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Re: P1028 – Infant Formula Call for Submissions

Dear Dr Cuthbert

Please accept this as our submission to the Call for Submissions on Proposal 1028 – Infant Formula issued 4 April 2022.

We welcome the care and attention, industry engagement and scope taken by Food Standards Australia New Zealand ('FSANZ') of the proposal to revise and clarify standards for the composition, labelling, category definitions and representation of infant formula product ('P1028'). That said, we have a number of concerns regarding how the Code regulates Infant Formula and the resulting custom and practice that arises from its interpretation.

Misunderstanding of the Code as the definition of best practice in Infant Formulas

The goal for the Code can be paraphrased as the regulatory approach to protect the community, particularly vulnerable sub-groups within the community such as infants, from potential harm from the food available to them as consumers. In considering food generally this can be summarised as ensuring accurate labelling of foods for allergens and ensuing food safety in that the food is not pathogenic or likely to cause illness from consumption. The Code is also best as facilitating broader consumer protection interests in ensuring a food is what it the label says and that products of foreign origin are labelled as such.

Infant Formula is not food generally. There is no substitute where breast milk is unavailable or short in supply. Infant Formula may be the only source of nutrition during a period where the infant will more than double in size, resolve the cognitive capacity to focus their eyesight and recognise faces, define their ability to focus on voices, and develop the majority of the gut-based immune system. The minimum to fuel an infant and the best to support the nutritional needs of an infant are not the same food and as such where products differ in performance on these factors, not the same product.

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The focus of the Code is to set a guide for what is the minimum and with it set parameters regarding factors where excess macro or micro-nutrients are seen as potentially harmful. The weakness in this for the consumers as caregivers for infants is that they falsely assume that any product compliant with the Code is like any other. It is well understood by consumers that not all mobile phones are the same and while standards are set to ensure they work, don't catch fire when being charged and so on, the consumers have a means to resolve and differentiate the available products on the market. This is not the case for Infant Formula.

The issue that consumers are not equipped to differentiate products is not uncommon. The Australia Government recognised this in the health insurance sector and following consultation implemented new regulations to ensure product comparisons where possible and resources existed to educate the consumer on the differentiating factors between the products and what they meant to the prospective insured. This is not available for Infant Formula.

It is outside the scope of P1028 to consider the vacuum of informed and balanced guidance as to what differentiates the more than 170 Infant Formulas available in Australia. However, the Code is part of the current regulation of communication with consumers and has a role to play in remedying this shortfall.

In considering the role of the Code, the glaring gap for Infant Formula is in considering the broader meaning for protecting the community from potential harm from food. The role of Infant Formula as the sole source of nutrition in such a key developmental phase of the human body means that sub-optimal nutrition leads to life-long impacts. The empirical science is clear with Infant Formulas meeting the minimum standard of the Code lead to measurable shortfalls in development for infants against solely human breast milk fed infants. However, science of the past few years sponsored by this understanding has shown factors not controlled by the Code can significantly and materially narrow the gap. That is, two Infant Formulas compliant to the Code can provide very different life-long health and wellness outcomes due to the control of or inclusion of composition that the Code is silent on. The lack of support to caregivers of infants to be informed of what their choice of Infant Formula means and the harm it may cause later in life is an emerging failing of the Code to serve its mission.

The science and the capacity for the supply chain and production processes to apply the science are quite new and as such this failing of the Code is a recent challenge. This submission seeks to bring this concern to the forefront, convey our willingness to participate in any action or consultation it sponsors, and clarify that our view is not to have the Code extend regulation into product design it is current silent on, but to recognise and support the communication that compliance to the Code is not a tick of approval as to the product being best practice in nutrition.

Labelling and advertising

Much is discussed as to the advertising of Infant Formula companies and the compliance to the WHO Code. It is a passionate debate and not one intended to be revisited here other than to note that Care A2+ fully supports the intent of the WHO Code and sees there is sufficient market for its products in those unable to breastfeed or where supply is short of the infants requirements. We support all efforts to lift breast feeding rates and extend the period of breastfeeding.

