INFANT NUTRITION COUNCIL
AUSTRALIA & NEW ZEALAND

Regulatory Divergence:
How Misalignment with International Food Standards Weakened Australia's Competitiveness.

A Case Study about Infant Formula

Summary

In July 2024, Australian food ministers adopted a new food standard for infant formula products intended for babies aged from 0 – 12 months. However, certain aspects of the new standard — particularly concerning ingredient and protein fraction labelling — have weakened Australia's global competitiveness by diverging from international standards.

This case study examines the disruptive consequences of misalignment with the international Codex Alimentarius (CODEX) standard and regulatory frameworks in the European Union, United States, and Hong Kong. We argue that insufficient consideration was given to the impact of deviating from the established international standard on the competitiveness of Australian manufacturers of infant formula in major export markets.

Key Consequences

- Weakened Consumer Choice: Australian families and their healthcare professionals are deprived of factual product information that is available to consumers in other comparable markets, limiting their ability to make informed decisions.
- Global Misalignment: The new Food Standard 2.9.1 in the food code isolates Australian products from international markets, reducing industry competitiveness and discouraging investment in scientific innovation.
- Trade Barriers: Domestic products previously supplied to markets such as China, Cambodia, Vietnam and Laos through modern trade routes now face competitive disadvantages on the international market; some companies will face significant commercial impacts due to this misalignment with internationally standards and practices.

1. Introduction

About Infant Nutrition Council (INC)

INC represents the interests of the infant formula and toddler milk drink industry in Australia and New Zealand, with a purpose of advocating optimal nutrition for all infants. Its membership is made up of local and global companies, including well-established local brand companies; formula manufacturers; and ingredient manufacturers and suppliers. All members have signed up to the INC Code of Conduct which requires that they accept and abide by the local industry marketing codes which are the official interpretations of the *International Code of Marketing of Breast-milk Substitutes* (WHO Code) in Australia and New Zealand.

2. Overview & Purpose

The new Food Standard 2.9.1 adopted by Australian food ministers in July 2024, and gazetted in September 2024, aimed to modernize infant formula regulations related to composition, labeling and sales channel. However, it failed to align with international standards and introduced additional labelling restrictions on ingredient and protein fraction claims.

These misalignments set Australia apart from Codex, EU, UK, and US frameworks, creating trade barriers, weakening global competitiveness, limiting consumer choice, and increasing costs for Australian families.

3. Labelling Restrictions: Misalignment from International Standards

The new Food Standard 2.9.1 introduced the prohibition of ingredient claims, including factual statements such as:

- "Contains A2 protein milk"
- "No artificial colours or flavours"
- "With Prebiotics" and "Probiotics"

This restriction set a new international precedent, as Codex Alimentarius – the international food standards published by the Food and Agriculture Organisation and the World Health Organisation - does not prohibit such claims. The international standards were reviewed by Codex in 2024, so further changes to this standard are unlikely within the next 10 years.

Australian Standard 2.9.1 introduced deviations from Codex and from how major manufacturing centres such as the EU, US and HK implement the standards locally.

Prohibition of ingredient labelling creates uncertainty about future consumer information limitations. In the decision by Food Ministers to deviate from Codex, insufficient weight was given to the economic and competitive impact of this deviation.

Australian infant formula products for Australian domestic consumers are sought after by international consumers, due to the perception that products sold in Australia are of higher quality than those made specifically for export. Specialized trade routes including Cross-Border E-Commerce

(CBEC) and Daigou Channels have been developed to accommodate this demand in key export markets such as China, Vietnam, Cambodia and Laos.

Products exported overseas to these countries must compete with products from the USA, EU and Hong Kong - countries where ingredients labelling is permitted, in line with Codex. This puts Australian infant formula products at a disadvantage compared to US and EU competitors who can include ingredients on labels.

Non-traditional routes to market such as CBEC and Daigou require imported products to be "freely sold" in the country of origin. Therefore, providing alternative products with special export labels is not an option for these routes to market.

Restricting ingredient labeling on Australian product - such as A2 protein, prebiotics and probiotics – also serves to discourage investment in Australian research and innovation capability. Research operations are likely to move offshore to comparable markets that are more aligned with international standards.

3.1. Labelling Comparison with International Standards

While Codex standards for infant formula have been widely adopted by most countries, the new Standard 2.9.1 has introduced discrepancies in its implementation compared to regions such as the major markets like EU, USA, and Hong Kong. These differences primarily stem from variations in ingredient labeling, protein fraction designation, and regulatory acceptance criteria. See table below for the comparison labelling regulation.

