Government of **Western Australia**
Department of **Health**

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FSANZ Submissions
PO Box 5423
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Dear FSANZ Submissions

Submission – Proposal P1028 – Infant formula – Consultation paper 3 – Regulatory framework and definitions (Consultation paper 3)

Thank you for providing the Department of Health Western Australia (the Department) the opportunity to input into this consultation. The Department commends Food Standards Australia New Zealand (FSANZ) for undertaking this important Australia New Zealand Food Standards Code (the Code) body of work on infant formula products.

The Department notes that the scope of infant formula products for P1028 Consultation paper 3 includes all the requirements for infant formula products in Standard 2.9.1 for infants aged up to 4 to 6 months and infant formula products for special dietary purposes (IFPSDU) for infants aged 0 - < 12 months, and that specific requirements for follow-on formula (FOF) will be addressed in the 1st Call for Submissions (CFS).

Please find the Department's comments in response to Proposal P1028 Infant formula – Consultation paper 3 – Regulatory framework and definitions (P1028 Consultation paper 3).

General Comments:

As stated in the Consultation paper 3 - The protection of public health and safety is the primary objective for FSANZ and this includes that Infant formula must be safe for formula-fed infants to consume, and its nutrient composition must support normal growth and development when infant formula is intended as the sole or principal source of nutrition.

The Department understands that the "overarching goal of Proposal P1028 is to ensure that infant formula remains safe and suitable by taking account of current science, market developments and the international regulatory context.

The proposal is considering issues raised by stakeholders relating to regulatory clarity, the application of Ministerial policy guidance and alignment with updated

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international regulations. This is a large and complex project prepared under section 113(6) of the Food Standards Australia New Zealand Act 1991 (the FSANZ Act) and assessed under the Major Procedure."

Given the mandate of protecting the health and safety of vulnerable infants, the Department notes that having well-designed and evidence-based regulation and supply of infant formula products will support the safety, integrity, innovation and competitiveness of infant formula industries now and into the future.

With this in mind, the Department highlights that the first call for submissions (1st CFS) which is expected to be released at the end of 2021, must be up to date with the current science and the risk assessments underpinned by suitably rigorous scientific review, along with a consistent approach to the goals of this major food regulation project.

In moving forward with this infant formula review work, it is important to support all of the risk analysis work on infant formula products having regard for all relevant principles of the Ministerial Policy Guideline on the Regulation of Infant Formula (Ministerial Policy Guideline). The Department would like to highlight that the Ministerial Policy Guideline clearly sets the Ministers expectation regarding the making of claims on infant formula products. At this stage, the Department does not consider there is confusion regarding the requirements for pre-market assessment noting that the need for pre-market assessments was clarified in the Ministerial Policy Guideline, which clearly provides stakeholders the Ministers intent and expectations specific to the addition of substances to the infant formula products and the need for pre-market assessment. Specifically, the Ministerial Policy Guidelines Policy Principle j) applies regarding a substantiated beneficial role.

The Department supports retaining products which are for the purpose of feeding infants under Standard 2.9.1, at this stage. The Ministerial Policy Guideline provides guidance on the expectations of the Australia and New Zealand Food Regulation Ministerial Council for the composition, labelling, advertising and promotion of infant formula products. These principles apply to all of the infant formula products. It would seem logical and reasonable to consider the regulation of infant formula products that partially meet an infant's need under the existing Standard 2.9.1, and having regard to the Ministerial Policy Guideline, including the specific policy principles for Infant Formula Products for Special Dietary Uses (IFPSDU).

The Department supports the retention of the requirement for labelling infant formula products with prescribed names. This is an important from a risk management. Infant formula products are highly specialised and the food identification requirements of a prescribed name' is proportionate measure to clearly indicate the true nature of this food and its intended purpose and for compliance and enforcement activities.

Please find attached responses and/or further preliminary comments to FSANZ proposed approach detailed in Consultation paper 3 in Table 1. as follows:

Table 1 – The Departments' response to FSANZ P1028 Consultation paper 3

Section	FSANZ proposed approach	The Department's response and/or preliminary comments to FSANZ's proposed approach
2. Novel Foods and Nutritive Substances		
2.1 **Pre-market assessment requirements**	The above arguments and the relatively small number of substances having uncertain regulatory status has persuaded FSANZ not to proceed with a separate review of novel foods and nutritive substances applicable to [Infant Formula Products] IFP under P1028. Future assessment of P1024 will consider the broader review of the Code's provisions for novel foods and nutritive substances applicable to all foods. The requirement that all food sold – including IFP – must be safe and suitable continues to apply in the interim. This proposed approach has relevance to the nutrition information statement for [Infant Formula Products for Special Dietary Purposes] IFPSDU which was raised in the 2016 Consultation paper and will be discussed in the 1st CFS (to follow this consultation paper).	**Does not support, at this stage.** Novel foods and nutritive substances are an important and significant part of Standard 2.9.1 and the risk management framework that this standard provides, and there is a lack of rationale provided for excluding them from the work P1028. The Ministerial Policy Guideline is specific to 2.9.1. This Ministerial Policy Guideline clearly indicates how novel foods and the addition of nutritive substances should be treated for IF products and IFPSDU i.e. pre-market approval is required. The review of novel foods and nutritive substances under P1024 has been significantly delayed for an extended period of time and may not be the best approach given the special nature of IF products and IFPSDU and the highly vulnerable nature of this population group. There is a shift in some countries to more plant-based diets and interest amongst industry and consumers to provide infants plant based infant formula and plant-based beverage options. It is unclear what risk assessment has been undertaken for these new formulas. Novel sources for protein include legumes, grains and so-called pseudo grains, and potato. Further information on FSANZ's level of confidence for safety of these products and what risk assessment work undertaken for novel plant-based protein formulations with respect to anti-nutrients, toxins and pesticides would be helpful. In

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Section	FSANZ proposed approach	The Department's response and/or preliminary comments to FSANZ's proposed approach
		addition to the potential short-term risk assessment considerations, are there any longer-term nutrition related issues of interest for the infant population moving onto these plants based infant formula products? The Sprout Organic website (Australian Company) is an example of new plant infant formula (0-12 months) and plant-based drinks which are located under the formula menu. The Department considers that 'safe and suitable' are insufficient for IFP, noting the Ministerial Policy Guideline policy j) Substances subject to pre-market assessment for use in infant formula and follow-on formula should have a substantiated beneficial role in the normal growth and development of infants or children, or a technological role, taking into account, where relevant, the levels of comparable substances in breastmilk. A substance's role in normal growth and development is substantiated where there is appropriate evidence to link the physiological, biochemical and/or functional effects of the substance to specific health outcomes for infants, in infancy or childhood. Particular caution should be applied by the Authority where such links are less clear.
2.2 Novel Foods – Schedule 25	FSANZ proposes to add the conditions listed in Table 5 to novel foods listed in Schedule 25. This will achieve the original intention of the assessments for these novel foods which is to restrict them from use in infant formula, infant foods, and [Formulated Supplementary Foods for Young Children] FSFYC.	Supports.
3. Specialised infant formula products		

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3.1 **Approach to regulation of IFPSDU**	It is proposed to retain the regulation of IFPSDU in Standard 2.9.1. Regulating IFPSDU in Standard 2.9.1 means it would be an IFP as defined. The classification of supplementary products for pre-term infants in Standard 2.9.1 or Standard 2.9.5 is discussed in greater detail in section 5.5.1 below.	Supports retaining the regulation of IFPSDU in Standard 2.9.1. Does not support moving these supplementary products for pre-term infants, from 2.9.1 to 2.9.5, at this time. Specialised IFPs should be regulated under this standard and the Ministerial Policy Guideline is relevant (captures) these products that are being fed to infants.
3.2 **Human milk fortifier and pre-term supplementary products**	IFPSDU that are sole or principal sources of nutrition are proposed to be regulated as IFP, whereas other infant products that serve a supplementary role are proposed to be regulated by Standard 2.9.5. Subsequent consideration will be given to any particular provisions relevant to infant products that are needed in Standard 2.9.5 at a later stage.	Supports IFPSDU that are sole or principal sources of nutrition being regulated as IFP. Does not support moving these other products for pre-term infants, at this time. Any specialised IFPs should be regulated under this standard and the Ministerial Policy Guideline is relevant (captures) these products that are being fed to infants.
4. Definitions		
4.1 **Definition of infant formula product**	The second part of the current definition of IFP relating to a product that is nutritionally adequate to serve by itself as the sole or principal liquid source of nourishment for infants, depending on the age of the infant, is proposed to be retained. As an IFP, this definition will also apply to IFPSDU. The first part of the current definition relating to base ingredients is proposed to be applied only to the compositional requirements for general IF and FOF and removed from the	Supports the approach of having a separate definition for IFPSDU as previously proposed based on FSANZ's preliminary view (P1028 Consultation paper 3, page 18) that the definition of IFP should be retained. It is unclear as to the potential benefits and/or ramifications of removing the reference to 'based on' from the definitions provided in Table 7 of P1028 Consultation paper 3. As such, further information is sought on what the implications might be for the approach proposed by FSANZ to remove 'based on' from

