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

[redacted]

FSANZ Submissions
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Dear FSANZ Submissions

Submission – Proposal P1028 – Infant formula – Consultation paper 1 – Safety and food technology

Thank you for providing the Department of Health Western Australia (the Department) the opportunity to input into this consultation. Please find the Department's comments in response to Proposal P1028 Infant formula – Consultation paper 1 – Safety and food technology (P1028 Consultation paper 1) and P1028 Supporting Documents 1-4.

Overall Summary:

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. In addition to the mandate of protecting the health and safety of vulnerable infants, 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.

The Department notes that the scope of infant formula products for P1028 Consultation paper 1 includes infant formula products 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 specifically excludes from the review infant formula products 6 - <12 months (known as follow on formula).

This review work covers a large scope of an important and technically complex area of food regulation, for the highest risk population of infants, including unwell, preterm, very preterm, and low and very low birth weight infants. L(+) lactate acid producing bacteria, in of itself, is a highly technical and complex area of high research interest. A significantly longer consultation period for submitters would assist in canvassing for information and expert opinions for the next phase at the 1st Call for Submissions. The Department supports the upcoming work by FSANZ to further investigate and describe the safety and food technology related issues of the supply of infant formula in Australia and New Zealand. In moving forward with this infant formula review

work, it is important to support the risk analysis of infant formula products with robust scientific processes and having regard for all relevant principles of the Ministerial Policy Guideline on the Regulation of Infant Formula (Ministerial Policy Guideline).

The probiotics research area has increased rapidly for infant formula products; and there still continues to be debate amongst, and between, experts and researchers on the substantiated safety and physiological benefit of these substances. The Department stresses that any decision on L-lactate acid microorganisms as probiotics must be supported by an appropriate risk analysis.

Comments in response to P1028 Consultation paper questions

Section 1. Food Additives

In general, the Department notes that FSANZ regards consistency with Codex Alimentarius (Codex) and the European Union (EU) and other relevant international regulations as being an important factor; and that industry is familiar with, and able to comply with, these explicit food additives permissions. The Department notes FSANZ 's stated approach for food additives is consistent with the general principle that food additive use should be minimised in products for infants, who are a vulnerable population. The Department also notes that "before a food additive is permitted for use in food, FSANZ ensures the food additive is safe at the permitted level in the particular food and that there is a technologically justified purpose for its use" (P1028 Consultation paper 1, p8).

Schedule 15 of the Code covers infant formula products up to 12 months. It is unclear what the implications are for infant formula products that are out of scope of the P1028 Consultation paper 1 and further clarity on this is needed.

The Departments' response to the FSANZ's proposed approach to Section 1 - Food additives used in infant formula products, that are in scope of the P1028 Consultation paper 1, is provided in Table 1 below.

Section 2 – Contaminants

The Department supports FSANZ specifying Maximum Limits (ML) for contaminants that pose a risk to infant health and safety. The Department notes that EU regulations state in the preamble to EU Commission Regulation 1881/2006 – Setting maximum levels for certain contaminants in foodstuffs, that "it is considered an appropriate risk management approach for the health protection of infants, to establish the lowest maximum levels [of contaminants], which are achievable through a strict selection of the raw materials used for the manufacturing of foods for infants and young children" (P1028 Consultation paper 1, p53).

Harmonisation with European Union (EU) and/or Codex contaminants where safe and appropriate is supported, in principle. The Department seeks more information on what, if any, are the potential risks of not harmonising with more stringent international ML for trade?

Table 1 – Response to FSANZ proposed risk management approach to Section 1 - Food additives

Food additives	FSANZ proposed approach	The Department's response to FSANZ's proposed approach
Food class system for food additive permissions (refer to section 2.2)	FSANZ considers a combination of minimising the food classes and use of qualification notes and conditions would best address the clarity issues and be consistent with international approaches. FSANZ proposes to reduce the subclasses to include just one for IFPSDU (Option 3).	Supports. Qualification and conditions should be consistent with the principle that food additive use should be minimised in products for infants who are a vulnerable population.
Carry-over principle for food additives and infant formula products (refer to section 2.3)	FSANZ proposes prohibiting the use of carry-over provisions for food additives unless permissions exist for such food additives used in raw materials and ingredients used to produce infant formula and IFSPDU. Codex and EU regulations do not permit the general carry-over of food additives for infant formula and IFPSDU except where explicit food additive permissions (provisions) already apply to them, so the industry is familiar with, and able to comply with, such regulations and provisions. The critical matter appears to be to ensure consistency with food additive permissions in the Code with relevant international infant formula and IFPSDU regulations. In this case, the carry-over principle is no longer an issue because the Code would be consistent with international infant formula regulations. The proposed approach is consistent with the general principle that food additive use should be minimised in products for infants who are a vulnerable population.	Supports
Updates to nomenclature and INS numbers (refer to section 2.6)	FSANZ's proposed approach is to retain the current nomenclature.	Supports

