

# **FSANZ - call for comment on combination of permitted oligosaccharides in infant formula: A1251**

**Response to consultation  
August 2022**

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## About Dietitians Australia

Dietitians Australia is the national association of the dietetic profession with over 8500 members, and branches in each state and territory. Dietitians Australia is the leading voice in nutrition and dietetics and advocates for food and nutrition for healthier people and healthier communities.

The Accredited Practising Dietitian (APD) program provides an assurance of safety and quality and is the foundation of self-regulation of the dietetic profession in Australia. Accredited Practising Dietitians have an important role in the food system to support consumers in making healthy food choices.

This submission was prepared by members of the Dietitians Australia following the [Conflict of Interest Management Policy](#) and process approved by the Board of Dietitians Australia. Contributors include Dietitians Australia members with wide ranging expertise in areas including public health, food systems, and academia.

## Recommendations

Dietitians Australia strongly recommends FSANZ:

1. Decline the application to amend the Australian New Zealand Food Standards Code (the Code) to permit 2'-fucosyllactose (2'-FL) to be added to infant formula products (IFP) in combination with galacto-oligosaccharides (GOS) and/or inulin-type fructans (ITF)
2. Decline the exclusive use permission
3. Consider the inconclusive evidence
4. Consider the lack of independence and transparency of research
5. Consider the cost/benefit for caregivers using a marketing and industry profit lens
6. Consider the long-term direct and indirect health and environmental costs to children, women, caregivers, and the government
7. Note the Applicants breaches of the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement
8. Note the need to implement the *International Code of Marketing Breast-milk Substitutes* in Australia

## Rationale

### Inconclusive evidence

As outlined by the FSANZ report<sup>1</sup> – the available evidence supports the conclusion that no difference in growth is likely to occur in infants fed IFP that contains 2'-FL, GOS and/or ITF at previously permitted levels (page 6). It is also noted, ... *that this combination does not occur naturally in human milk* (page 8).

This may suggest that the Applicant is intending to commercially exploit the addition, through unethical marketing,<sup>2</sup> inflated price points and compound existing inequalities within the Australian population.<sup>3</sup>

### The lack of independence and transparency in research

Although no public health or safety concerns were identified, it should be recognised that the infant formula industry uses corporate-funded research to portray formula products as safe, scientific, and medically endorsed. Corporate research focuses on product fortification, reformulation, and function – that is, novel ingredients such as oligosaccharides.<sup>4</sup>

A recent systematic review<sup>5</sup> addressed the quality and potential for bias of 125 formula product comparative trials, involving 23,757 infants and young children. A high risk of bias (80% based on the Cochrane risk-of-bias assessment 2.0); selective reporting (90% of trials had a positive conclusion); and significant formula industry research funding and influence (84% of trials were funded by industry and 77% had at least one industry-associated author) were reported. The authors' concluded that formula trials lack independence and transparency.

### **Consideration of costs and benefits**

There is no evidence for the benefit of permitting the ingredients (as outlined in the report), however, if permitted there is a significant risk for consumers/caregivers, as there is a robust body of evidence which demonstrates the unethical marketing tactics of formula companies, its influence on infant feeding decisions and practices, and the consequences for health and human rights of women and children.

Science is a dominant theme in the marketing of formula, including scientific imagery, language, and pseudo-scientific claims. Formula products are positioned as close to, equivalent and sometimes superior to breast milk, presenting incomplete scientific evidence and inferring unsupported health outcomes.

Ingredients, such as human milk oligosaccharides (HMOs) and docosahexaenoic acid (DHA), are often advertised as “informed” or “derived” from breast milk and linked to child developmental outcomes.<sup>6-8</sup>

A recent WHO/UNICEF report *How the marketing of formula products influences our decision in infant feeding*,<sup>2</sup> found that many the study respondents thought expensive formula products – sometimes containing specific ingredients such as human milk oligosaccharides (HMOs) or polyunsaturated fatty acids (PUFA) were better than cheaper alternatives, and that price influenced their purchasing behaviours. Some of the respondents spoke of how price was important because they wanted to give their child ‘the best’ sometimes as a result of feeling guilt about not being able to breastfeed. This, despite systematic reviews reporting no health or brain development benefits from the addition of specific ingredients such as HMOs or PUFA.<sup>6,9</sup>

### **Industry**

Given the Applicant (Nutricia Australia Pty Ltd) is owned by Danone, one of the six multinationals formula companies, granting the permission requested would neither favour trade nor any growth of overseas markets for the Applicant.

### **Government**

The costs considered in the report are short term. Long-term direct and indirect costs should be considered.

### **Health and Environmental**

Globally, scaling up breastfeeding could prevent an estimated 800 000 deaths of children under 5 and 20 000 breast cancer deaths among mothers each year.<sup>10</sup>

Infant feeding practices have a profound impact on child survival, growth, and development, with lifelong consequences for women, children, and society as a whole. Compared with breastfeeding, infant formula products have significant health,<sup>10</sup> economic<sup>11,12</sup> and environmental costs.<sup>13,14</sup>

Exclusive breastfeeding has health, nutritional and developmental benefits for infants, including:

- reduced risk of sudden infant death
- reduced risk of necrotising enterocolitis (a condition with high risk of fatality)
- protection against infectious diseases, including gastrointestinal illness, respiratory tract infections and middle ear infections
- protection against overweight and obesity
- reduced risk of type 1 and type 2 diabetes
- reduction in malocclusion (misalignment) in baby teeth
- improved cognitive development

### **Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement**

It should be noted for full transparency, that the Applicant, have at least two breaches of the self-regulated, *Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement*.<sup>15</sup>

More information can be here:

<https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-strateg-foodpolicy-apmaif.htm>

### **International Code of Marketing Breast-milk Substitutes**

We strongly advocate for the implementation and enforcement of the *International Code of Marketing Breast-milk Substitutes*.<sup>16</sup> The self-regulated approach and mechanisms of the *Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement* are not as effective as government-led mandatory policies and other measures to protect and promote appropriate infant and young child feeding.

The Australian Government have an obligation to ensure all Australians have access to impartial information about infant and child feeding and to enact policies that are free from commercial influence.<sup>17</sup>

## References

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<https://www.who.int/publications/i/item/9241541601>

17. The United Nations Convention on the Rights of the Child.  
<https://www.unicef.org/media/60981/file/convention-rights-child-text-child-friendly-version.pdf>