SA Health submission to Proposal P1028 - Infant Formula

June 2022

SA welcomes the opportunity to provide comment to Food Standards Australia New Zealand on Proposal P1028 – Infant formula.

Breastfeeding is the normal and recommended way of feeding infants and formula fed infants have a higher risk of adverse health outcomes. Infants are a particularly vulnerable population predominantly relying on a single food as a source of nutrition and sustenance.

In the FSANZ Act, the primacy of public health and safety remains a key to its objectives. FSANZ is also required to show regard to the ministerial policy guideline for the regulation of infant formula products that sets out the principles for regulating infant formula in reviewing P1028.

A 'majority of submitters support' approach is often stated in Proposal P1028. This approach should not be used to justify a proposed position in the proposal assessment without clear reasoning for the preferred position being given.

Key Issues

1. Regulatory Framework

Pre-market assessment requirements for any new substances in infant formula must be clarified under P1028 on the basis that ministerial policy direction for P1028 must be shown regard. The Policy Guideline sets out that pre-market assessment is required for any new substance that:

i. does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or
ii. has a history of safe use in these products in Australia and New Zealand, but which, having regard to source, has a different form/structure, or is produced using a substantially different technique or technology.

The specific policy principles applying to all infant formula products are:

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.

While harmonisation with international standards is a requirement of WTO agreements, FSANZ may set a regulation that is different from international standards providing there is scientific evidence that the regulation is to protect public health and safety of its population. Adoption of Codex regulations just because they are international regulations may not be appropriate in all instances since there are existing differences in the regulatory structures of Australia/New Zealand and Codex

for food additives, processing aids, nutritive substances etc such that some substances are not recognised in the same regulatory groups. As such the addition of any substance to an infant formula should be based on risk analysis taking into account the vulnerability of the population.

2. Technological justification of food additives

It is important that food additives are not permitted in infant formula if they are not technologically justified for being present.

The technological justification provides the reason why the food additive is present in the infant formula. A technological justification is necessary to maintain trust in the food by the public.

The use of food additives is justified only when such use has an advantage, does not present an appreciable health risk to consumers, does not mislead the consumer, and serves one or more of the listed technological functions and only where these objectives cannot be achieved by other means that are economically and technologically practicable.

For new permissions for food additives in infant formula it is not demonstrated in Proposal P1028 that an assessment of the technological justification for the additives has been completed. An existing permission for a food additive in other food categories should not be extended to infant formula without demonstration of technological justification for its use specifically in infant formula.

If the food additive is determined to be technologically justified, then on the basis of this determination, in combination with the assessment of the safety of the food additive and the overall safety of the food category in which it may be used, a decision to approve the food additive may be made.

Although the evaluation by JECFA supports the safety of the food additives, there has been no FSANZ evaluation presented in Proposal P1028 of the technological justification for use of these additives. Technological justification is not equivalent to stating that a substance has a “technological function” (See figure 1.).

