Else Nutrition Submission

Consultation Paper 2 P1028 - Nutrient Composition

Protein source - section 4.3

September 1st, 2021

[redacted]

Executive summary

Else Nutrition supports the status quo, that is maintaining the current approach to protein source that permits ingredients from animal or plant sources, as long as they are nutritionally suitable to feed infants as sole source or main nutrition.

Plant based proteins have a history of safe use in the broader food supply, including foods for infants and children, and are a safe alternative to animal protein sources. They present lower allergenicity hazard than some animal proteins, processing has the ability to mitigate anti-nutrient factors of concern and protein quality can be readily adjusted where needed.

Else Nutrition supports an effective and flexible Code that does not limit ingredients and protein sources as long as they are safe and suitable from nutrition point of view, and which encourages industry to continue in creative research to provide evidence-based innovative, suitable and viable options for infant feeding.

Else Nutrition

The submission is made in the name of Else Nutrition, an Israeli/US and Canadian-based group of companies focused on developing innovative, clean plant-based nutrition products for infants, toddlers, and children. Else Nutrition products were developed to provide an alternative to the existing formulas. Else Nutrition products use minimally processed complete plant foods as source for all macronutrients, providing the nutritional needs for the age group and following the appropriate regulations.

This concept of using whole foods is very different from the current infant and toddler formulas, which are based mainly on a combination of isolated or fractionated nutrients, i.e., combination of a protein ingredient, a fat ingredient, and a carbohydrate ingredient separately. By using whole foods, the products enable keeping the natural way of digestion, where nutrients are in their food matrix and the proteins are intact (Fleischer et al. and Aguilera et al.), while minimizing the need of food processing.

Else Nutrition thanks FSANZ for the consultation paper and welcomes the opportunity to provide comment and information to Food Standards Australia New Zealand (FSANZ) relating to the Regulation of Infant formula.

Infant formula has many available safe and suitable protein sources including plant proteins

Breast milk is the best nutrition for infants. However, when an infant is not solely breastfed an appropriate an infant formula is needed. The majority of the infant formulas available on the market are based on cow milk proteins. Most infants and young children tolerate cow milk-based formulas and milks, while 2-7.5% have true cow protein allergy or intolerance. These infants and children suffer adverse medical consequences from consuming cow milk-based infant formulas and milk products.

Soy formulas, the most common plant-based formulas, are an alternative to cow milk formulas, however a number of the infants that are allergic to milk present also allergy to soy.

The most common option for infants who are not tolerating regular milk based infant formulas are formulas based on hydrolysed cow milk protein. Unfortunately, those formulas suffer from disadvantages related to aroma, taste, texture and price that incline parents to look for plant-based alternatives.

Pediatricians and pediatric gastroenterologists are seeing families where parents are increasingly feeding infants and young children plant-based ‘‘milk’’ alternatives due to cow milk allergy, intolerance or the perception that these conditions are present, or from reasons related to health beliefs or cultural values (Merritt et al). Those parents may use commercial non-dairy milk alternatives (or milk analogues), which are water extracts of plants, and though have become increasingly popular for human nutrition, unfortunately, they are often nutritionally unbalanced (Tangyu et al) thus bearing a risk of significant nutrient deficiencies (for review see Merritt et al).

The nutritional problem of plant based commercial “milk” and the need from the market for such an option, emphasize there is a huge need for suitable, scientifically formulated plant based infant formula products meeting the nutritional requirements, as well as the regulatory standards.

Protein source in the Code

The current Australia New Zealand Food Standards Code (Code) Standard 2.9.1 states: “***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.”

The current Code enables broad use of ingredients from animal or plant sources, as long as they are nutritionally suitable to feed infants as sole or main nutrition. As the Standard does not limit source of fat or carbohydrate, there shouldn’t be any limitation of protein source as long as its incorporation in the infant formula is nutritionally adequate.

Moreover, Standard 2.9.1—10 Infant formula and follow-on formula—protein—further requirements refers to the table in section S29—6 listing the amino acids and their minimal level and also enables adding L-amino acids to infant formula or follow-on formula in an amount necessary to improve protein quality.

This is similar to some limitations agreed in the fatty acids profile without limiting the source of those fatty acids.

Previous considerations supporting Standard 2.9.1 were that setting minimum requirements for protein content and essential amino acid amounts to align with breast milk, and pre-assessment requirements of novel foods and novel sources of ingredients would manage any potential risks of new ingredients (i.e. new sources of proteins) in infant formula. Those considerations should be still valid.

This is also in alignment with Codex STAN 72-1981 and the US FDA, neither specifying protein sources.

Specifying protein sources through the infant formula regulation, leading to requiring specific application to FSANZ for approval of plant-based proteins, may lead to reduced appropriate choices for parents, who are looking for an alternative formula to feed their babies. This may eresult in use of regular plant-based drinks (“milks”) which are not nutritious and adequate for infant feeding.

