Food Standards Australia New Zealand
Email: standards.management@foodstandards.gov.au.
Sprout Organic submission P1028 Infant Formula Products

Dear Standards Management,

Sprout operates as a manufacturer of children's food products, specifically infant and follow-on formula. Our products fall under the regulatory purview of FSANZ section 2.9.1. Currently, our formula is distributed and sold in Australia, New Zealand, the Middle East (KSA & UAE), and Malaysia. As part of our strategic growth initiatives, we are actively pursuing expansion into additional global markets.

Sprout Organic embarked on the development of its infant formula in 2015, meticulously aligning it with the guidelines stipulated by FSANZ. The arduous process of developing an infant formula that satisfied the prescribed FSANZ 2.9.1 standard, as well as meeting market demands for texture, taste, solubility, and colour, spanned approximately five years. In 2020, we initiated the formal commercialisation process, diligently seeking independent legal and industry recommendations, conducting pre-production sampling and testing, and ultimately transitioning to full-scale production. On July 1, 2021, Sprout Organic Infant Formula was commercially launched, marking its official entry into the market. It is important to note that Sprout's involvement in P1028 commenced subsequent to 2021, although we had closely monitored and displayed considerable interest in its evolution.

Based on our current understanding, the comprehensive 12-year assessment of the P1028 review has indicated that the existing FSANZ standards have predominantly achieved their intended objectives. It is extremely disappointing to observe that FSANZ has deviated from the majority of consultative inputs and the internationally recognized Codex Alimentarius Standards. Specifically, its proposal to restrict protein sources in infant formula solely to cow's milk protein, goat milk protein, sheep milk protein, soy protein isolate, and partially hydrolysed protein derived from these specified proteins. This proposed change contradicts and undermines the ministerial definition:

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 either the sole source or principal liquid source of nourishment for infants, depending on the age of the infant.

Manufacturers bear a significant responsibility to ensure the production of safe, effective, and compliant products that adhere to established standards. However, it is equally crucial to emphasise the importance of applying the same burden of validation to

assumptions or the absence thereof “based on the recent focus of new proteins being used in foods and the potential safety risks associated with their use in infant formulas if not approved through the pre-market assessment process.” FSANZ preferred approach to prescribe protein sources and require pre-market assessment of sources outside those specified, is not aligned with the Ministerial Policy Guideline on the Regulation of Infant Formula Products (ANZ FRMC, 2011) and the international Codex Alimentarius Standards (CXS 72–1981). In Australia, only “basic milk protein” (2015) and “soy protein’ (2010) has undergone pre-market assessment, yet goat and sheep proteins have been included in P1028’s restricted list of “allowed” protein sources despite their use being relatively new and innovative in infant formula (FSANZ 2023a).

The sale of infant formula in Australia spans over a century, indicating that all protein sources were once considered new. This historical context raises concerns about the proposed process, as it suggests a lack of rigorous evaluation prior to 2015 regarding milk-based infant formula. Additionally, when assessing proteins that have not undergone specific assessments for use in infant formula, the notion of default approval being granted to a "normal" protein requires clarification. How is "normal" protein defined, especially if the criteria extends beyond simply considering the time it has been on the market?

Taking into account the aforementioned points, it is important to highlight that during the consideration of protein sources from CP1 to CP2, it was explicitly stated that sheep protein was not included. Moreover, it was emphasised that any impact analysis should encompass the costs associated with obtaining approval to utilise sheep milk as a protein source. However, it is perplexing to observe that FSANZ has now included sheep milk as a prescribed protein source in CP2, thus there will be no impact. This raises questions about the consistency of FSANZ's decision-making process. Why has the rule been bent or disregarded in the case of sheep milk, while other protein sources remain excluded? What evidence or justifications were presented by sheep milk manufacturers to warrant such a swift change, assuming that the necessary pre-market approval had not been completed? Clarity and transparency regarding these matters are crucial for stakeholders to understand and evaluate the reasoning behind this sudden modification.

Sprout Organic dedicated years of extensive effort and substantial financial resources to meticulously develop our product line in strict accordance with FSANZ 2.9.1 and the specified nutrient composition for infant formula products. Right from the outset, we diligently pursued the development of our Infant Formula products within the framework established by FSANZ. This approach proved successful as it offered comprehensive guidance and clearly defined responsibilities, and our commitment to operating within this framework has been instrumental in our ability to deliver a range of infant formula that fulfils the stringent safety and effectiveness criteria established by FSANZ.

1. History of safe use

The ministerial guidance 2009 which underwrites P1028, as to the requirement of a composition states:

(d) The composition of infant formula must be safe, suitable for the intended use and must strive to achieve as closely as possible the normal growth and development (as measured by appropriate physiological, biochemical and/or functional outcomes) of healthy full term exclusively breastfed infants when infant formula used as the sole source of nutrition up to six months of age.
where
Pre-market assessment, relative to principles (d) and (e), should be required for any substance proposed to be used in infant formula and follow-on formula 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.

1.1. Sprout Organic Infant formula has been successfully available in the Australian and New Zealand markets for a period of two years. During this time, we have proudly sold over [redacted] units of our product, and we are pleased to report that there have been no reported safety or health concerns. This outcome aligns with our meticulous adherence to the rigorous standards set forth by FSANZ 2.9.1. In addition to the absence of any safety or health issues, we have been privileged to receive an overwhelmingly positive response from mothers, parents, and health professionals alike. The feedback we have received thus far has been filled with gratitude and appreciation for the quality and efficacy of our infant formula. These factors serve as a testament to our unwavering commitment to producing a product that not only meets regulatory standards but also delivers on the expectations and needs of our valued consumers.

