aids under the Code. NZFS supports additional permissions for these additives for use in nutrient preparations where they are technologically justified and do not raise any safety concerns in infants.

Processing aids

NZFS supports retaining the current standards for processing aids.

Contaminants

NZFS supports the proposed approach for acrylonitrile, arsenic, cadmium, lead, melamine, vinyl chloride, aflatoxins B1 and M1, ochratoxin A, polycyclic aromatic hydrocarbons, perchlorate, and chloropropanol, glycidol and their esters. We also support the approach to apply maximum levels (MLs) for infant formula to an 'as consumed' form in mg/kg. We have the following comments about the MLs and drafting for aluminium and tin.

Aluminium

A single ML of 0.5 mg/kg is proposed for aluminium in infant formula and follow-on formula, including soy-based formula. FSANZ noted that no new information was provided to show that the ML cannot be met for soy products.

NZFS is aware of some literature[4,5] (though we did not perform a complete literature review) showing soy products could contain higher levels of aluminium. However, the 23rd and 24th ATDSs indicated that the upper range of the concentration of aluminium is below the proposed ML of 0.5 mg/kg.

NZFS is open to the ML for aluminium in soy-based formula being reviewed and potentially increased (up to the current ML of 1 mg/kg), if new information shows the proposed ML cannot be met due to natural variation in levels in soybeans. It is important that soy-based formula products can continue to be sold as an option for the management of dairy intolerance and allergy, or for those caregivers who wish to use a plant-based product.

Tin & inorganic tin compounds

NZFS supports retaining the ML of 250 mg/kg. However, it appears the drafting needs to be amended to clearly show that the ML for tin relates to infant formula products. Currently the S19—4 entry for tin lists 'all canned food', which does not capture all infant formula products (e.g. ready-to-drink products in a tetra pak). We recommend S19—4 entry for 'Tin' lists both 'all canned food' and 'infant formula products' for maximum clarity.

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[4] Chuchu N, et al. The aluminium content of infant formulas remains too high. BMC Pediatrics 2013; 13: 162.
[5] Stahl T, et al. Aluminium content of selected foods and food products. Environmental Sciences Europe 2011; 23, 37.

We also question whether the contaminant in S19—4 should refer to 'Tin' or 'Tin & inorganic tin'. The Codex ML is for 'Tin' with a definition: *Tin, total (Sn-tot) when not otherwise mentioned; inorganic tin (Sn-in); or other specification.* However, the Code of Practice (CAC/RCP 60-2005) refers to inorganic tin. As it is scientifically correct to include inorganic tin, it would be useful to clarify or add a definition in S19—2.

6. COMPOSITION OF INFANT FORMULA AND FOLLOW-ON FORMULA

NZFS continues to support FSANZ's primary objective to protect the public health of infants by specifying compositional requirements that support normal growth and development when infant formula is used as the sole or principal source of nutrition up to 12 months of age. This approach underpinned the criteria used in the 2016 and 2021 nutrition risk assessments, which reviewed the scientific basis of current standards through an independent and transparent risk assessment process reviewing new scientific evidence, international regulation and scientific assessments, and taking into account the Australian and New Zealand context.

Conversion of kcal to kJ

We support assessment of the composition for infant formula with Codex CXS 72-1981 and for follow-on formula with the draft Codex FuFOI. As noted by FSANZ, Codex Alimentarius standards are adopted globally by many national authorities and are developed with the dual aim of protecting consumers' health and ensuring fair practices in the food trade.

NZFS is pleased to note that the compositional values that align with Codex are correctly converted from 100 kcal to 100 kJ using International Standard Unit conversion factors and conventional rounding. The only exceptions are: (1) the minimum value for niacin for both infant formula and follow-on formula, which needs to be corrected to 72 µg/100 kJ as correctly converted from kcal in the draft Codex FuFOI, and (2) the guidance upper level (GUL) for myo-inositol for follow-on formula, which needs to be corrected to 10 mg/100 kJ to align with infant formula and the draft Codex FuFOI.