Based on Consultation Paper 2 (Proposal P1028), Government submitters did not support FSANZ’s preliminary view that protein source does not need to be regulated if the quantity

and quality of protein is regulated, on the basis that plant-based sources of protein may contain anti-nutrient factors that can interfere with nutrient absorption. While this may be correct in unprocessed plant products, there is little evidence given to support this statement in relation to appropriately designed infant formula products.

The concern around anti-nutrient compounds may be resolved as methods for reducing the levels of those compounds are known, simple and readily applied in food applications such soaking, peeling, etc. Those were overcome in soy based formulas and thus no concern should be for other plant based protein sources. Soy based formulas are the most common plant-based protein alternative for infant formulas, recognising that plant based proteins may be a suitable alternative. The potential use of plant-based proteins for infant nutrition was acknowledged by ESPGHAN that wrote in their position paper: *"Proteins from the various plant sources are considered potentially suitable for use in infant formulae."*

Allergenicity

Another issue to be addressed is allergenicity. Food sensitivity reactions may arise from ingestion of many proteins. However, some foods and food ingredients or their components can cause severe allergic reactions including anaphylaxis, which is why declaring allergens is important.

Milk and soy, which are recognized as a safe protein source in infant formulas, are on the list of the most common foods that can cause allergic reactions in Australia and New Zealand together with peanuts, tree nuts, eggs, sesame seeds, fish, shellfish, lupin and wheat. Many infants that are allergic to cow milk protein, may be allergic also to soy or goat thus their only viable option is using hydrolysed protein based infant formula, which are industrially digested and suffer from palatability issues.

Else Nutrition products

Else Nutrition has developed infant and follow-on formulas that meet the requirements of Standard 2.9.1 of the Australia New Zealand Food Standards Code ('the Code'). These products are based on a combination of common food ingredients, specifically Almond butter and Buckwheat flour, together with additional ingredients which are commonly used in infant formulas, i.e., vegetable oil, vitamins, minerals and free amino acids.

Almonds are readily accepted worldwide and are used in a variety of food products. Except for a few sensitive individuals allergic to almonds, almonds are globally enjoyed and used either as a snack food or as an ingredient in other foods (Ahrens et al). Almonds, as being tree nuts are also a common allergen, though to a lesser extent compared to milk. A longitudinal Health-Nuts study in Melbourne, Australia, followed 5276 children. At age of 1 year, only 6 parents (0.1%) reported a history consistent with tree nut allergy (Varshney et al). Those reported allergenicity is much lower compared to cow milk which is well accepted protein source in infant formula. Almond milk was shown as a potential alternative "milk" for infant with cow milk allergy in a clinical study, supporting proper growth without any secondary sensitization (Salpietro et al). This was in spite the possibility that almond milk could be rich in compound that may act as anti nutrients such as tannins.

Furthermore, in recent years, studies demonstrate benefit for early introduction of potential allergens with continuous use. Recent guidelines worldwide for the prevention of food

allergies recommend not to delay the introduction of allergenic foods. Studies show that introducing common allergy causing foods by 12 months may reduce the chance of babies developing food allergy. These foods include egg, peanut, cow's milk (dairy), tree nuts, soy, sesame, wheat, fish and other seafood.

Continuous exposure is important for maintaining tolerance and preventing food allergy development (https://www.allergy.org.au/patients/fast-facts/introducing-foods-and-allergy-prevention). Thus, providing additional protein sources suitable for infant feeding, especially in an infant formula or follow on formula is of high importance.

Conclusion

Else Nutrition supports an effective and flexible Code that does not limit ingredients and protein sources as long as they are safe and suitable from nutrition point of view, and which encourages industry to continue in creative research to provide evidence-based innovative, suitable and viable options for infant feeding.

References

Aguilera JM. The food matrix: implications in processing, nutrition and health. Vol. 59, Critical Reviews in Food Science and Nutrition. 2019.

Ahrens S, Venkatachalam M, Mistry AM, Lapsley K, Sathe SK. Almond (Prunus dulcis L .) Protein Quality ∗. 2005;(869):123–8.

Fleischer DM, Venter C, Vandenplas Y. Hydrolyzed Formula for Every Infant? Nestle Nutrition Institute Workshop Series. 2016;86.

Merritt RJ, Fleet SE, Fifi A, Jump C, Schwartz S, Sentongo T. North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition Position Paper: Plant- based Milks. 2020;71(2):276–81.

Salpietro C.D, Gangemi S, Briuglia S, Meo A, Merlino M V, Muscolino G, et al. The almond milk: a new approach to the management of cow-milk allergy/intolerance in infants. 2005;57:173–80.

Tangyu M, Muller J, Bolten CJ, Wittmann C. Fermentation of plant-based milk alternatives for improved flavour and nutritional value. 2019;9263–75.

Varshney P. Patterns of tree nut sensitization and allergy in the first 6 years of life in a population-based cohort. Vol. 144, Pediatrics. 2019.