[redacted]

[redacted]

1.3. Rice and pea protein have a well-established history of safe usage in both Australia and New Zealand. Sprout has diligently produced and supplied infant formula that adheres to the rigorous guidelines outlined in FSANZ 2.9.1 within these regions for a period exceeding two years. Most importantly, throughout this time, we have not received any reports of safety concerns or adverse events through our dedicated support centre or from any external sources. This track record of safe use underscores the fact that rice and pea protein, when incorporated into infant formula, has been consumed by infants without any negative effects. Moreover, this consumption has consistently supported normal growth and development, aligning with the principles emphasised in the aforementioned statement.

1.4. Sprout Organic's infant formula is produced using traditional or standard, well-established techniques and technologies. It is produced in a HACCP / GMP certified, specialised Infant manufacturing facility alongside other infant formula products. The company follows rigorous quality control measures and adheres to ISO industry standards to ensure the safety and suitability of its products. The production processes used by Sprout Organic do not deviate from commonly accepted practices in the industry. The robustness of our production techniques and the reliability of our sources validate the safety and suitability of pea and rice protein within our infant formula, negating the necessity for additional pre-market assessment.

1.5. There is a very clear and known (to FSANZ) history of safe consumption of rice-based infant formula exceeding 30 years in Australia, New Zealand, and numerous countries throughout Europe. In fact, rice-based formula consumption in France now accounts for 4.9% (in volume) of all formulas for children 0-3 years of age. A study of 78 healthy term infants fed exclusively with rice-based formula until the introduction of solids demonstrated good tolerance and normal growth when compared to WHO growth standards (Girardet et al. 2013). Another study conducted by the Nutrition Committee of the French Society of Pediatric showed the effectiveness of formulas based on rice protein hydrolysates, proving that these formulas provide for satisfactory growth within both healthy infants and those with a diagnosed cows milk allergy in alignment with WHO growth standards (Bocquet et al. 2019). In addition, a study conducted by Vandenplas et al in infants with a

diagnosed cow's milk protein allergy demonstrated catch up growth within 1 month as demonstrated by normalised z-scores according to WHO growth standards (Vandenplas & Hauser 2014). Cumulatively, these studies suggest that rice-based infant formula is safe and supports normal growth in both healthy infants and infants presenting with a diagnosed cow's milk protein allergy.

1.6. Extensive evaluation of pea-protein in infant formula has also been conducted, employing an advanced in vitro static gastro-intestinal model that accurately simulates the conditions in an infant's digestive system. The outcomes of these studies have demonstrated that the protein hydrolysis degree (DH) and amino acid bioaccessibility (AAB) in pea-based formulas are not only comparable but also, in some cases, higher than those found in traditional milk-based infant formulas. This significant finding underscores the safety and efficacy of pea protein as suitable for infant nutrition (Le Roux et al. 2020).

1.7. P1028 disregards plant protein sources other than soy, due to undertones of safety which are difficult to reconcile with knowing the proliferation and high use of these products.

1.8. Although not inside the FSANZ remit, P1028 proposes to remove plant based options from the Australian Market, which inhibits a transition to more sustainable diets which are being promoted by health bodies globally. A move away from plant-based infant formula alternatives appears contradictory to this message. It seems premature to remove plant-based options from the Australian market given that it is likely to be encouraged from both a health and environmental perspective in the near future (Alae-Carew et al. 2022).

1.9. The proposed changes by FSANZ explicitly exclude any protein sources that can be used in infant formula outside of cow, goat, sheep, and soy. This is despite the FSANZ own findings that state that "50% of infants experience gastrointestinal symptoms" from consuming these proteins (FSANZ 2023b). The Australasian Society of Clinical Immunology and Allergy also state that 1 in 50 infants have a cow's milk allergy which points to an overwhelming need for an alternative to these "normal" dairy and soy proteins, such as rice and pea (ASCIA 2022). Furthermore, a number of infants present with functional gastrointestinal disorders (FGIDs), for which plant-based formula may provide a useful alternative. This strategy can help to avoid inappropriate use of medication and can be used in addition to feeding routine modifications (Vandenplas, Hauser & Salvatore 2019).

1.10. Would this not by definition and FSANZ own findings indicate that "normal" dairy and soy infant formulas have some level of a safety concern?

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2. Protein Hydrolysates

2.1. Specifically focusing on the compliance of proteins used in Sprout Organic Infant Formula with the P1028 proposing:

> *The proposed protein sources for infant formula include protein hydrolysates of one or more proteins normally used in infant formula. Protein hydrolysates in infant formula must only be partially hydrolysed with the purpose of meeting protein and amino acid requirements prescribed in the essential nutrient composition. A protein source that has been concentrated, refined or synthesised (e.g. hydrolysed) to a point of purification is considered a nutritive substance and will require pre-market approval (as per section 1.1.2 —12). Further to this, any enzyme used in the preparation of protein hydrolysates for infant formula needs to be approved within the Code.*

Our submission aims to demonstrate that Sprout Organic infant formula, which incorporates rice and pea protein sources, meets the necessary criteria for protein hydrolysates in infant formula.

2.1. Sprout Organic Infant Formula has undergone partial hydrolysis of rice and pea proteins, ensuring that the resulting hydrolysates meet the prescribed protein and amino acid requirements necessary for infant nutrition. Through this hydrolysis process, the digestibility and bioavailability of the protein components are optimised, supporting healthy infant growth and development (Rani, Pooja & Pal 2018).

2.2. The rice and pea proteins utilised in Sprout Organic Infant Formula have undergone a specific concentration and refining process to ensure the highest quality and safety standards. It is important to acknowledge that this processing does not extend to a level that would classify the proteins as purified substances. Consequently, the proteins do not fall within the scope of requiring pre-market approval, as outlined in section 1.1.2—12. This distinction underscores the adherence to regulatory guidelines.