Guidance Upper Levels (GULs)

NZFS supports the continued use of GULs for the composition of infant formula and follow-on formula and the accompanying notes which provide an explanation. The proposed note states that a GUL *"is a recommended upper level for nutrients which pose no significant risks on the basis of current scientific knowledge. These Guidance Upper Levels should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formula and follow-on formula or due to technological reasons."*

NZFS notes there is a discrepancy in the GUL note compared to the equivalent statement in the relevant Codex standards, which highlight that GULs are set when there is insufficient evidence for a science-based risk assessment and are derived based on meeting nutrient requirements and an established history of safe use. We note that in some instances FSANZ is proposing values lower than found in products currently on the market, and for which there is an apparent history of safe use and insufficient scientific evidence to inform a maximum or GUL. As GULs will be specified in the standard, these levels need to provide a useful guide to both manufacturers and enforcers as to the nutrient level the formula should be manufactured within, particularly as the note states that they should not be exceeded, and that any exceedance is due to technological reasons or the natural variability within the constituents of the product.

Two notable examples of the proposed GUL lower than used in current practice, and for which there is no significant risks based on current scientific knowledge, are docosahexaenoic acid (DHA) and L-carnitine. NZFS requests that FSANZ reconsiders the proposed GULs for DHA and L-carnitine.

Docosahexaenoic acid (DHA)

NZFS does not support the proposed GUL for DHA of 7 mg/100 kJ. There is currently product on the market that exceeds this value for DHA and there is no scientific justification to set the value so much lower than the EU regulatory maximum of 12 mg/100 kJ where the addition of DHA is mandatory. Using the GUL explanatory note, manufacturers should not exceed the value of 7 mg/100 kJ for DHA as this represents the recommended upper level that poses no significant risks on the basis of current scientific knowledge. Therefore, the proposed DHA GUL and associated explanatory note do not clearly achieve FSANZ's intent to provide flexibility for manufacturers in DHA upper levels compared to setting a higher GUL or maximum level of 12 mg/100 kJ. The proposed standard also applies other mechanisms to ensure suitability of product formulations in relation to DHA levels through the specified ratios for arachidonic acid and long chain polyunsaturated fatty acids.

L-carnitine

A GUL for L-carnitine of 0.8 mg/100 kJ is proposed for infant formula. NZFS notes that neither the EU or relevant Codex standards specify a maximum or GUL. If a GUL is to be established for infant formula, our preference is that the value reflects current product formulations and the apparent history of safe use in the absence of evidence to inform a science-based risk assessment. The information provided in submissions highlights that dairy-based formulations will typically contain higher levels of L-carnitine than the proposed GUL.

Protein requirements

NZFS supports the proposed approach to establish separate minimum protein requirements for milk-based and soy-based infant formula products, as per 2.9.1—6(2). It is noted that the drafting simply states the requirement 'for a milk-based infant formula' and 'for all other infant formula' rather than specifying a minimum for soy-based products. Now that the definition of soy-based formula has been removed it provides some ambiguity as to whether a product that contains a mixture of soy protein isolate and milk proteins is considered 'milk-based' or 'other'. The proposed drafting is not specific to soy and it is unclear if the provision 'for all other infant formula' is intended to apply to product that only contains soy protein isolate, or if it also applies to product that contains a mixture of soy protein isolate and other sources of milk protein as per the EU regulation. This is particularly relevant as 2.9.1—6(1) allows for infant formula and follow-on formula to be derived from one or more of the listed protein sources.

Fluoride

Based on the current drafting, standard 2.9.1—5(4) must be interpreted in light of standard 2.9.1—4. Consequently, the maximum limit on fluoride content applies to infant formula and follow-on formula that has been reconstituted with water, and infant formula in a ready to drink form. This is problematic because the water added to reconstitute the product may in some instances contain additional fluoride. We are of the view that standard 2.9.1—4(1) should not apply to the fluoride limit (standard 2.9.1—5(4)). Instead limits for fluoride should apply to infant formula and follow-on formula "as sold" (not as reconstituted).