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	definition of IFP. Extension of use beyond infancy is discussed in section 5.6.2 below. So far, the proposed definition is: An infant formula product means a product that 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 definitions given all the new protein sources seeking entry to the market.
4.2 **Definition of infant formula**		Does not support the proposed approach, at this stage. The Department supports the following definition which FSANZ previously canvassed which is Option 3 (Options 2 and 3) with slight modification to the text as follows: *"Satisfies by itself the nutritional requirements of infants up to the introduction of appropriate complementary feeding as part of a progressively diversified diet, of infants around 6 months of age".*
		Clarity is sought on whether there is a need for definitions for other protein sources, particularly given, the new products which are on, or coming onto, the market including such as pea protein, or buckwheat protein, infant formula product.
4.3 **Other definitions**	FSANZ proposes to retain the definition of pre-term formula for the time being, particularly because it might need further differentiation from HMF.	Supports

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	Question 3. Are definitions needed for any of the new terms proposed to be introduced as conditions for the use of food additives in CP1, such as gastrointestinal reflux, gastrointestinal disorders, or impairment of the gastrointestinal tract, inborn errors of metabolism etc.?	The Department supports all special purpose formulas being required to state the condition that they have been formulated to manage. This includes providing: 1. compositional information which is specific to the formula being suitable for this condition 2. a statement that reflects the warning statement, for example, 'not for general use, suitable only for XX condition under medical supervision'.
5. Regulatory framework		
	Table 12. Current regulation of IFPSDU and positioning on the market: that products for colic and constipation are listed as being 2. Products for metabolic, immunological, renal, hepatic and malabsorptive conditions.	The Department notes that some care should be as these products may not be recommended by professionals for these conditions and there may be associated health claims issues for these products on the market place.
	Table 12. Current regulation of IFPSDU and positioning on the market: 3. Products for specific dietary use based on a protein substitute.	The Department has a query regarding whether partially hydrolysed formula may increase risk of allergy and seeks clarification on managing this risk for classification.
5.2 **Options for regulatory framework**	FSANZ proposes that subcategories should only be established if specific regulation beyond that set for all of Division 4 is needed	Supports
5.3 **Principles for purpose, composition, use and sale of IFPSDU**		Supports principles related to nutrient composition, scientific evidence, and appropriate use can be formulated whereby IFPSDU: • should meet the nutritional requirements of infants to support growth and development • should be effective and beneficial for the intended purpose

Section	FSANZ proposed approach	The Department's response and/or preliminary comments to FSANZ's proposed approach
		• are intended for the dietary management of infants with a specific disorder, illness or condition and not incorrectly used by healthy infants. • the nutrient composition should be based on – IF or FOF other than where necessary to meet the purpose of the product (compositional deviation) – appropriate scientific evidence • should be used under medical supervision to manage the risk to unhealthy infants.
		The Department notes that in addition to 'safe and suitable' the Ministerial Policy Guideline policy j) specifies that "Substances subject to pre-market assessment for use in infant formula and follow-on formula should have a substantiated beneficial role in the normal growth and development of infants or children, or a technological role, taking into account, where relevant, the levels of comparable substances in breastmilk. A substance's role in normal growth and development is substantiated where there is appropriate evidence to link the physiological, biochemical and/or functional effects of the substance to specific health outcomes for infants, in infancy or childhood. Particular caution should be applied by the Authority where such links are less clear."
		The Department supports the proposed approach on the proviso of the inclusion (in bold italics) that the need for IFPSDU to be, as follows: "specially manufactured and formulated in accordance with appropriate scientific evidence that demonstrates the efficacy of the product in meeting its intended ***special medical*** purpose.

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5.3.3 **Extension of use beyond infancy**	IFSPDU used in infancy and beyond should be accommodated in regulation	Unclear that FSANZ should regulate this permission. There may be times when medical practitioner determines a medical need to use a specific formula past infancy, then could they not do this at their own medical discretion as is the current situation?
5.3.3 **Restriction on sale**		The Department notes that partially hydrolysed formula may increase risk of allergy and seeks clarification on the risk associated with this. Are there any risks associated with unnecessary restriction of lactose from longer term perspective?
5.3.4 **Proposed consolidated principles – purpose, composition, use, sale**	The proposed principles guide the framework for the regulation of composition, use and access of IFPSDU. These consolidated principles are that IFPSDU: • serve as a sole or principal source of nourishment for infants (IFP definition) • serve as a substitute for human milk, and replacement for infant formula and follow on formula • are formulated for infants with a specific disease, disorder or medical condition • are intended to meet an infant's nutritional requirements to support growth and development • are formulated in accordance with scientific evidence that demonstrates the efficacy of the product in accordance with its intended purpose • have a nutrient composition that reflects that of IF or FOF except	Supports the consolidated principles with the exception of the principle relating to "used in infancy and beyond should be accommodated in regulation". Further consideration on the need for FSANZ to regulate may be useful.