2.3. The enzymes employed in the hydrolysis process of the rice and pea proteins within Sprout Organic's infant formula are approved in accordance with the relevant code. The proteins undergo hydrolysis through a pH-controlled process, utilising the enzyme Ananas comosus (Fruit Bromelain) (EC 3.4.22.33). Importantly, this enzyme is explicitly listed as permitted under section 1.3.3—6—Enzymes of plant origin, following a thorough evaluation to ensure its safety and compatibility with the nutritional requirements of infants. As such, the usage of this enzyme in Sprout Organic's infant formula fully complies with the regulatory guidelines concerning

enzyme utilisation in food products (Nakase, Kudo & Matsutomo 2014; Rozali et al. 2019).

2.4. In summary, Sprout Organic infant formula, incorporating rice and pea protein sources, fulfils the stipulated requirements for protein hydrolysates in infant formula. The proteins have undergone concentration and refinement without reaching the threshold of purification that would necessitate pre-market approval, and the partial hydrolysis process maintains the essential protein and amino acid composition. Finally, all enzymes utilised in the hydrolysis process comply with the relevant code provisions.

3. Meeting protein and amino acid requirements prescribed in the essential nutrient composition.

3.1. Our submission aims to demonstrate that Sprout Organic infant formula, which incorporates rice and pea protein sources, meets the necessary criteria for protein suitable amino profiles as proposed by P1028.

3.2. Sprout Organic utilised datasets provided by the suppliers of its rice and pea protein inputs. The company also undertook multiple independent validation tests of the inputs to confirm the consistency of the provided COAs. The base of reference to the protein source was derived from 3 data sets for rice, and 22 data sets for pea (Herreman et al. 2020). These data sets indicate that the pea and rice protein sources are not varied by seasonality as is seen in mammalian milks, predominantly sheep and goat. This provided Sprout Organic with high confidence in the consistency and accuracy of the protein profiles.

Table 1 -A direct comparison of the L-Aminos in comparison to protein sources shows variation.

Amino Acid	Soy (mg/g)	Rice(mg/g)	Pea (mg/g)	Cow (mg/g)
Histidine	25	21	21	16
Isoleucine	55	30	47	47
Leucine	105	77	92	110
Lysine	69	28	75	51
Methionine	15	17	15	25
Threonine	45	25	35	48
Tryptophan	12	8	8	13
Valine	61	46	58	58

3.3. Where the base protein levels in a raw commodity are valid, the benchmark in protein quality is the digestible indispensable amino acid score (DIAAS). This method first established the amino breakdown of breastmilk as the primary

analogue and actual whole protein digestibility. This protein quality method is well suited to the assessment of products for infants and young children due to the reference pattern acknowledging 0-6 months, 6 -36 months and over 36 months with specific amino acid requirements, as well as amino acid limiting factors of various protein sources.

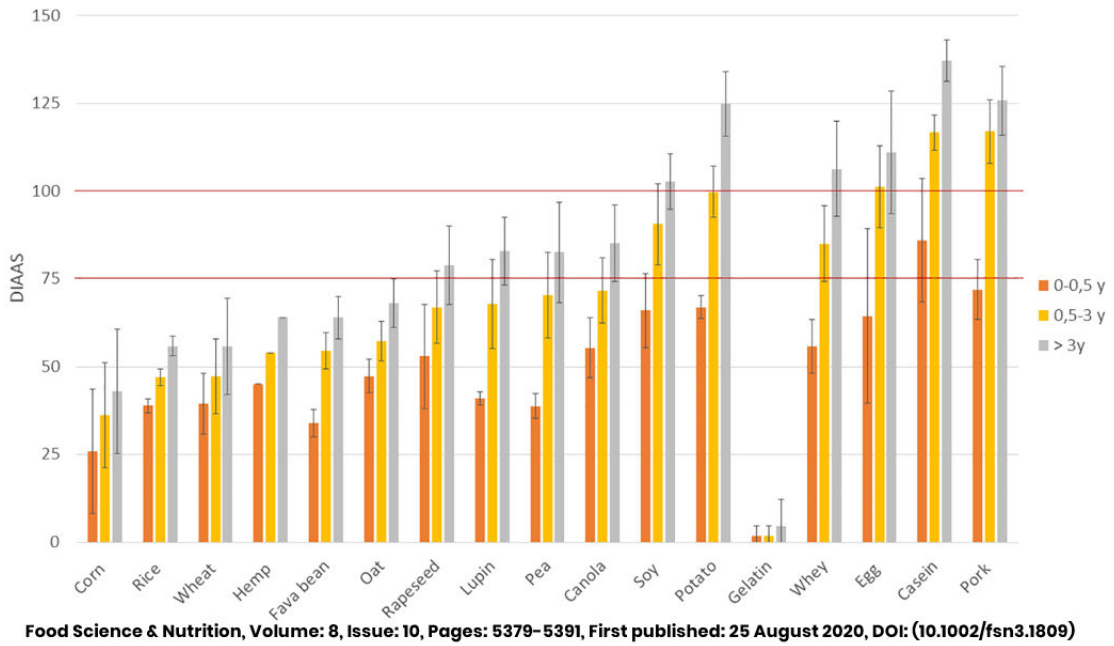
Sprout utilised this methodology to establish primary protein scores and ratios thus establishing a complete amino acid profile with one or more plant based protein sources.

Protein Source	**Digestible Indispensable Amino Acid Score (DIAAS)**
Soy	1.00
Rice	0.47
Pea	0.69
Cow	0.92

3.4. The DIAAS (Digestible Indispensable Amino Acid Score) serves as a valuable tool for assessing protein quality, taking into account both digestibility and amino acid composition. A score of 1.00 reflects a complete protein that supplies all essential amino acids in adequate proportions. When examining proteins in isolation, it is noteworthy that rice protein tends to have a lower DIAAS score compared to other protein sources. Conversely, pea protein demonstrates a moderately higher DIAAS score.