Section 3. L-lactate acid producing microorganisms
Question 13:

Does the current permission for L(+) lactic acid producing microorganisms need to be clarified? For example, some L(+) lactic acid producing microorganisms are pathogenic.

Do these need to be explicitly excluded or is the base 'safe and suitable' requirement considered sufficient to manage this risk?

The Department notes that the current permission for L(+) lactate producing microorganisms (L-lactic acid producing microorganisms) was originally intended as being limited to the purpose as an additive for acidity regulators and for pH adjustment). The current permission for the amount of L-lactic acid producing microorganisms as an acidity regulator/pH adjuster is set at good manufacturing purposes (GMP). As indicated by FSANZ, this permission as an additive was not meant to be a permission for L-lactic acid producing microorganisms as an optional ingredient in infant formula as a probiotic.

The Department agrees that the base 'safe and suitable' requirement is not sufficient to manage the risk, at this time and noting that FSANZ has a low risk appetite for this population subgroup[1]. The Department notes policy principles c) d), i), j), k) - m)[2], of the Ministerial Policy Guideline, are relevant for FSANZ to have regard to during this important risk analysis work.

The Department acknowledges the general acceptance by standard setting bodies that scientific evidence does not suggest harm for healthy infants consuming L-lactic acid producing microorganism as probiotics. There is concern expressed amongst the experts and/or researchers that consumption of the extent and range of the probiotic supply is increasing rapidly, and that there is insufficient weight of scientific evidence base of health benefit to warrant recommending their inclusion in infant formula products [1, 2].

In addition to sepsis, potential safety issues raised in the literature include transfer of antimicrobial resistance, gastrointestinal problems, quality issues and cross contamination in hospital setting [2-6]. The scientific community has raised concerns about safety and quality control issues related to the contamination of probiotics with pathogens, strain purity and dose, [potential for difference in therapeutic grade used for clinical trials and food grade in infant formula], cross contamination in clinical settings, licensing and regulatory issues, [3, 4, 7-9].

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[1] FSANZ undertakes its risk analysis processes to achieve its objectives in a low overall risk range. Our lowest risk appetite relates to meeting our key objective in setting standards, which is protecting public health and safety through a safe food supply. In meeting this objective, we adopt a conservative approach. This is particularly the case where there is a level of uncertainty in the risk assessment due to a paucity of data or when dealing with susceptible population sub-groups. In such cases, FSANZ operates with a zero to negligible tolerance for residual risk (FSANZ 2013, Risk Analysis in Food Regulation).

[2] Ministerial Policy Guideline on the Regulation of Infant Formula. https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-Infant-Formula-Products (accessed1 July, 2021).

An informed decision on what is, in effect, a new permission, requires FSANZ to conduct an appropriate risk analysis. Care should be taken not to create a potential precedent; whereby any substance permitted as a food additive at the lowest level concentration to achieve a food technology function, can then be added to infant formula products at unrestricted and untested levels.

> FSANZ 's stated approach for food additives is consistent with the general principle that food additive use should be minimised in products for infants, who are a vulnerable population. "Before a food additive is permitted for use in food, FSANZ ensures the food additive is safe at the permitted level in the particular food and that there is a technologically justified purpose for its use" (P1028 Consultation paper 1, p8).