NZFS would like to ensure that the maximum of 17 µg/100 kJ is appropriate to all forms of formula as sold. The current requirement of 17 µg/100 kJ for fluoride is specific to powdered and concentrated formula and a separate requirement is listed for ready-to-drink formula. The original proposal was to establish a maximum level of 24 µg/100 kJ for all types of formula as prepared, including ready-to-drink. As the ready-to-drink will not require any further addition of water, NZFS would like to question whether the maximum for ready-drink products should be set at 24 µg/100 kJ as was the original intent.

Vitamin D

FSANZ has proposed a minimum of 0.24 µg/100 kJ and maximum of 0.63 µg/100 kJ in both infant formula and follow-on formula, on the basis that there is no need to differentiate for the different product categories. NZFS notes that the maximum is not aligned with the draft Codex FuFOI and EU regulation, which both establish a maximum of 0.72 µg/100 kJ, contrary to the SD2 rationale which states this value is in alignment with international regulations.

This higher maximum of 0.72 µg/100 kJ was agreed at Codex for follow-up formula for older infants as there were no safety concerns, it did not lead to intakes in excess of the tolerable upper level, and enabled a suitable range in formulation to accommodate regional variation in vitamin D requirements. We do not support differentiation in the compositional requirements for infant and follow-on formula for vitamin D. As noted by FSANZ the nutrient reference value for vitamin D for the two age groups are the same, which does not warrant a need to differentiate. A similar discussion was had at CCNFSDU, where it was noted the higher maximum for follow-on formula was not due to the unique nutrient requirements of older infants. NZFS would support increasing the maximum to 0.72 µg/100 kJ for both infant and follow-on formula as there are no safety concerns.

7. LABELLING

Directions for preparation and use

NZFS supports the proposed directions for preparation and use in 2.9.1—22(5) of the drafting.

We support consistent use of the term ‘must’ (in place of ‘should’) in the statements relating to directions for preparation and use. The term ‘must’ conveys the importance for caregivers to follow the directions.

Required statements on use

Subsection 2.9.1—22(2) of the draft variation proposes that the required statements for infant formula and follow-on formula are ones indicating that:

(a) for infant formula—the infant formula may be used from birth; and
(b) for follow-on formula—the follow-on formula should not be used for infants aged under the age of 6 months; and
(c) for infant formula and follow-on formula—it is recommended that infants from the age of 6 months should be offered foods in addition to the infant formula or follow-on formula.

We agree with statements (a) and (c) but recommend a change to the drafting of (b). We consider statement (b) should be framed as a positive statement on the front of the package to clearly

communicate to caregivers the appropriate age for use of a follow-on formula. This will help caregivers select the appropriate product for the age of their infant, particularly as this statement is mandated on the front of the package (2.9.1—22(3)) and will appear immediately adjacent to the stage number '2', if used (2.9.1—28(2)(b)). We therefore recommend that 2.9.1—22(2)(b) is amended to: *(b) for follow-on formula—the follow-on formula may be used from 6 months,* which also provides consistency with the definition of follow-on formula.

Notwithstanding the above, NZFS is of the view that the current statement (b) remains an important safety message to communicate on label to caregivers (i.e. that follow-on formula should not be used for infants aged under the age of 6 months). NZFS would encourage FSANZ to consider adding a requirement to place the current statement in (b) elsewhere on the label (i.e. not on the front of the package). We suggest the current statement in (b) would be well suited to be co-located with the required warning statements.

Statements on front of package

NZFS supports the approach for the name of the food (i.e. prescribed name), the required statements on use and the required statement of protein source on the front of a package of infant formula and follow-on formula.

We support the change at 2nd CFS to require this information on the 'front of the package' (rather than a 'prominent position') and note FSANZ's view that the ordinary meaning of 'the front of the package' will apply. Though we note that 'front of the package' on a round tin of infant formula product would be open to interpretation. Ideally this information would be provided in the same field of view as the brand name or on the principal display panel, but we appreciate that further prescribing the location on the package in regulation is highly restrictive for a globally traded product and would go beyond what is currently required internationally.