Table 2

Comprehensive overview of the quality of plant- And animal-sourced proteins based on the digestible indispensable amino acid score



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3.5. It is important to re-emphasise that these individual DIAAS scores focus on proteins in isolation and do not account for the potential synergistic effects that can arise when different protein sources are combined. The overall protein quality and amino acid profile of a product can be optimised by strategic combinations of protein sources, enhancing its nutritional benefits (Gilani & Xiao 2012).

3.6. Rice protein is generally lower in lysine, threonine, and sulphur-containing amino acids like methionine and cysteine, while pea protein is lower in methionine and cysteine but comparatively higher in lysine and threonine. By combining these two protein sources, their respective deficiencies in specific amino acids can be compensated for, resulting in a balanced complete amino acid profile.

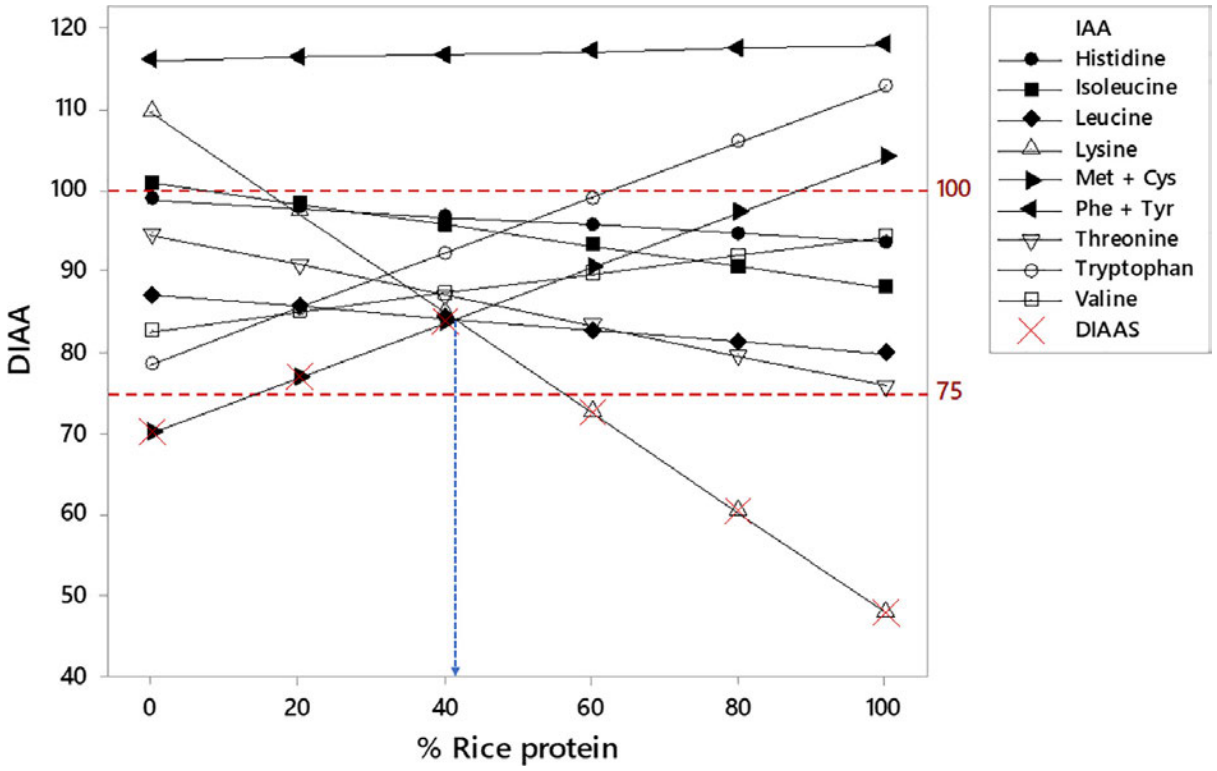
3.7. This combination strategy aligns with the principles of protein complementation, a well-established concept in nutrition. When consumed together, rice and pea protein can provide a more diverse array of essential amino acids, similar to the composition found in complete protein sources like animal proteins.

3.8. Research studies have shown that protein combining, such as rice and pea protein, can result in improved protein utilisation and muscle protein synthesis compared to consuming single plant-based protein sources alone (Gorissen et al. 2018).

3.9. The digestibility score of each indispensable amino acid highlights the complementarity between protein sources (Table 2). Cereal-based proteins, scoring low in lysine but high in methionine and cysteine can to some extent complement leguminous proteins, scoring high in lysine but low in methionine