Section	FSANZ proposed approach	The Department's response and/or preliminary comments to FSANZ's proposed approach
	where necessary to meet the intended purpose of the IFPSMP • are intended for use under medical supervision to manage risk to unhealthy infants • used in infancy and beyond should be accommodated in regulation • are subject to a restriction on sale.	
5.4 **Name and definition of IFPSDU**	FSANZ considers there is merit in changing the name of IFPSDU to Infant Formula Products for Special Medical Purposes (IFPSMP).	Supports
		Supports the following definition: *IFPSMP means a product that:* • *is specifically formulated for the partial or full dietary management of infants who have medically determined* *(i) altered nutrient requirements, or* *(ii) limited or impaired capacity to digest, absorb, metabolise or excrete food, including another type of IFP,* • *Is considered to be safe, beneficial and effective in the dietary management of the specific condition based on generally accepted scientific data, and* • *Is to be used under medical supervision.*
5.5 **Provisions for IFPSMP — composition**	FSANZ considers subcategories may be required only if specific requirements are needed beyond those that apply to the entire Division.	Supports

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	That the current arrangement to allow compositional deviation from the composition of IF is proposed to be retained	Supports on the proviso that the compositional deviation from IF composition with the principles applied: • is only for the intended condition of the IFPSMP and that this is on the basis of scientific evidence and • pre-market approval of new substances for special purpose formula is required and • Optional ingredients not permitted unless they are specifically required to manage the intended medical condition.
5.6 Provisions for IFPSMP — purpose, use and sale		
5.6.1 **Scientific evidence of purpose**	It is proposed to enshrine in regulation the principle that IFPSMP are formulated in accordance with scientific evidence that demonstrates the efficacy of the product in accordance with its intended purpose.	Supports
	FSANZ's Preliminary view: In regulatory terms, this might mean a requirement that: manufacturers of IFPSMP must have established the efficacy of the product as an IFPSMP; and retain evidence that demonstrates both that they have undertaken that step and the efficacy of the product as an IFPSMP.	Supports preliminary view in principle. Do not support claims on IFPs.
5.6.2 **Extension of use beyond infancy**	FSANZ is open to permitting the use of IFPSMP beyond infancy in the regulation of IFP but needs further information to determine what requirements are needed to allow for such use. For example, is there a	Unclear that FSANZ should regulate this permission. There may be times when medical practitioner determines a medical need to use a specific formula past infancy, then could they not do this at their own medical discretion as is the current situation.

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	maximum age or other parameters that indicates when the product is no longer appropriate?	Suggest consideration of text to the effect that product use beyond infancy must be on medical advice only.
5.7.6 **Exemption from 'breast milk is best for babies' warning statement**	FSANZ's preliminary view is to apply the exemption from the 'breast milk is best' warning statement to all IFPSMP.	Supports
5.7.7 **Exemption from statement about offering foods in addition to IFPs**	For the above reasons, FSANZ's preliminary view is that the general directions for preparation and use requirements are appropriate for IFPSMP, and there are no additional, specific directions that should be mandated.	Considers this may warrant further teasing out of the issue of the proposed exemption for IFPSMP before landing on a position. Is this approach consistent with the approach for 2.9.5 and Codex? The information provided in the Consultation paper indicates that Codex does have provisions related to labelling "in such a way to avoid the risk of confusion between infant formula, follow-up formula and formula for special medical purposes, noting that Codex does not specify how this provision needs to be achieved.
5.7.9 **Labelling information on safe preparation and use**	For the above reasons, FSANZ's preliminary view is that the general directions for preparation and use requirements are appropriate for IFPSMP, and there are no additional, specific directions that should be mandated.	Supports

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Specific questions listed in Consultation paper 3
No further comments, at this time.

Some references of interest:

Bowen, Jaclyn. "Infant Formula: An Analysis of the Contents of Plant-Based vs. Whey-Based Formulas (P11-056-19)." Current developments in nutrition 3.Suppl 1 (2019).

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Romo-Palafox, Maria J., and Jennifer L. Harris. "Caregiver's Provision of Non-Recommended Commercially Prepared Milk-Based Drinks to Infants and Toddlers." Journal of Nutrition Education and Behavior 53.8 (2021): 643-653.

Schatz. 2020. Israeli Startup Shakes Up The Formula Market With Plant-Based 'Milk' For Toddlers. https://www.forbes.com/sites/robindschatz/2020/09/17/israeli-startup-shakes-up-the-formula-market-with-plant-based-milk/?sh=6434ab885703

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https://library.wur.nl/WebQuery/wurpubs/fulltext/545554

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Yours faithfully

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