Labelling	CODEX (review completed 2024)	EU Regulation	USA's & HK's Regulation	Australia implementation of P1028
Prohibition on ingredient labelling e.g. probiotic, prebiotic, no palm oil, no added preservatives and added artificial flavours.	**No prohibition exists.**	**No prohibition exists.**	**No prohibition exists. Ingredients claims are permitted.**	**Restriction on ingredient labelling**
Prohibition on labeling protein fraction e.g. "A2 protein milk"	**Source' of protein refers to origin of protein (e.g. cow's milk) and**	**No prohibition of protein fractions. Intent is that 'source' of**	**No prohibition of protein fractions.**	**Prohibited from applying A2 protein name, logo, and ingredient on label.**

	not protein type (e.g. whey protein or casein).	**protein refers to origin of protein. Can also include reference to protein fractions (e.g. whey protein or casein) elsewhere on label.**		
Prebiotic and Probiotic labelling restrictions	**No prohibition exists**	**Restrictions on the terms "probiotic" and "prebiotic" in products for 0-6 months formula only.**	**No prohibition exists**	**Can not reference "Prebiotic" or "Probiotic" in the Nutrition Information Statement (NIS).** **Restriction on 'biotics' references generally (eg. Symbiotic blend).**
Mandate a prescribed format for Nutrition Information Statement (NIS)	**Specific nutrients are declared in a specific order, but the format is not prescriptive**	**Specific nutrients are declared in a specific order, but the format is not prescriptive**	**Specific nutrients are declared in a specific order, but the format is not prescriptive**	**Prescribed NIS with the strict regulation of additional nutrients to be stated under " Additional", including no statements of** **" PROBIOTIC" and " PREBIOTIC".** **Only allowed the scientific name of Prebiotic to be put in the NIS.**

3.2. Consequences of ingredients labelling restriction:

Australia's infant formula regulation deviates from Codex standards and the regulatory frameworks of major markets such as EU, USA, and Hong Kong. Codex considered factors such as economic and competitive impact assessment during development of the international standard, however local implementation in Australia has resulted in uncertainty. The strict prohibition on ingredient labelling

isolates Australia from global markets, leading to trade inefficiencies, competitive disadvantage, and consumer confusion.

The Impacts on Global Competitive Advantage are:

- Global competitors can continue to label ingredients to benefit consumers and informed choice, while Australian brands are restricted from the same practices.
- Hong Kong, a major export market, allows ingredient claims; making Australian products less attractive to international buyers.
- US & HK brands can promote probiotics and prebiotics, giving them a marketing edge over Australian formulas.
- Growing markets such as China, Hong Kong, Vietnam, Cambodia and Laos require importers to retain labelling permitted in the country of origin. In the situation like this, Australian infant formula product will have competitive disadvantage compared to the products from other markets, which cannot be resolved by providing different labels for export.

These deviations from established international norms create uncertainty regarding further restrictions on ingredient disclosures. This makes Australia an unattractive market for further investment in research and development, putting it at a disadvantage compared to other major manufacturing centres.

4. Conclusion & Recommendation

Australia's new infant formula standard introduces misalignments with international standards, particularly in ingredient labeling. These deviations have created consumer transparency challenges, trade inefficiencies, and barriers to scientific innovation, weakening the nation's global competitiveness in the infant formula market.

By prohibiting factual ingredient claims—such as A2 protein, prebiotics, and probiotics—Australian families and healthcare professionals lose access to vital product information that supports informed nutritional decisions. At the same time, restrictions on industry communication hinder scientific progress, discouraging local research and innovation in infant health.

From a trade perspective, Australia's regulatory divergence risks isolating its infant formula industry from key international markets, including the USA, EU, and Hong Kong, where such ingredient claims are permitted. This misalignment negatively impacts export opportunities, industry investment, and long-term innovation, reducing Australia's global competitiveness.

To address these challenges, a comprehensive policy review is essential for future regulatory amendments — including a substantive evaluation of the economic impact, trade alignment, and long-term market positioning to ensure regulatory decisions do not impose unnecessary barriers to global trade. Additionally, strengthened collaboration between industry stakeholders, government bodies, and international trade partners is necessary to minimize competitive disadvantages and ensure Australia remains aligned with global food standards.