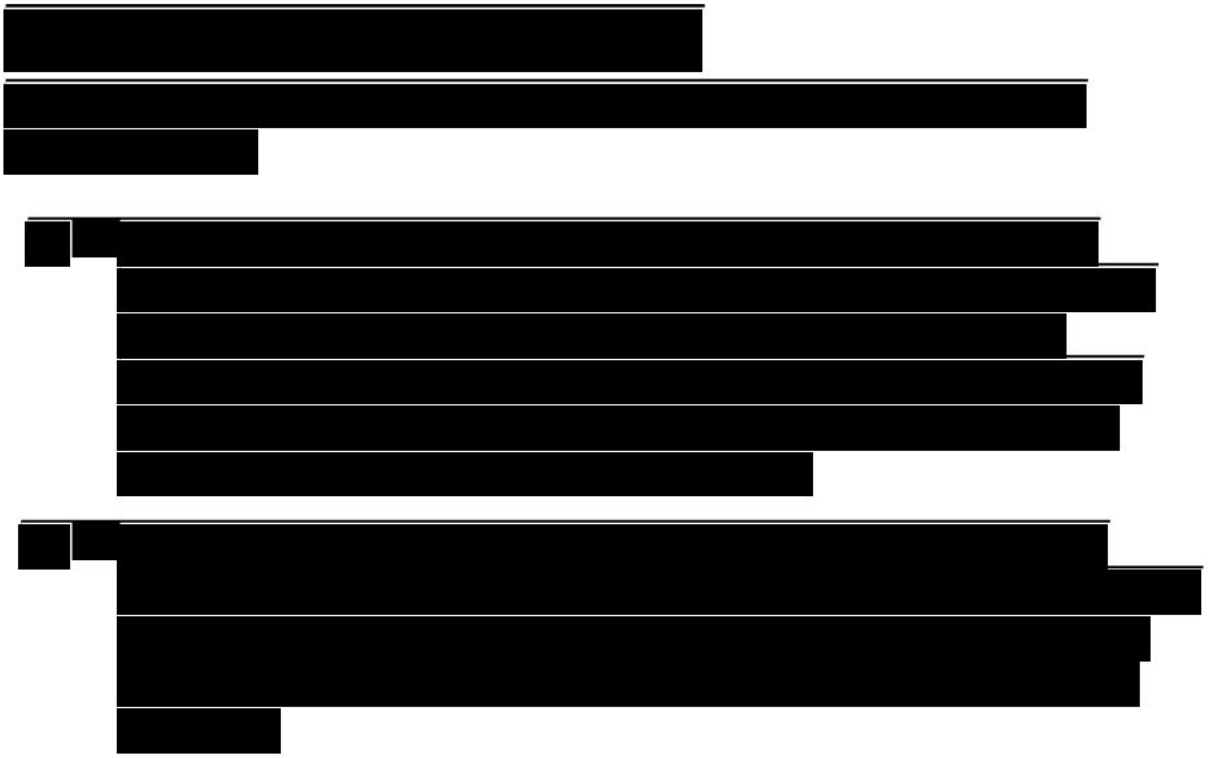
and cysteine. The degree of complementarity depends on the ratio of the combined protein sources, as illustrated below in Figure 3.

Figure 3



Variation in digestible indispensable amino acid values and resulting DIAAS in pea/rice protein mixture. Illustration based on the average SID and average IAA composition obtained from pea protein and rice protein datasets. A DIAAS of 84 (High Quality Protein) can be obtained when just a 41% rice protein ratio is used in composing the pea/rice protein mixture as indicated by the blue arrow.

3.10. In conclusion, combining rice and pea protein offers a scientifically justified approach to obtain a complete amino acid profile. This combination provides a wider range of essential amino acids, compensating for the deficiencies in each protein source individually and allowing infants to meet their amino acid requirements more effectively, particularly in plant-based or vegetarian diets.