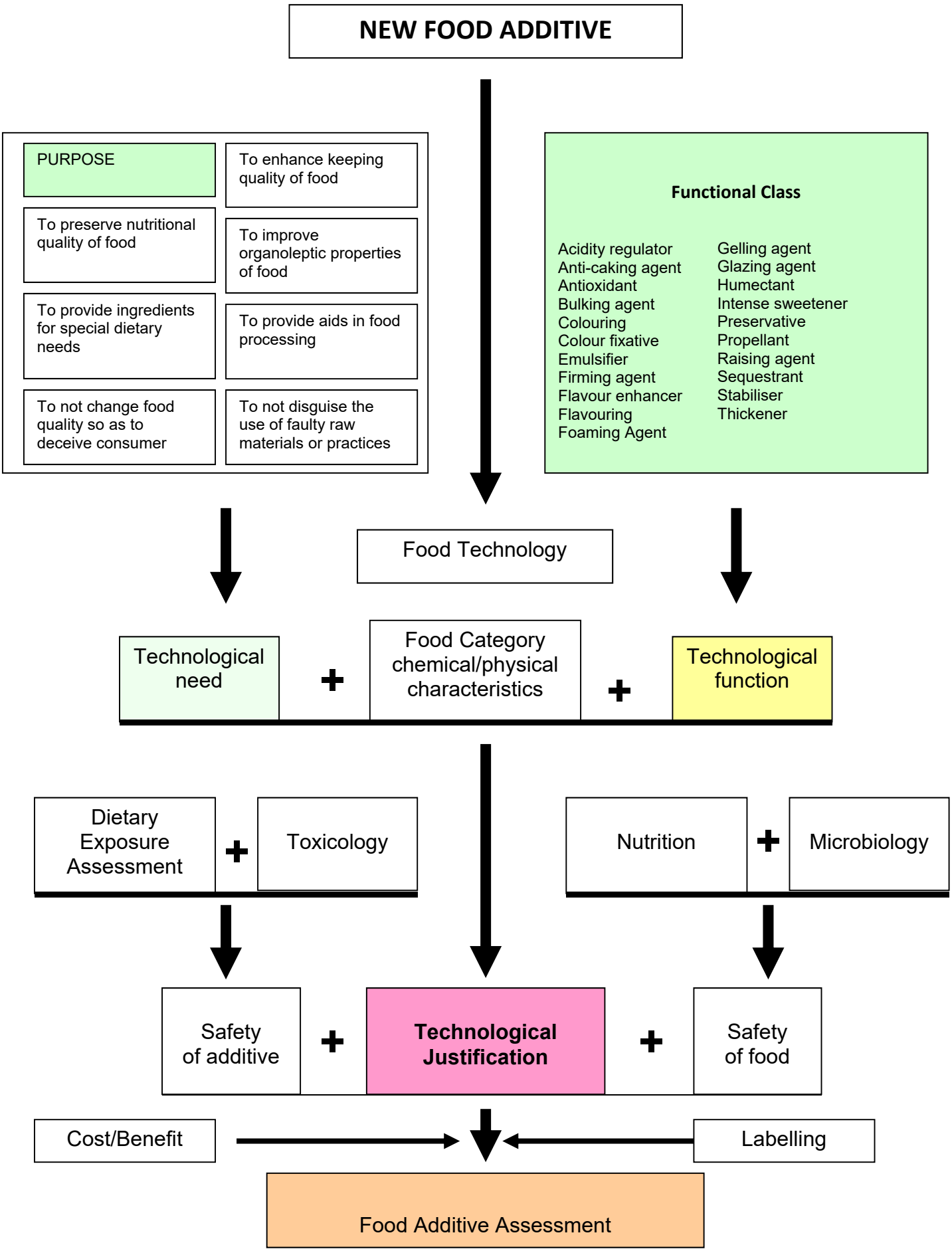

Figure 1. The role of "Technological justification" in the FSANZ food additive assessment process

3. Processing aids

FSANZ proposes to not require pre-market assessment for processing aids in infant formula. While processing aids have no technological function in the final product, they may have nutritional, microbiological and safety implications for the food for infants that should be evaluated. As this is a special food category it should require a specific assessment of processing aid use in infant formula and not just a general assessment that applies across food categories.

4. Trademarks

FSANZ should address in this proposal, the issue of infant formula products labels making health claims through the use of trade marks on infant formula. This should not be out of scope of the proposal. FSANZ should seek a legal opinion if it could include a specific regulation in the infant formula standard that would make it illegal to use a health claim trademark on infant formula by providing grounds for rejection under the Trade Mark Regulations 42(b) (the trade mark is contrary to law). '[a]n application for the registration of a trade mark must be rejected if … its use would be contrary to law'. In assessing whether a 'healthy' trade mark is contrary to law, the Registrar is obliged to take into account the operation of law and legislation other than the *Trade Marks Act 1995* (Cth).

The following comments are adapted from Sanderson J. 'Health conscious and confused: Why 'healthy' trade marks matter to consumers'. UNSW Law Journal 39(2) 658.

> Standard 1.2.7 defines health claims as 'a claim which states, suggests or implies that a food or a property of food has, or may have, a health effect'. Although trade marks are not explicitly mentioned in Standard 1.2.7, 'healthy' trade marks can 'state, suggest or imply' that the foods bearing them have a health effect.
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> Given that food manufacturers and marketers may use trade marks to 'health wash' their products by making unsubstantiated, exaggerated or misleading claims about the health qualities or status of their food products. Consumers are affected by 'healthy' trade marks by perceptions of healthiness. Foods carrying 'healthy' trade marks are generally perceived to be healthier than the same foods not carrying the trademark.
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> 'Healthy' trade marks may influence consumers in the choice and purchase of food products. Consumers whose purchasing decisions are motivated by health and wellness may base their purchasing decisions at least in part on the product's 'healthy' trade mark.
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> In Australia, trade marks are registered under the *Trade Marks Act 1995* (Cth). While the Act does not explicitly deal with 'healthy' trade marks, they can be rejected, opposed, revoked or cancelled on numerous grounds.
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> Once a 'healthy' trade mark application is lodged with the Australian Trade Mark Office (ATMO), it is assessed by an examiner to see if it meets the requirements of the Act. Perhaps most importantly, the presumption under the

Act is that trade mark applications are registrable. Specifically, section 33(1) of the Act provides that the Registrar must accept a trade mark for registration unless satisfied that the trade mark application has not been made in accordance with the Act and the associated *Trade Marks Regulations 1995.*

At the initial stage of examination, the applicant is not required to justify that the 'healthy' trade mark is registrable. Rather, the onus is on the Registrar to demonstrate that there are grounds to reject the 'healthy' trade mark. This means that a 'healthy' trade mark will be accepted by the Registrar unless the application has not been made in accordance with the Act or there are clear grounds for rejecting the applicant's mark.

