17 June 2022

Food Standards Australia New Zealand

Email: standards.management@foodstandards.gov.au.

***Sprout Organic submission  P1028 Infant Formula Products***

Dear Standards Management,

Sprout is a manufacturer of children's food products, in particular, an infant formula and follow-on formula which are regulated under FSANZ section 2.9.1, currently sold in the Australian and New Zealand markets, and we are actively expanding into global markets.

Sprout welcomes the opportunity to be heard and considered in this review process. Sprout was established in 2020, and therefore did not participate in any consultation process prior to 2021.  We have undertaken to submit in regards to P1028 to which we will address the points of most relevance to Sprout.

Sprout Organic is a member of the Infant Nutrition Council (INC) and for the most part, supports the INC position as stated in its submission. Comments below relate to points most relevant for Sprout Organic in relation to the nutrient composition of Infant Formula Products.

From the onset in developing our Infant Formula products, under the FSANZ regulatory framework, provided adequate guidance and very clear responsibilities for us to create a safe and effective Infant Formula.

**Section 4 : Protein**

***Definitions***

Sprout Organic is strongly opposed to any change to the existing definition of Infant Formula, or to at all part ways beyond that of the ministerial guidance. The proposed definition clearly serves its purpose.

> **"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."**

**Protein Source**

**4.2 Protein Range**

Fundamentally, soy should be applied to plants in that Sprout supports the FSANZ proposal for a protein minimum of 0.54 g/100kJ, (Soy) based on using an NCF of 6.25. Additionally it must consider the current circumstance of Sprout (Rice) and potential future innovation using other plant proteins. FSANZ must avoid adding a footnote similar to footnote 5 from Codex STAN 72-19811 which highlights that other minimum values *may,* need to apply for formulas based on other non-milk proteins, and place the minimum as applied to plant sourced protein.

**4.3 Protein Source**

Sprout Organic strongly disagrees with FSANZ's proposed approach to prescribing a specific list of permitted protein sources. The proposal for change to the Code disregards innovation, such as Sprout Infant Formula which is not a 'new' protein source. There are numerous safeguards in place to ensure safety and suitability of any protein sources. One of which is the, novel foods provision which already requires novel foods to undergo pre-market assessment, and this would include the novel food definition, such a position by the Advisory Committee on Novel Foods (ACNF). Sprout Organic believes the existing list and definition of novel foods serves it purpose with infant formula.

Protein sources used in the manufacturing of infant formula should be demonstrated safe and suitable for use in infant formula products. The Code is clear "…foods produced from new sources, or by a process not previously applied to food".

FSANZ has knowledge that there are other protein sources, as cited in submissions. Where FSANZ indicates protein (cow) and open for consideration a change to protein (milk) for the purpose of goat, yet disregards sheep, a well established safe and market accepted protein source. The term Milk, should refer to any mammalian milk, that meets the fundamental requirements of Infant Formula.

The consideration of Soy, as a standalone or only plant based protein source is simply wrong as such contradicts the definition of Infant Formula. If any such prescriptive list is prescribed it must include Plant, for the same clarity provided to Milk.

FSANZ proposing to prescribe protein sources will not only inhibit innovation, it disregards the fact that other than time in market and incumbency, Milk and Soy in Australia has had no pre-market approval nor any approval hurdles been met.

**Protein Quality**

Sprout agrees with the FSANZ proposal that the protein quality must be based on minimum amino acid amounts.

**Amino Acid Content**

Sprout agrees with the FSANZ proposal to align the minimum amounts of all amino acids with Codex STAN 72-19811 and to define the ratios.

This approach is based on the known amino acid content requirements and forces manufacturers to balance amino acids to the correct levels, limiting the fortification and introduction of fractured proteins for the purpose of an individual amino acid requirement.

Manufacturers may need to adjust compositions to meet the proposed regulatory minimums and of changes and therefore must be granted a significant time period to process. With global supply chains being difficult to predict, forward purchasing of existing ingredients could be sourced for years or more in advance.

**Section 5: Fat**

**5.1 Fat Content**

Sprout supports the FSANZ proposal for alignment of fat content with International regulations**.**

**5.2 Units of Expression**

Sprout supports the FSANZ proposal to align the units of expression with Codex and EU as per 100kJ.

**5.3 Essential Fatty Acid Composition LA and ALA**

Sprout supports the current minimum LA level of 90 mg/100 kJ within Standard 2.9.1 (S29—8)**.**

**5.4 Fat Source**

Sprout agrees with FSANZ's preferred approach which restricts specific fats, with no definition of fat source required.

**5.6 Restrictions of Certain Fats**

Sprout supports the FSANZ proposal on restriction of certain fats.

**Section 6: Carbohydrates**

Sprout supports the FSANZ proposal on all matters relating to carbohydrates.

**Section 7 : Micronutrients**

**7.3.8 Iodine**

Sprout believes the iodine range should be aligned with the codex and provide a range of 2.5 to 14µg/100kJ

**7.4.2 Vitamin E**

Sprout agrees with the INC position in increasing the minimum to 0.14 mg/100kJ, removing PUFA requirement.

**Transition**

Sprout Organic recommends a minimum of a five-year period with an additional period for stock in market and forward purchased ingredients provision. It would all so require a concurrent approval period for products currently in the market, as all Infant Formula products would be required to undertake the proposed market approvals. This period would be reasonable with only the consideration to the complexity and development required and enough time to allow for the necessary planning, reformulation, packaging implementation and potential regulatory permissions.

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