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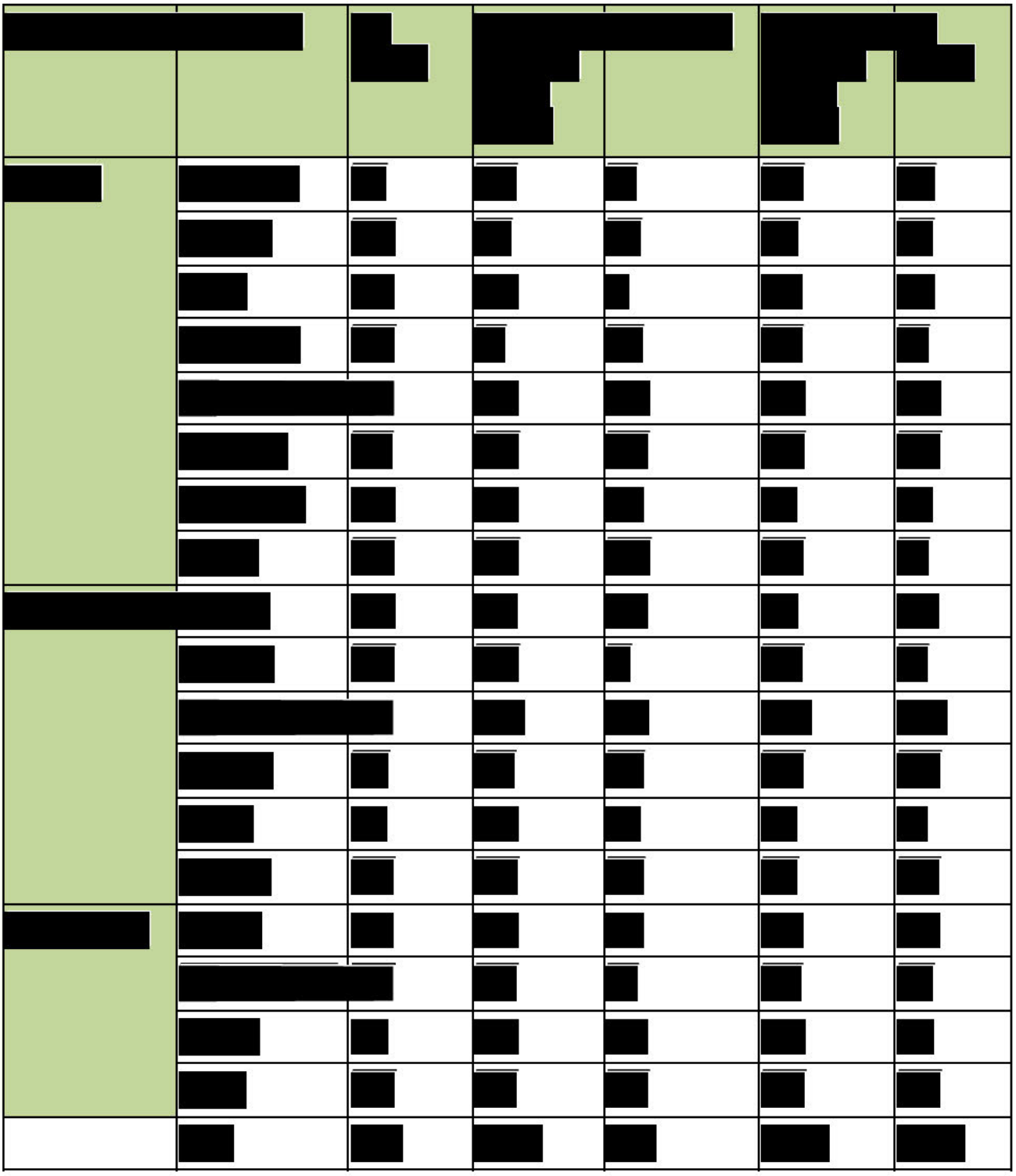
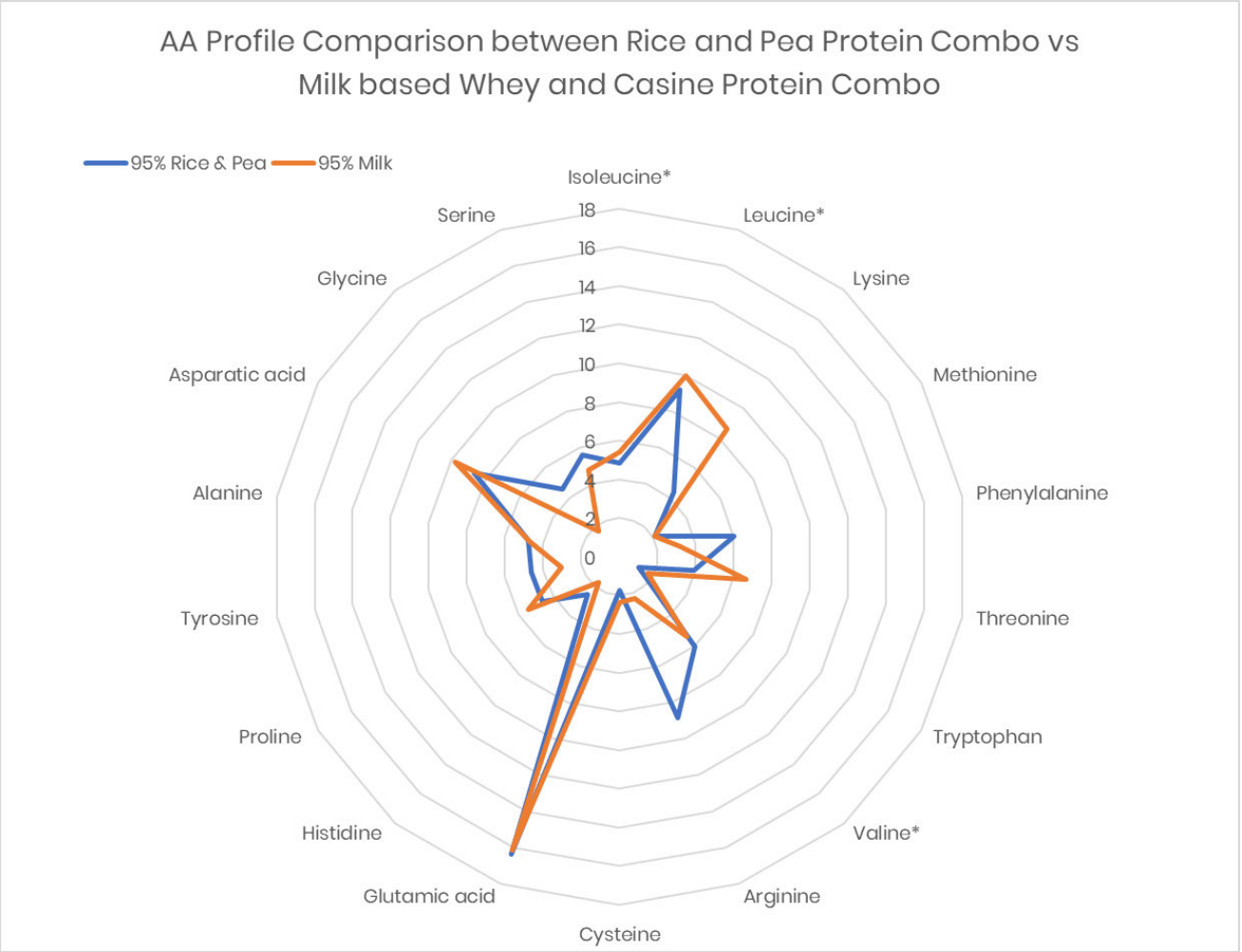


3.13. Figure 4 shows a comparison of 95% protein blends of both milk (casein & whey) and plant-based (rice & pea), demonstrating the balance of essential amino acids.

Figure 4



Finished product against the proposed P1028 standards

3.14. The compliance of Sprout Organic as a finished product with the proposed P1028 profile can be objectively assessed through a scientific lens. By examining the formulation of the product in relation to the proposed requirements outlined in P1028, it is possible to determine that Sprout Organic meets the specified criteria. Additionally, Table 4 provides a direct comparison of Sprout Organic infant formula alignment with the proposed P1028 protein profile.

3.15. Objective evaluation enables a systematic examination of Sprout Organic's formulation and composition to determine its adherence to the proposed P1028 requirements. This objective assessment allows for an unbiased analysis, focusing on the specific parameters outlined in the proposed profile.