Nutrition Information Statement (NIS)

NZFS continues to support prescribing a format for the NIS for infant formula and follow-on formula as outlined in S29—10 of the drafting, with the following comments.

Subheadings for mandatory and optional substances

The proposed NIS format requires mandatory substances (other than vitamins and minerals) to be listed under the subheading of 'other nutrients' and voluntary substances under the subheading of 'additional'.

We support use of the 'other nutrients' subheading for mandatory substances as the term 'nutrients' infers essentiality, which is appropriate for these substances. While we consider 'additional' could infer additional benefits, which is straying towards a claim, we note the consumer research found a high level of understanding of this term and that nutrition information about substances voluntarily added will not appear elsewhere on the label.

Formatting of NIS

To assist caregivers' use of the NIS, we recommend that substances under the subheadings 'vitamins', 'minerals', 'other nutrients' and 'additional' are indented in the required format for the NIS, as done for the subcategories of macronutrients. As the format of the NIS will be prescribed, we understand current industry practice to emphasise subheadings from surrounding text using lines, bolding or shading will be restricted, so the format required under S29—10 needs to resolve this issue.

Base units of expression

Paragraph 2.9.1—25(1)(a) of the draft variation to the Code requires the unit quantity of the food to be expressed in per 100 mL (of prepared formula), and paragraph 2.9.1—26(2)(f) prohibits the use of any other unit quantity.

We support use of per 100 mL prepared formula as the base unit of expression required for nutrition information in the NIS. However, we do not support prohibiting use of other base units of expression in the NIS. To prohibit use of other base units of expression is not aligned with relevant Codex standards that require nutrition information to be expressed per 100 g or per 100 mL of the food as sold as well as per 100 mL of the prepared food. In addition, providing flexibility to state additional base units of expression will facilitate trade of the same product sold domestically to smaller markets that may follow Codex requirements (e.g. some Pacific Island nations), creating efficiencies for businesses and maintaining access to product in these smaller countries. Also, to require per 100 mL but allow for use of other base units on a voluntary basis is unlikely to change current industry practice, with most labels displaying nutrition information in per 100 mL only.

8. STAGE LABELLING, PROXY ADVERTISING AND PRODUCT DIFFERENTIATION

Proxy advertising

NZFS supports the proposed prohibition on proxy advertising achieved by 2.9.1-29(1)(c). This position is supported by research from Australia demonstrating that some caregivers may confuse toddler milk with infant formula products in advertisements and may associate claims featured on toddler milk with infant formula. In Australia and New Zealand proxy advertising has been identified on over half of infant formula products on the market, many of which also included health claims or nutrition content claims for the toddler milk advertisement.

Furthermore, the prohibition on proxy advertising aligns with Section 8.6.5 of the draft Codex FuFOI. The intent of this statement is to incorporate recommendation 5 of the WHO Guidance on ending the inappropriate promotion of foods for infants and young children.

Stage labelling

NZFS supports FSANZ's proposed approach to allow stage labelling as achieved by 2.9.1—28. Findings from the available consumer evidence are aligned with the decision to permit stage labelling on the front of pack and immediately adjacent to the required age statement, since caregivers do report using stage labelling to differentiate between formula products, but also consider age labelling to be the most important element.

NZFS considers that stage labelling and product differentiation need to be considered together to address the concerns that current labelling may promote a progressive feeding regime. This could be achieved through strengthening the requirements for product differentiation or through the possibility of restricting the use of stage numbers only for infant formula and follow-on formula; thereby prohibiting their use on formulated supplementary foods for young children or food for infants. This restriction would further strengthen the effort to not promote a progressive feeding regime.

Product differentiation

NZFS supports the conclusions of FSANZ that a lack of distinguishing features such as colour, images and text may cause confusion for caregivers, and to include a provision to address this concern. NZFS suggests that the proposed drafting of Section 2.9.1—15(2) may not achieve this intent and could be more prescriptive, so that the drafting specifies that colour, text and images

must be different between products, to assist in product differentiation. This would be aligned better to the equivalent clauses in the draft Codex FuFOI and EU regulations.