As a consequence, 'healthy' trade marks are not given the scrutiny required to assess unsubstantiated, exaggerated or misleading claims. For example, 'healthy' trade mark applications are not examined by the ATMO for their nutritional content or healthiness. It is, therefore, unlikely that 'healthy' trade marks will be rejected at the examination stage.

While anyone can file an opposition, it is often done by a person who will be affected by the trade mark in some way. Concerned health groups and bodies can also challenge 'healthy' trade marks after they have been registered. When challenging a registered trade mark, an aggrieved person must show that they are 'appreciably disadvantaged in a legal or practical sense' by the maintenance of the registration.

In addition to opposition and challenge by third parties and aggrieved persons, 'healthy' trade marks can be challenged or revoked by the Registrar of Trade Marks. Section 84A of the Act sets out the circumstances in which the Registrar may revoke the registration of a trade mark. Under section 84A(1), the Registrar may revoke the registration of a trade mark if satisfied that:

(a) the trade mark should not have been registered, taking account of all the circumstances that existed when the trade mark became registered (whether or not the Registrar knew then of their existence); and

(b) it is reasonable to revoke the registration, taking account of all the circumstances.

The three main grounds for opposing or challenging 'healthy' trade marks are

- sections 43 (the use of the trade mark would be likely to deceive or cause confusion),
- 41 (the trade mark is not capable of distinguishing the applicant's goods or services from the goods or services of other persons), and
- 42(b) (the trade mark is contrary to law). '[a]n application for the registration of a trade mark must be rejected if … its use would be contrary to law'. In assessing whether a 'healthy' trade mark is contrary to law, the Registrar is obliged to take into account the operation of law and legislation other than the *Trade Marks Act 1995* (Cth).

> Broadly speaking, the Registrar may only cancel, amend or remove a trade mark if it is in the 'public interest' to do so.

It would seem evident that it would be in the public interest not to allow the use of healthy trade marks on infant formula where the products are purchased for the use of feeding a vulnerable population.

5. Novel Foods and Nutritive Substances - Pre-market assessment requirements

FSANZ's proposed approach to delay the consideration of novel foods and nutritive substances in infant formula until Proposal P1024 Novel Foods and Nutritive Substances is completed is not supported.

Regulatory certainty is essential for infant formula products and the assessment of novel foods and nutritive substances should be specific for the food category of infant formula. It is not appropriate to assess the addition of novel foods and nutritive substances by generalising it into the wider food categories assessment. Infant formula is a distinct food category for a vulnerable population and has a separate regulatory framework consisting of its Standard in Part 2.9 of the Code and an associated Policy Guideline for Infant Formula.

FSANZ has proposed to amend the definition of a novel food so that a novel food is defined as "a non-traditional food for the intended consumer population". The amendment to the definition of novel food attempts to address concerns about the use of protein sources that do not have an established history of use in infant formula products. FSANZ also notes that the definition of 'used as a nutritive substance' could be amended to indicate 'for the intended population' as a safeguard that the nutritive purpose must be appropriate for the infant population. It is considered that the amendments will not achieve the required regulatory certainty for enforcement purposes.

6. Protein substitutes

The P1028 Proposal regarding protein substitutes in infant formula will be difficult to enforce by jurisdictions as regulation will be based on the extent of the hydrolysation of proteins.

While some differentiation between partially and extensively hydrolysed infant formulas may be possible, there may be overlap in the extent of hydrolysation in products. It may be difficult to analytically distinguish the "partially hydrolysed protein" product from the "extensively hydrolysed protein" product.

Please address how infant formulas containing partially hydrolysed proteins (regulated as infant formula and subject to a prohibition on health claims) will be differentiated from infant formula with extensively hydrolysed proteins (which form the basis of some Special Medical Purpose Products for infants which are permitted to indicate the relevant medical condition).

7. Contaminants

FSANZ's proposed approach for contaminants in infant formula based on their alignment with exposure and risk data, and international regulations is supported.