Further clarity on the purpose and use of L-lactate producing microorganisms as probiotics in infant formula is needed to inform this risk analysis, such as:

- What is/are the defined need(s) and the specific purpose(s) for the inclusion of probiotics in infant formula products.
- What level does industry add L-lactic acid producing microorganisms under existing permission for their intended purpose as acidity regulator/pH adjuster.
- Does the current permission for L-lactic acid producing microorganisms as acidity regulators/pH adjusters include DL-lactic acid producing microorganisms?
- What level does industry add L-lactic acid producing microorganisms to infant formula as a probiotic?
- If probiotics are to be permitted, what controls are required to manage risk? For example:
    - Are any limitations required – is there a need to identify what subgroups of infants should use formula with added probiotic(s), and on which strain?
    - What probiotic(s) strain and dosage controls are required?
    - Are manufacturing sources of probiotics controls required?
    - Given probiotics can be drugs, supplements and food grade, used for treating and preventing disease, who should be the regulatory agency?
    - What regulatory agency approval processes are required to assess a probiotics safety and efficacy?
    - What appraisal of quality and safety, authenticity, source, and dosage levels of probiotics for infant formula products on the Australian and New Zealand market is required?
    - What labelling is required to manage risk?
    - What on-going monitoring is required?

Given the literature review is being used to underpin strong concluding statements about risk to vulnerable infants' health and safety, more detail in the updated literature reviews on the search strategy, study methodology (including what were the negative effect outcomes the method was set to detect/observe), and statistical power to detect these negative outcomes is needed; along with considerations of limitations and generalisability of the findings. A more comprehensive critical appraisal of the evidence is required. Findings from relevant systematic or critical reviews, including those by expert bodies, looking at the strength and totality of

evidence, would support FSANZ risk assessment, and overall risk analysis, on probiotics for Proposal P1028- Infant formula, such as:

- *Van den Akker CH, van Goudoever JB, Shamir R, Domellöf M, Embleton ND, Hojsak I, et al. Probiotics and preterm infants: a position paper by the European Society for Paediatric Gastroenterology Hepatology and Nutrition Committee on nutrition and the European Society for Paediatric Gastroenterology Hepatology and Nutrition Working Group for probiotics and prebiotics. Journal of pediatric gastroenterology and nutrition. 2020;70(5):664-80. [2]*
- *Sharif S, Meader N, Oddie SJ, Rojas-Reyes MX, McGuire W. Probiotics to prevent necrotising enterocolitis in very preterm or very low birth weight infants. Cochrane Database of Systematic Reviews. 2020(10). [4]*
- *Martinelli M, Banderali G, Bobbio M, Civardi E, Chiara A, D'Elios S, et al. Probiotics' efficacy in paediatric diseases: which is the evidence? A critical review on behalf of the Italian Society of Pediatrics. Italian journal of pediatrics. 2020;46(1):1-13. [10]*
- *Su GL, Ko CW, Bercik P, Falck-Ytter Y, Sultan S, Weizman AV, et al. AGA clinical practice guidelines on the role of probiotics in the management of gastrointestinal disorders. Gastroenterology. 2020;159(2):697-705. [11]*
- *Depoorter L, Vandenplas Y. Probiotics in Pediatrics. A Review and Practical Guide. Nutrients. 2021;13(7):2176. [12]*

L-lactic acid fermented infant formula

The Department notes that FSANZ has concluded strongly that fermented infant formula does not pose a potential risk to healthy full-term infants; and is unlikely to pose a potential risk to healthy full-term infants, on the basis of evidence from 4 clinical research studies. These studies appear to have used the same fermented formula, i.e using *S. thermophilus* O65 and *B. breve* C50. Given the lack of studies, further information on fermented infant formula is needed (in addition to the questions listed on p.5 of this submission) to inform the consideration of the risk assessment, and the overall risk analysis, such as:

- What is the definition of a fermented formula?
- What probiotics are used for fermented formula?
- What proportion of the infant formula product is fermented?
- What are the protein sources of fermented formula on the market?
- What is known about fermented infant formula product on the market?
- What are postbiotics and what is known about their safety and efficacy?
- Are there any limitations for using these four studies to conclude risk to public health and safety; and can the findings be generalised to all fermented infant formula products?