NZFS are of the view that the proposed drafting will likely not result in a change in practice, and it may be difficult to enforce the requirement 'not represented as another food', since this stipulation can be achieved by using a different product name and stage labelling only, with all other packaging elements being the same. We consider that the available evidence does not conclude that New Zealand and Australian consumers have no difficulty in differentiating between infant formula, follow-on formula, and toddler milks. One Australian study demonstrated that some infants were given follow-on formula before the age of 6 months. The two cross-sectional studies which indicated that infants were consistently served formula appropriate for their age used a population sample that was not representative of the broader Australian population, so these studies cannot be used to conclude that there are no concerns with product differentiation.

NZFS requests FSANZ considers the following proposal to revise the drafting to address the concerns outlined. This includes revision of 2.9.1—15(2) with the following text:

> (2) A food represented as infant formula or follow-on formula shall be differentiated from one another and other foods through the text, images and colours used.
>
> ***Example***: A food represented as infant formula must be distinguishable from, among other things, follow-on formula, a special medical purpose product for infants, or a formulated supplementary food for young children.
>
> ***Note*****:** The purpose of differentiation is to avoid any risk of confusion between infant formula, follow-on formula and other foods, particularly formulated supplementary food for young children.

This drafting proposed by NZFS would align with the equivalent draft Codex FuFOI and EU regulations whilst taking into consideration the proposed drafting language of FSANZ. We consider that the inclusion of the Note provides context to this clause and is in line with some other notes used in the proposed drafting of 2.9.1 (i.e. guidance upper levels). If it was deemed inappropriate to include in Standard 2.9.1, we suggest that instead this concept be included in the explanatory note to assist with the interpretation of the standard.

9. SPECIAL MEDICAL PURPOSE PRODUCTS FOR INFANTS (SMPPi)

Overall, NZFS supports the proposed approach for the SMPPi subcategory of infant formula products.

Baseline composition

The proposed definition of SMPPi appears to suitably capture the nature of these products as specifically formulated to meet a medical purpose, not suitable for general use and for use under medical supervision. The definition also clearly restricts the SMPPi category to those products suitable as the sole or principal liquid source of nourishment for the infant.

We agree the intent for SMPPi composition should be to require that SMPPi contain the baseline composition of infant formula except when it is required to satisfy the particular disease, disorder or medical condition, or would otherwise prevent the sale of the product. However, we ask that FSANZ revises the variation to the Code to fully capture this intent, as 2.9.1—32 and the associated S29—5 of the draft variation only relate to vitamins, minerals, electrolytes and other required substances. The variation to the Code should also capture protein source, macronutrient composition, food additives and other relevant compositional aspects prescribed for infant formula.

NZFS also requests that FSANZ revises the proposed wording of 2.9.1—32(2) for situations when a SMPPi may vary from the baseline composition of infant formula. We agree with (a) when the deviation is required for a particular medical purpose. However, while we agree with the intent of (b) to retain flexibility to allow the continued import of specialised products that are compliant with overseas regulatory compositional requirements, we consider the wording proposed (i.e. "would otherwise prevent the sale of the food") is too broad and reasons other than those intended could be used by a business to deviate from the baseline composition. NZFS proposes that (b) could be amended to "subject to a FSANZ equivalent independent assessment by a competent overseas regulatory authority", or similar wording.

Permission for use of novel substances and components

Standard 2.9.1—30(a) proposes that paragraph 1.1.1—10(6)(f) relating to novel foods will not apply to SMPPi, and therefore a SMPPi may contain as an ingredient or component a novel food without express permission in the Code.

NZFS supports the intent of this provision to provide flexibility for SMPPi composition to reflect the specialised nature of these products and that many products are manufactured in small volumes for multiple markets that may have differing regulatory requirements. However, we are concerned that 2.9.1—30(a) as currently drafted would allow ingredients and components produced by cell culture or precision fermentation to be added to SMPPi without pre-market assessment by FSANZ.