FSANZ's preferred approach that MLs for infant formula apply to an as consumed form in mg/kg is supported for the reasons outlined by FSANZ, including that it is consistent with international requirements.

8. Definitions for Infant formula product, Infant formula and Follow-on formula

FSANZ's proposed approach to retain the proposed definition from the consultation paper for infant formula and to include the existing definitions in the Code for infant formula products and follow-on formula is supported.

FSANZ preferred options for the definitions of infant formula product, infant formula and follow-on formula are:

> **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 as the sole or principal liquid source of nourishment for infants, depending on the age of the infant.
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> **Infant formula** means an infant formula product that:
>
> a. is represented as a breast milk substitute for infants; and
> b. satisfies by itself the nutritional requirements of infants under the age of 6 months.
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> **Infant** means a person under the age of 12 months.
>
> **Follow-on formula** means an infant formula product that:
>
> a. is represented as either a breast milk substitute or replacement for infant formula; and
> b. is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months.

If the age limit of 12 months for an infant is written into the definitions for 'Infant formula product', 'Infant formula' and 'Follow-on formula' then there may be no need to write a definition for 'Infant'.

It is further proposed that the clarity of definitions for the definitions could be simplified to read -

> **Infant formula product** means

a. Infant formula
b. Follow-on formula.

Infant formula means a product that:

a. is represented as a breast milk substitute for infants; and
b. satisfies by itself the nutritional requirements of infants under the age of 6 months.

~~**Infant** means a person under the age of 12 months.~~

Follow-on formula means a product that:

a. is represented as either a breast milk substitute or replacement for infant formula; and
b. is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months *to 12 months.*

9. Definition for Special Medical Purpose Product for infants

FSANZ proposed definition modified as follows to include the age limit and remove need for a separate definition of "infant" is supported:

A Special Medical Purpose Product for infants *under the age of 12 months* means a food that is

a. specially formulated for the dietary management of infants
    (i) by way of exclusive or partial feeding, who have special medically determined nutrient requirements or whose capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food; and
    (ii) whose dietary management cannot be completely achieved without the use of the food; and
b. intended to be used under medical supervision; and
c. represented as being
    (i) a food for special medical purposes intended for infants; or
    (ii) for the dietary management of a disease, disorder or medical condition in infants.
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    (i) a food for special medical purposes intended for infants; or
    (ii) for the dietary management of a disease, disorder or medical condition in infants.

10. Definition for "Pre-term formula"

The FSANZ approach to "Pre-term formula" is consistent with the NHMRC Infant Feeding Guidelines and the Healthy Eating Guidelines for New Zealand Babies and Toddlers (NHMRC 2012, MoH 2021). Guidance about infant feeding of pre-term and underweight infants should be obtained from medical professionals.

It is outside the scope of P1028 to provide a medical definition for “pre-term” or “premature”. The existing definition provides regulatory clarity about pre-term infant formulas, as it is currently classed as an “infant formula product”. The proposed regulatory framework would shift pre-term infant formulas to SMPPi. For these reasons, it is considered that the definition for pre-term is not needed.

11. Labelling

- Support FSANZ’s proposed requirements for directions for preparation and use.
- Support the proposed approach to continue the requirement for a date mark due to deterioration in nutrient content over time. .
- Support the proposed approach to maintain the existing requirements for storage instructions.
- Support the proposed approach to maintain the existing requirements for legibility.
- Support the proposed approach to require the preparation instructions to
    - For powdered and concentrated infant formula product not to change proportions of powder/concentrate or add other food except on medical advice
    - For ready to drink infant formula products not to dilute or add anything except on medical advice.
- Continue to support the ongoing ‘breast is best’ statement.
- Support the proposed approach to retain the prescribed names of ‘infant formula’ and ‘follow-on formula’ to identify and distinguish these products that facilitates enforcement of their standards.
- Support the proposed approach to continue the requirement that infant formula states it may be used from birth.
- Support the proposed approach to continue the requirement that follow-on formula should not be used for infants aged under the age of 6 months.
- Support proposed approach to maintain the current requirement for a statement that recommends that infants from the age of 6 months should be offered food in addition to infant formula.
- Support proposed approach to retain the requirement for the label to state the specific source of protein and regulate a list of permitted protein sources.
- Support proposed approach to retain the requirement for the co-location of the protein source statement and the prescribed name of the product in a prominent position on the label.
- Support proposed approach to the grouping of vitamins and minerals in the ingredient list and listed in descending order. This approach would simplify the presentation on the label.
- Support improving the format of the nutrition information statement to better inform consumers.