Given probiotics/fermented infant formula/postbiotics is a research area of high current interest, recent research studies and/or reviews that may be of interest to inform the risk assessment are as follows:

- *Béghin L, Tims S, Roelofs M, Rougé C, Oozeer R, Rakza T, et al. Fermented infant formula (with Bifidobacterium breve C50 and Streptococcus thermophilus O65) with prebiotic oligosaccharides is safe and modulates the gut microbiota towards a microbiota closer to that of breastfed infants. Clinical Nutrition. 2021;40(3):778-87. [13]*
- *Martí M, Spreckels JE, Ranasinghe PD, Wejryd E, Marchini G, Sverremark-Ekström E, et al. Effects of Lactobacillus reuteri supplementation on the gut microbiota in extremely preterm infants in a randomized placebo-controlled trial. Cell Reports Medicine. 2021;2(3):100206. [14]*
- *Poindexter B. Use of Probiotics in Preterm Infants. Pediatrics. 2021;147(6). [3]*
- *Vandenplas Y, de Halleux V, Arciszewska M, Lach P, Pokhylko V, Klymenko V, et al. A Partly Fermented Infant Formula with Postbiotics Including 3'-GL, Specific Oligosaccharides, 2'-FL, and Milk Fat Supports Adequate Growth, Is Safe and Well-Tolerated in Healthy Term Infants: A Double-Blind, Randomised, Controlled, Multi-Country Trial. Nutrients. 2020;12(11):3560. [15]*
- *Morniroli D, Vizzari G, Consales A, Mosca F, Giannì ML. Postbiotic Supplementation for Children and Newborn's Health. Nutrients. 2021;13(3):781. [16]*
- *Malagón-Rojas JN, Mantziari A, Salminen S, Szajewska H. Postbiotics for preventing and treating common infectious diseases in children: a systematic review. Nutrients. 2020;12(2):389. [17]*
- *Lerner A, Shoenfeld Y, Matthias T. Probiotics: if it does not help it does not do any harm. Really? Microorganisms. 2019;7(4):104. [1]*

Section 4. Labelling for safe preparation and use

The Department would like to extend its appreciation to FSANZ for the additional research work undertaken on labelling for safe preparation and use of infant formula products, which is highly informative and useful to support decision making. On-pack instructions for preparation and use are highly important risk management and risk communication factors.

Question 14.

Do you support the amendments proposed (see section 5.7)? If not, what new evidence can you provide to support a different approach?

The Department's response to the FSANZ's proposed approach to labelling and safe preparation and use of in-scope infant formula products in Section 4 of the P1028 – Consultation paper 1 are provided in Table 2 below.

Table 2 – The Departments' response to FSANZ proposed risk management approach to labelling - Consultation paper 1

Labelling	**FSANZ proposed approach**	**The Department's response to FSANZ's proposed approach**
Prepare bottles individually	Maintain existing direction to prepare bottles individually is appropriate and should be retained (paragraph 2.9.1—19(3)(a)),	Supports.
Storage of made up formula	Maintain without change the mandatory requirement for directions instructing that if a bottle of made up formula is to be stored before use, it must be refrigerated and used within 24 hours (paragraph 2.9.1—19(3)(b)).	Supports
Water used to reconstitute powdered infant formula	Revise the direction for water used to reconstitute powdered infant formula to include the word 'cooled' (paragraph 2.9.1—19(3)(c)).	Supports
Discarding leftover formula	Revise the direction instructing to discard unfinished formula to include the text 'within 2 hours' (paragraph 2.9.1—19(3)(e)).	Supports the inclusion of a time period. The Department notes that the NHMRC Infant feeding guidelines (2012) specifies 'that any formula at room temperature for longer than one hour should be discarded. The Department considers that the proposed approach to increase the time period recommended by NHMRC Infant feeding guidelines (2012), which considered the specific Australian environmental context, the two hours should be supported by an assessment by FSANZ on the microbiological risk of increasing this time from one hour to 2 hours. Clarity is also sought on what the start time for this time period e.g. within X hours of the formula being made up?