In November 2022, the Food Ministers Meeting affirmed FSANZ's view that foods produced by cell culture and precision fermentation will be captured within existing standards in the Code and require pre-market approval under Standards 1.5.1 and 1.5.2.

NZFS considers the FMM and FSANZ intent that foods/ingredients/components produced by cell culture and precision fermentation undergo pre-market assessment prior to use must also apply to SMPPi. NZFS requests FSANZ considers this matter further prior to approval report and restricts the application of 2.9.1—30(a) for ingredients and components produced by novel technologies.

10. TRANSITION PERIOD

We note the draft variation provides for a five year transitional arrangement inclusive of stock-in-trade. We note FSANZ's rationale for the need for an extended transitional arrangement, and that a period inclusive of stock-in-trade should provide more flexibility to manufactures and food businesses than a three year transition period plus a two year stock-in-trade period.

We support the proposed five year transitional arrangement but would not like to see it extended further. In advance of gazettal, the relevant authorities will need to consider how to communicate these regulatory changes to health professionals, pharmacies and consumers during this five year transition period.

11. DRAFT STANDARD

NZFS recommends the following amendments are made to the variation to the Code proposed under P1028.

The background for many of the recommended amendments is explained in the more substantive part of this submission. We have also recommended some smaller technical or wording changes that are not mentioned elsewhere.

Drafting reference	Recommended amendment
2.9.1—3 and 1.1.2	Amend the definition for infant formula: *infant formula* means an infant formula product that is represented as: (a) a breast milk substitute for infants; and (b) satisfying by itself the nutritional requirements of infants under the age of **~~4 to~~** 6 months.
2.9.1—3 and 1.1.2	Remove the definition of 'soy-based infant formula' in the notes to 2.9.1—3 and to repeal this definition as part of 1.1.2 amendments.
2.9.1—3	Amend definition for inner package: ***inner package***, in relation to special medical purpose **~~food~~ product** for infants, means an individual package of the food that is:…..
2.9.1—4	Amend heading for section (2) to: Calculation of energy, **~~and~~** protein **and vitamin A**
2.9.1—5(4)	Amend so that the maximum fluoride content applies to the product 'as sold', and not as reconstituted (which currently applies through 2.9.1—4(1)). If required, specify different maximums for fluoride in powdered/concentrated formula and in ready-to-drink formula.
2.9.1—6(2)(b) and (3)(b)	Amend if necessary, to specifically refer to soy protein isolates.
2.9.1—7(1)(c)	Amend for consistency to: (c) have an arachidonic acid (20:4 **n-6**) content of equal to or more than docosahexaenoic acid (22:6 n-3) content; and
2.9.1—7(1)(f)	Amend the first sentence of the note to: It is recommended that infant formula and follow-on formula contain a fatty acid listed in Column 1 of the table **in S29—4** in an amount that is not more than the amount (if any) specified for that substance in Column 3 of the table.
2.9.1—8	Insert the revised ratio of calcium to phosphorus, which appears to be missing from the drafting. The intent is that the ratio of calcium to phosphorus in infant formula and follow-on formula must be no less than 1 to 1 and no more than 2 to 1.
2.9.1—8(1)	Amend (for consistency with 2.9.1—9) to: Infant formula must contain each substance listed in Column 1 of the table to section S29—5 in an amount **(including any naturally-occurring amount)** that is:

2.9.1—13(b)	Amend to incorporate the term 'free' (as per intent in Table 7 of SD1): (b) more than 3.8 mg/100 kJ of **free** nucleotide-5′-monophosphates.
2.9.1—13 note	Suggest this note is amended to reflect that there are other MLs for contaminants than lead in S19 that will apply to infant formula products.
2.9.1—15(2)	NZFS proposes the following alternate text to reflect the intent of this requirement around product differentiation: (2) A food represented as infant formula or follow-on formula shall be differentiated from one another and other foods through the text, images and colours used. *Example*: A food represented as infant formula must be distinguishable from, among other things, follow-on formula, a special medical purpose product for infants, or a formulated supplementary food for young children. *Note:* The purpose of differentiation is to avoid any risk of confusion between infant formula, follow-on formula and other foods, particularly formulated supplementary food for young children.
2.9.1—22	Amend heading to 'Location of ~~**warning statements and**~~ required statements'. Subsections (3) and (4) of 2.9.1—22 refer only to the required statements on use in subsection (2) and not the warning statements in subsection (1).
2.9.1—22(2)(b)	Amend statement to: for follow-on formula—the follow-on formula ~~**should not**~~ **may** be used ~~**for infants aged under the age of**~~ **from** 6 months; and
New	Add a requirement to place the current statement in 2.9.1—22(2)(b) that "for follow-on formula—the follow-on formula should not be used for infants aged under the age of 6 months" elsewhere on the label (i.e. not on the front of the package). We suggest the current statement in (b) would be well suited to be co-located with the required warning statements.
2.9.1—25(2)	Insert an asterisk with 'average quantity' (i.e. *average quantity), for consistency across the Code as average quantity is a defined term.
2.9.1—26(2)(f)	Remove (f) that states: not include a *unit quantity other than per 100 mL. Amend the drafting to require the base unit of expression in the NIS to be per 100 mL, and to permit other base units on a voluntary basis.
2.9.1—29(1)(c)	Amend to clearly capture FSFYC and other foods: (c) information relating to another **food** ~~**product**~~; or
2.9.1—30(a)	Revise provision to ensure that all foods/ingredients/components produced by novel technologies are required to undergo a pre-market assessment prior to use in SMPPi.

2.9.1—31(1)	Insert an asterisk with 'responsible institution' (i.e. *responsible institution), for consistency across the Code as responsible institution is a defined term.
2.9.1—32(1)	Amend to achieve the intent that all compositional requirements for infant formula should form the basis of SMPPi, unless for reasons covered in (2). The current drafting only captures vitamins and minerals, but not other compositional requirements such as protein source and macronutrients.
2.9.1—37(1)(g)	Amend to reflect the requirements for infant formula and follow-on formula under 2.9.1—22(5): (g) directions for the use **and preparation** or the storage of the food, if the food is of such a nature to require such directions for health or safety reasons;
2.9.1—38(2)(a)	Recommend FSANZ considers whether all of these required advisory statements and declarations are applicable for SMPPi, noting some relate to guarana, aspartame and other substances that should not be used in SMPPi.
S15—5	Consider if provisions for INS 339 and 340 need to be listed in 13.1.1 for use in SMPPi given these permissions at the same dosage are listed under 13.1 for infant formula products (which includes SMPPi).
S19—4	Recommend the entry for 'Tin' lists both 'all canned food' and 'infant formula products' for maximum clarity.
S19—4	FSANZ to consider whether the contaminant should refer to 'Tin' or 'Tin & inorganic tin'.
S19—4	FSANZ to consider if the first entry for aluminium that states 'infant formula and follow-on formula' should be extended to include SMPPi that are not formulated for pre-term infants. Currently, it is not clear which ML applies for these products but assume the intent is for the ML of 0.5 to apply.
S29—6	Amend niacin minimum amount to 72 µg/100 kJ.
S29—6	Amend for consistency with S29—5: Folic acid ~~**(not including naturally occurring folate)**~~
S29—8	Amend myo-inositol GUL to 10 mg/100 kJ, as per assessment of issue and consistency with draft Codex FuFOI.
S29—10	Recommend the individual vitamins, minerals and substances are indented under the respective subheading, as for the macronutrient subheadings for ease of use of the NIS.
S29—10	Amend the units for vitamin E to mg.
S29—10	Amend the units for niacin to µg.

S29—10	Recommend replacing the * (next to choline, inositol etc) with another icon, as the asterisk is used elsewhere in the Code to indicate a term is defined.
S29—23	Recommend the new permitted forms of vitamins, minerals and electrolytes are integrated alphabetically into the lists in S29—23, for consistency and ease of use.

NZFS would welcome the opportunity to participate in targeted consultation to resolve residual issues before the Approval Report is notified to the Food Ministers Meeting.