Our concern is that labelling and by the controls in Standard 1.2.1-23 advertising or more broadly consumer communication, is misleading consumers and bringing about a risk of harm. The reality that unlike a product like paracetamol, not all Infant Formulas are equal. This is not well understood by consumers and labelling should support the communication to consumer to make an informed choice. To be clear, Care A2+ has no interest in seeing health claims occur for Infant Formula.

Care A2+ does see three areas of concern from the broad application of the prohibitions and constraints of the Code for the labelling and consumer communication for Infant Formulas:

1. the misrepresentation of regulatory requirements as features;
2. the inability to identify ingredients not required by regulation or the absence of ingredients or allergens outside of the NIP (particularly where their inclusion or absence is a remedying feature of the performance gap between Infant Formula and Human Breast Milk); and
3. the need for communication to clarify that compliance is not best practice.

This submission seeks to have the community interest for the life-long health and wellbeing of infants as a vulnerable cohort drive a more nuanced consideration of the current controls and lead to both additional constraints, express permissions, and in respect of point three above, a new mandatory statement.

Express permission of nutritive substances

In 4.1.2 of the P1028 call for submission, FSANZ expresses that the milk fraction α-lactalbumin is a nutritive substance from a strict reading of Section 1.1.2-12. That is FSANZ sees that it is a concentrated, refined, or synthesised part of cows' milk used to achieve a nutritional purpose when added to the food. This view if applied generically makes every product non-conforming.

The Code does not expressly permit any milk faction, including the most basic of skim milk powder or lactose. The Code also does not expressly permit amino acids as ingredients. These are concentrated, refined, or synthesised parts of a 'natural source' and materially, are not part of the normal food supply for an infant. Moreover, the Government's advice on the subject specifically recommends not to feed cows' milk to infants. That is, the common ingredients of Infant Formula are not expressly permitted and are nutritive substances derived from a food not recommended for the consumption by the target consumer.

Milk Solids of various forms and types are added for the nutritional purpose, often to facilitate compliance with Section 2.9.1 and Schedule 29 of the Code. The view expressed in the response to the Stakeholder Views would mean that the majority of ingredients in Infant Formula would require pre-market assessment that has not occurred. It would also appear challenging to see how assessment could occur for a single amino acid or a faction of milk in the absence of other fractions of milk to verify safety to that fraction uniquely. Instead, it is commonly recognised that cows' milk as a whole and by implication any fraction of cows' milk as a 'Milk Solid' is already a permitted ingredient.

The use of numerous different milk solid factions is a common practice, supply constraints often cause the specific fraction to vary and foreign manufactured products often do not explicitly identify what fraction is being used in the food on the label. The inclusion of specific amino acids typically sourced from cows' milk as ingredients occurs in standard Infant Formulas when levels are shown from testing of the elected protein source of the product requires supplementation to meet the Code and are a common approach for the building of the entire protein component of infant formulas for special medical purposes. In short, it is impractical to consider express permission of concentrated, refined or synthesised part of a 'natural source' where the natural source is 'milk' and/or 'cream'.

We look forward to supporting FSANZ in its role and it's governance of the Code to support improved health and wellness in the community. Please feel free to contact me regarding any clarifications sought on this submission.

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About Care A2 Plus

Care A2 Plus Pty Ltd ('Care A2+') is an Australian health and wellness food manufacturer based in Sydney with a manufacturing facility in Mulgrave, Victoria. Care A2+ was founded in 2018 and launched its first range of products, being Infant Formulas and a Toddler Formula in October 2020.

A key point of difference of Care A2+ is its control and management of the product from Grass-to-Tin® where from purchasing and processing the milk, Care A2+ establishes the specifications for each interim ingredient and product that combined becomes the finished product. This approach affords Care A2+ the capacity to incorporate innovation into the process and finished product along with flexibility to respond to the requirements of our various export markets regulations and consumer preferences.