Application of preparation and use directions to concentrated and ready-to-drink formula	Proposing not to apply the following directions to ready-to-drink infant formula: • that each bottle to be prepared individually (paragraph 2.9.1—19(3)(a)) • to refrigerate formula and use within 24 hours if it is made up and stored prior to use (paragraph 2.9.1—19(3)(b)) • to use potable, previously boiled water (paragraph 2.9.1—19(3)(c)).	Supports.
Standardised wording or pictures for directions for preparation and use	Maintain the current approach not to prescribe the exact wording or pictures to be used for the required directions of use and preparation on infant formula products.	Supports, on the proviso that: the FSANZ suggested approach for warning statements includes the specific additional text of “or add anything to this formula” is included as per proposed approach on page 105, of the P1028 Consultation Paper 1 and the wording direction for only using the enclosed measuring scoop should be prescribed.
Date marking	Maintain existing date marking requirements for infant formula products.	Supports
Storage instructions for infant formula	Maintain the existing requirements for storage instructions including the specific requirement for infant formula products, to cover the period after the package is opened.	Supports
Direction regarding using a measuring scoop	Maintain the existing requirement for a direction instructing that, where a package contains a measuring scoop, only the enclosed scoop should be used, without prescribing the exact wording for this direction.	Supports maintaining the existing requirement for a direction instructing that, where a package contains a measuring scoop, only the enclosed scoop should be used. The Department supports prescribing the exact wording for this direction based on the research findings described in the P1028 Consultation paper 1 – Supporting document 4, consumers are confused by the current directions where

		nearly a third (28%) of consumers believe any measuring scoop can be used. Given the risk to infants, risk management of this direction needs further consideration by FSANZ.
	Proposing not to apply this requirement to concentrated infant formula and ready-to-drink formula from the direction to only use the enclosed scoop	Supports
Standardised scoop and ratio for preparation	Proposing not to make any amendment.	Supports, on the proviso that FSANZ further considers exploring other risk management options for this safety issue noting that industry have previously indicated that a "standard reconstitution ratio can be applied (e.g. one scoop to each 50 ml water)". It is also noted that one scoop to 30 mL ratio is used in the UK and has been recommended by Dietitians/ Midwives. Overfeeding, underfeeding and osmolality issues are some of the risks when the ratio is incorrect.
Legibility requirements for warning statements	Maintain the existing legibility requirements for generic or specific warning statements on infant formula labels.	Supports
Warning statements about following instructions exactly	Based on the discussion above, FSANZ proposes to maintain the existing requirement for a warning statement on ready-to-drink infant formula labels about following instructions exactly (paragraph 2.9.1—19(1)(c)).	Supports
	For the two remaining warning statements to follow instructions exactly (paragraphs 2.9.1—	Supports

	19(1)(a) and (b)), FSANZ is proposing to include new additional text (that is bolded here for identification only and would not be required to be bolded on labels): 'Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of [powder/concentrate] **or add anything to this formula** except on medical advice. Incorrect preparation can make your baby very ill'.	
Warning statement 'breast is best'	Maintain the existing 'breast is best' warning statement as currently required by paragraph 2.9.1—19(1)(d).	Supports
Prescribed name	Maintain the requirement to use the prescribed name 'Infant formula' as the name of the food on the labels of infant formula	Supports
Statement that infant formula product may be used from birth	Maintain the existing statement indicating that the infant formula product may be used from birth.	Supports
Statement about age to offer foods in addition to infant formula	Maintain the existing labelling statement indicating that infants from the age of 6 months should be offered foods in addition to infant formula as currently required by paragraph 2.9.1—19(4)(c).	Supports
Co-location of protein source statement with the name of food	Maintain the requirement for the co-location of the protein source statement and the name of the product.	Supports.

Should you wish to discuss the above matter, please do not hesitate to contact me on [redacted]

[redacted]

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1. Lerner A, Shoenfeld Y, Matthias T. Probiotics: if it does not help it does not do any harm. Really? Microorganisms. 2019;7(4):104.
2. van den Akker CH, van Goudoever JB, Shamir R, Domellöf M, Embleton ND, Hojsak I, et al. Probiotics and preterm infants: a position paper by the European Society for Paediatric Gastroenterology Hepatology and Nutrition Committee on nutrition and the European Society for Paediatric Gastroenterology Hepatology and Nutrition Working Group for probiotics and prebiotics. Journal of pediatric gastroenterology and nutrition. 2020;70(5):664-80.
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6. Kowlgi NG, Chhabra L. D-lactic acidosis: an underrecognized complication of short bowel syndrome. Gastroenterology research and practice. 2015;2015.
7. Fusco V, Fanelli F, Chieffi D. Authenticity of probiotic foods and dietary supplements: A pivotal issue to address. Critical Reviews in Food Science and Nutrition. 2021:1-18.
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