Table 4

Nutrient	Unit	P1028 Infant formula		Sprout Infant Formula
		Min	Max	
Energy	kJ/L	2510	2930	2907
Carbohydrates	g/100 kJ	NS	NS	3
Total fat	g/100 kJ	1.1	1.4	1.2
Linoleic acid (LA)	mg/100 kJ	90	335*	106
α-Linolenic acid (ALA)	mg/100 kJ	12	NS	15.2
Protein (milk)	g/100 kJ	0.43	0.72	
Protein (soy) Protein (Rice & Pea)*	g/100 kJ	0.54	0.72	0.57*
L-amino Acids				
Histidine	mg/100 kJ	10	NS	13.0
Isoleucine	mg/100 kJ	22	NS	23.1
Leucine	mg/100 kJ	40	NS	43.3
Lysine	mg/100 kJ	27	NS	28.4
Cysteine	mg/100 kJ	9	NS	10.5
Methionine	mg/100 kJ	6	NS	6.2
Phenylalanine	mg/100 kJ	19	NS	19.1
Threonine	mg/100 kJ	18	NS	19.0
Tryptophan	mg/100 kJ	8	NS	8.3
Tyrosine	mg/100 kJ	18	NS	19.5
Valine	mg/100 kJ	22	NS	28.2

4. Anti nutritive inputs

4.1. Anti-nutritive foods, often referred to as anti-nutrients, are substances naturally present in certain foods that can interfere with the absorption or utilisation of nutrients in the body. These substances include phytates, oxalates, tannins, lectins, and enzyme inhibitors (Awuchi et al. 2022). While these compounds can have health benefits in moderation, excessive consumption or poor preparation methods can hinder nutrient absorption and contribute to deficiencies.

4.2. While rice, pea, and soy (depending on the cultivar) are commonly recognised as having elevated levels of "anti-nutrient" constituents, it is important to note that this is primarily in reference to their raw wholegrain or legume forms. In practice, human diets extensively utilise suitable cooking and processing methods, which have been employed for thousands of years since the advent of agriculture. These techniques effectively mitigate the potential negative effects associated with anti-nutrients, thereby rendering them largely insignificant in terms of their impact on human health (Reddy, Sathe & Salunkhe 1982).

4.3. Rice, pea, and soy protein hydrolysates are not considered anti-nutritive foods.

4.4. The hydrolysis process used to produce rice and pea protein hydrolysates used in Sprout Organic Infant Formula effectively removes the interactive levels of anti nutritive properties of rice and pea proteins. This process involves breaking down the proteins into smaller peptides, which improves digestibility and nutrient absorption (Samtiya, Aluko & Dhewa 2022).

5. International regulations that prescribe rice or pea as a protein source in infant formula products for healthy infants

5.1. FSANZ through P1028 proposes to limit the types of protein sources where this position is speculatory and in contradiction with the fundamental primary goal of P1028 in aligning Australia with the international Codex for infant formula. This change would misalign FSANZ with the international Codex STAN 72-1981 which does not restrict protein sources, not to mention dozens of other country-specific standards.

5.2. Sprout Does not support this change as it does not align with the Codex Infant Formula Standard, or draft Codex Standard for Follow-up Formula. The Codex standards state:

> *1) Infant formula is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be suitable for infant feeding.*
> *The nutritional safety and adequacy of infant formula shall be scientifically demonstrated to support growth and development of infants. All ingredients and food additives shall be gluten-free.*
>
> *2) Follow-up formula for older infants is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the feeding of older infants. The nutritional safety and adequacy of follow-up formula for older infants shall be scientifically demonstrated to support growth and development of older infants.*

5.3. There does not appear to be any valid justification to exclude protein from plant sources other than soy as proposed by P1028, which disregards existing products such as Sprout Organic infant formula that are currently available in the market. In the Codex standard, along with most country specific standards, it states that formulas based on non-milk protein are required to meet minimum values. With this applied, it allows for other protein sources to be used in the future.

5.4. The following are examples of international standards where FSANZ position will contradict:

5.4.1. USA

Under the regulations of the United States Food and Drug Administration (FDA), infant formula is subject to specific requirements and standards. The Infant Formula Act of 1980 and subsequent amendments, as well as the Infant Formula Regulations (21 CFR Part 107) do not prescribe specific protein sources that must be used in infant formula. Instead, the regulations focus on establishing standards for the overall nutritional composition and safety of infant formula products. The FDA requires that infant formula provides the necessary nutrients to support the growth and development of infants without specifying protein sources.

5.4.2. Singapore

Singapore follows specific regulations for infant formula set by the Agri-Food & Veterinary Authority of Singapore (AVA), which is now known as the Singapore Food Agency (SFA). Under Regulation 252 of the Food Regulations, infant formula shall be any food described or sold as an alternative to human milk for the feeding of infants. It shall be a product prepared from milk of cows or other animals or both or from other edible constituents of animals, including fish, or plants and which have been proved suitable for infant feeding.

5.4.3. Malaysia

Malaysia is primarily governed by the Food Regulations 1985 under the Food Act 1983. These regulations set standards and requirements for various food products, including infant formula. Regarding protein sources, the regulations in Malaysia do not prescribe specific protein sources that must be used in infant formula. Instead, the focus is on ensuring that infant formula products meet certain nutritional and safety standards.

5.4.4. The Kingdom of Saudi Arabia

The Kingdom of Saudi Arabia (KSA) is primarily governed by the Saudi Food and Drug Authority (SFDA). The SFDA is responsible for ensuring the safety and quality of food products, including infant formula, in Saudi Arabia. Regarding protein sources, the SFDA regulations do not prescribe specific protein sources that must be used in infant formula.

5.4.5. Indonesia

Indonesia is primarily governed by the Indonesian Food and Drug Authority, known as Badan Pengawas Obat dan Makanan (BPOM). Regarding protein sources, the regulations in Indonesia do not prescribe specific protein sources that must be used in infant formula. However, the focus is on ensuring that infant formula products meet certain nutritional and safety standards.

