P1028 Second Call for Submissions - Living Document

This document is intended to address issues as they arise during the call for submissions period and provide clarification to all stakeholders.

Question/comment	***Response***
The Sprout Organic submission was listed incorrectly within *Table 1.6.2.1 - Submitters to the 1st CFS* within the 2nd Call for Submissions.	The 2nd Call for Submissions (CFS) and Supporting Document 2 – Nutrient Composition (SD2) were amended on 1 June 2023 to clarify that the Sprout Organic submission was not a late submission to the 1st CFS. The amendments extend to Section 1.6.2 and Appendix 1, Table 5 within the 2nd CFS and Table 4 and Table 5 within SD2. The amendments are reflective of the submission from Sprout Organics.
Clarification sought regarding section 2.3.4 within the 2nd CFS.	On review, FSANZ acknowledges how some of the bracketed text (cow milk protein allergy (lactose intolerance)) adds uncertainty to our overarching rationale and decision. To clarify our position, FSANZ is proposing that low lactose and lactose free formulas are <u>not</u> considered or categorised as *Special Medical Purpose Products for infants* (SMPPi). The proposed compositional parameters and label requirements are prescribed for infant formula only and do not extend to SMPPi. Formula represented for allergies are categorised as SMPPi. ***Rationale*** Adverse food reactions are categorised into either food allergy or food intolerance, with allergies being immune mediated and intolerances being non-immune mediated. Lactose intolerance is very rare in infants and is attributed to primary lactase deficiency, which is uncommon before 2-3 years of age in all populations. Secondary lactase deficiency is more common in infancy and results from a small bowel injury. This can be seen in infants who have experienced food intolerances, such as cow's milk protein intolerance (non-IgE-mediated). Secondary lactase deficiency, separate from or in combination with cow's milk protein intolerance, is typically managed with low lactose / lactose free formulas as a starting intervention. The purpose of section 2.3.4 was to explain that low lactose and lactose free formulas are not typically consumed by infants with lactose intolerance due to its rarity in infants.

Inconsistency between the definitions noted in Attachment A Variation to Standard 2.9.1 and the conclusion to Section 3.1.4 of the 2nd CFS.	FSANZ's clarifies that correct text and definitions for infant formula and follow-on formula are as follows: **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 6 months. **follow-on formula** means an infant formula product that is represented as: (a) either a breast milk substitute or replacement for infant formula; and (b) being suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months.
Inconsistency between the draft text noted in Attachment A Variation to Schedule 15-5 and the comment made in SD1 Appendix 1 regarding the permission to use sodium ascorbate as a food additive for nutritive preparations to be consistent with CXG 10-1979, section D.	This was an omission. FSANZ intended to include what was written in Appendix 1 of SD1 within the drafting. During our early consideration of the five provisions for food additives considered as carriers for nutritive preparations within section D (Advisory list of food additives for special nutrient forms) in CXG 10-1979. FSANZ noted that industry did not require explicit permissions for carriers since they are processing aids and permissions already exist for such. Therefore earlier drafting was amended to remove such entries. However, after further consideration it was considered that sodium ascorbate does not have a technological function as a carrier but is more appropriately considered to have the function as an antioxidant food additive. It is proposed to correct the drafting in the Approval Report to be consistent with the explanation, and to be consistent with CXG 10-1979. This will require a new entry under 13.1 for sodium ascorbate with the MPL of 75 mg/L with the condition for use only in coating of nutrient preparations containing polyunsaturated fatty acids.
New express permissions not introduced for DHA from: – Dried marine micro-algae (Schizochytrium sp.) rich in docosahexanoic acid (DHA) – Oil derived from marine micro-algae (Schizochytrium sp.) rich in docosahexanoic acid (DHA)	This was an omission. Schedule 25 should only be amended to restrict use of α-cyclodextrin, γ-cyclodextrin, diacylglycerol oil (DAG oil), isomaltulose, and D-tagatose from being used in infant formula products. In line with the 1st CFS, there was no intent to include restrictions on use of micro-algal sources of DHA which are

– Oil derived from marine micro-algae (Ulkenia sp.) rich in docosahexanoic acid (DHA).	currently permitted. This will be amended in the drafting for the Approval Report.
Supporting Document 4 - Costs and benefits (SD4) notes on page 19 'industry stakeholders report that most infant formula is purchased in supermarkets, with the remainder purchased through pharmacies. A significant portion of these sales are online. Online sales account for half of purchased consumer goods by Australian households, of which FSANZ assumes infant formula products are included.'	Stakeholder submissions to the 1st CFS appeared to support the conclusion that half of all consumer goods (including infant formula) is purchased online. However on review this is not correct. In the next version of the cost and benefit analysis, ABS data will be used which shows that around 10% of retail sales are online, with around 5% accounting for food retail sales.