5.4.6. Vietnam

Infant formula regulations in Vietnam are primarily governed by the Ministry of Health (MOH) and the Vietnam Food Administration (VFA). Regarding protein sources, the regulations in Vietnam do not prescribe specific protein sources that must be used in infant formula. However, the focus is on ensuring that infant formula products meet certain nutritional and safety standards.

5.5. With the major markets around the world not prescribing or restricting the protein source in Infant Formula, Australia and New Zealand under the current proposed P1028 will be "going it alone". This will not only inhibit innovation, but misalign FSANZ with some of its nearest neighbours and largest markets in the world which in no way supports 'safer' infant formula products.

6. Special Medical Purpose Products for infants (SMPPi)

6.1. Sprout has no disagreement with the proposed definition of Special Medical Purpose Products for infants (SMPPi):

6.2. *Extensively hydrolysed proteins are only permitted in Special Medical Purpose Products for infants (SMPPi). SMPPi are highly specialised products, specifically formulated to satisfy the medically determined nutritional requirements of infants with a diagnosed disease, disorder or medical condition for which standard infant formula or follow-on formula is not suitable. Further, extensively hydrolysed proteins require higher levels of differing food additives to support the feasibility and stability of the formula, which are not permitted in infant formula. The SMPPi category enables this increased flexibility to support the products special medical purpose. Further information on SMPPi can be found in section 2 and 3 of the CFS and SD4. Further information on modified infant formula products can be found in section 4.4 below. For the above reasons, FSANZ's preferred approach is that the protein sources in infant formula be specified to be cow's milk protein, goat's milk protein, protein hydrolysates of one or more proteins normally used in infant formula and soy protein isolate. This does not include extensively hydrolysed proteins or proteins hydrolysed for other nutritive purposes. Any protein sources outside of those specified will need to undergo a premarket assessment through FSANZ.*

6.3. Sprout maintains the same objection to the specification of the protein source. This is a significant point since "normal" proteins have a high rate of causing gastrointestinal symptoms, as stated by FSANZ "50% of infants experience gastrointestinal symptoms" (FSANZ 2023).

6.4. Sprout Organic infant formula is **not** a highly specialised product, specifically formulated to satisfy the medically determined nutritional requirements of infants with a diagnosed disease, disorder, or medical condition; nor does Sprout make any claims or references to acting for any purpose as a SMPPi.

6.5. Sprout Organic is an alternate protein product to cow, goat or sheep milk or soy that meets FSANZ 2.9.1. Sprout simply provides a choice to consumers. Sprout Organic does not include any food additives that would not be permitted in infant formula, and achieved a complete amino acid profile from the combination of two appropriate protein sources.

7. Conclusion

Sprout Organic's journey in developing its infant formula, aligning with FSANZ guidelines, has been a meticulous process spanning over seven years. In 2020, after diligent preparations and extensive testing, the company successfully transitioned to full-scale production. On July 1, 2021, Sprout Organic infant formula officially entered the market. Although Sprout's involvement in P1028 began after 2021, the company closely monitored its progress and demonstrated a keen interest in its evolution.

Recent assessments of the P1028 review indicate that the existing FSANZ standards have largely achieved their intended objectives. However, Sprout Organic finds it disappointing that FSANZ has deviated from consultative inputs and internationally recognised standards by proposing restrictions on protein sources in infant formula.

Sprout Organic has diligently adhered to FSANZ 2.9.1 guidelines in producing and supplying infant formula in market for over two years within Australia and New Zealand. Throughout this period, the company has not received any reports of safety concerns or adverse events, reinforcing the safety and efficacy of rice and pea protein in infant formula. These proteins have a well-established history of safe consumption in various countries, including France, where they account for a significant portion of infant formulas consumed by volume.

Studies have demonstrated that rice-based formulas exhibit good tolerance and support normal growth which align with WHO growth standards. Additionally, formulas based on plant-based protein hydrolysates have proven effective for infants with diagnosed cow's milk protein allergies. These findings support the safety and normal growth of allergic and non-allergic infants consuming rice protein based infant formulas.

Sprout Organic's infant formula, incorporating rice and pea protein sources, fulfils the requirements for protein hydrolysates. The concentration and refinement processes meet the necessary standards, while the partial hydrolysis process maintains essential amino acid composition. All enzymes used in the hydrolysis process comply with relevant code provisions.

The combination of rice and pea protein offers a scientifically justified approach to achieve a complete amino acid profile, compensating for deficiencies in isolated protein sources. This broader range of essential amino acids is particularly beneficial for infants following plant-based or vegetarian diets.

The hydrolysis process effectively removes anti-nutritive properties of rice and pea proteins, enhancing digestibility and nutrient absorption. This ensures that Sprout Organic Infant Formula provides a safe and nutritious alternative to milk or soy-based formulas, meeting FSANZ 2.9.1 requirements without the need for additional food additives.

It is important to note that major markets around the world do not prescribe or restrict protein sources in infant formula. By adopting the proposed P1028, Australia and New Zealand would be diverging from major standards, inhibiting innovation and misaligning with neighbouring markets. Sprout Organic's inclusion of rice and pea protein provides consumers with a choice and supports the availability of safer and diverse infant formula options.

Sprout Organic's infant formula, incorporating rice and pea protein, meets stringent guidelines, offers a complete amino acid profile, and undergoes a hydrolysis process that enhances safety and digestibility.

In light of Sprout Organic's diligent efforts in producing a safe and effective infant formula, we kindly request the Minister for Health, FSANZ, and all major voting bodies to carefully consider the validity of our work. We urge FSANZ to modify the proposed P1028 position to include "plant-based" proteins, specifically aligned with soy comparisons, which meet the required standards. This adjustment will ensure the availability of safe, diverse and nutritionally sound options for infants and support the principles of innovation, choice, and optimal infant nutrition.

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