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Tēnā koe

Attached are the comments that the New Zealand Food and Grocery Council wishes to present on the *Call for Submissions – Application A1277: 2'-FL from GM* Escherichia Coli K-12 *(gene donor:* Helicobacter Enhydrae*) in infant formula products.*

Ngā mihi nui

Raewyn Bleakley
Chief Executive

Call for submissions: Application A1277: 2'-FL from GM *Escherichia Coli K-12* (gene donor: *Helicobacter Enhydrae*) in infant formula products

Submission by the New Zealand Food and Grocery Council

20 November 2023

NEW ZEALAND FOOD AND GROCERY COUNCIL

1. The New Zealand Food and Grocery Council (**NZFGC**) welcomes the opportunity to comment on the *Call for Submissions – Application A1277: 2'-FL from GM* Escherichia Coli K-12 *(gene donor:* Helicobacter Enhydrae*) in infant formula products.*

2. NZFGC represents the major manufacturers and suppliers of food, beverage and grocery products in New Zealand. This sector generates over $40 billion in the New Zealand domestic retail food, beverage and grocery products market, and over $34 billion in export revenue from exports to 195 countries – representing 65% of total good and services exports. Food and beverage manufacturing is the largest manufacturing sector in New Zealand, representing 45% of total manufacturing income. Our members directly or indirectly employ more than 493,000 people – one in five of the workforce.

THE APPLICATION

3. Inbiose NV is a Belgian biotech company that has been focussed on novel production processes for the synthesis of human identical milk oligosaccharide (**HiMO**) for a wide range of applications primarily for infant nutrition. Inbiose has applied to FSANZ to amend the Australia New Zealand Food Standards Code (**the Food Standards Code**) to permit the voluntary addition of a specified HiMO, 2'-FL derived from a genetically modified (**GM**) strain of Escherichia coli (**E. coli**) K-12 to be used as a nutritive substance in infant formula products. This is to be known as '2'-FL Inbiose'. Inbiose has also requested an exclusive use permission for a period of 15 months for its HiMO 2'-FL Inbiose after gazettal.

COMMENTS

4. NZFGC has commented on, and supported, several Applications for the addition of HiMOs since the first application in 2020 (Application A1255). Our support of these Applications has been on the basis of their safety, the improvement to the infant's well-being and the innovation that is demonstrated in their production. We comment on these aspects in the following.

5. ***Content of human milk*** – it is internationally recognised that after lactose and fat, the third main solid component in human milk is neutral and acid oligo- (and poly) saccharides. The structure of about 200 human milk oligosaccharides has been identified and many more are present, at least in small quantities. These oligosaccharides occur in concentrations between 10-15 g/L in mature breast milk and up to 20 g/L in colostrum. Neutral fucosylated oligosaccharides such as 2'-FL are the predominant oligosaccharides in human milk.

6. The permitted addition of HiMOs in infant formula products is in line with *Ministerial Policy Guideline on Regulation of Infant Formula Products*, Principle (h), relating to composition in the Policy Guideline.

7. As the most prevalent of the HiMOs found in human breast milk, 2'-FL is reported to have a role in the gut and immune system of, reduce the risk for lower respiratory tract illnesses through a protective effect on mucosal barrier function and an immunomodulation role in prevention of allergic diseases in early life. References for these roles and benefits are provided by the Infant Nutrition Council **(INC**) in its submission on this Application.

8. Inbiose has produced 2'-FL Inbiose from E. coli K-12 derived from an organism using gene technology using a gene from the Heliobacter enhydrae (H. enhydrae).

9. ***International status*** – 2'-FL is permitted for use in over 37 countries. Harmonisation with international standards that are based on relevant science and scientific expert opinion is

essential to allow the manufacture and availability of these types of products for consumers in Australia and New Zealand and for export.

10. Inbiose has received an approval to its March 2022 application for its 2'-FL substance (that is a 'no questions' to the self-assessment for 2'-FL Inbiose) from the US Food and Drug Authority.

Risk and Safety Assessment

11. There are already permissions to add 2′-FL to infant formula products in the Food Standards Code and the 2'-FL Inbiose is chemically and structurally identical to 2'-FL previously assessed. It did not raise any safety concerns for FSANZ since the *E.coli* K-12 host organism has a long history of use for the production of recombinant proteins and other products and poses no risk to humans. Further, FSANZ did not identify any safety concerns arising from the gene donor. FSANZ concluded that, based on previous assessments of 2'-FL and the toxicological assessment in the Inbiose application, there were no public health or safety concerns.

12. FSANZ's ***nutritional assessment*** concluded that 2′-FL Inbiose added to infant formula products was unlikely to pose a risk to the normal growth of infants. Since Inbiose did not request any change to the level of 2'-FL that might be added to infant formula products, the benefits to infants remains the same as in previous assessments as we noted at the outset.

13. NZFGC has been monitoring developments in HiMOs over time and it is clear that the research continues to strengthen the case for beneficial effects of these substances for infants. We note the several papers over the past 2-3 years relating to benefit that the INC identified in its submission on this Application and consider these are important for the Ministerially instructed review in 2025. NZFGC therefore strongly supports FSANZ's **beneficial health effects assessment.** This considered anti-pathogenic and bifidogenic effects and concluded that there was no evidence that implied any antagonistic effects of HiMOs and that there was a growing body of evidence to support a direct effect of HiMOs on pathogenic bacteria in particular.

Risk Management

14. On **labelling**, in light of existing permissions and labelling requirements whereby ingredients must be declared and nutrition information provided and certain representations are prohibited, no additional labelling requirements were proposed, a position which NZFGC supports.

15. Nonetheless, we continue to agree with the INC, that the prohibition on the use of the term, 'human identical milk oligosaccharides' or HiMO, is counter to building consumer confidence in, and understanding of, labelling information. The prohibition ignores the existing protections in the Food Standards Code and other legislation in New Zealand (and equivalent in Australia) such as the *Fair Trading Act 1987* concerning truthfulness of the description of ingredients by manufacturers. NZFGC notes these terms and abbreviations are permitted to be used on labels under other internationally recognised standards.

Other Aspects

16. **Investment in innovation** – Both Australia and New Zealand gain consideration of future investments in innovation if alignment of regulations to permit ingredients that are safe and permitted internationally continues. Without such investment our infants in particular stand to lose the public health benefits of such innovation and they face the prospect of having less than optimal foods in the future. Consumers also gain from the added competition that additional HiMOs in the market for such products.

17. **Trade impacts** – Alignment with other jurisdictions where the 2'-FL Inbiose is approved will occur in 15 months from gazettal (after the exclusivity period). At that time, Australia and New Zealand will be aligned with other jurisdictions where the 2'-FL Inbiose is approved. This is important for competition in export markets.

18. **Food industry impacts** and exclusivity – NZFGC supports the application of exclusivity in this Application. We have previously sought clarity and consideration around the current and future scope of the application of exclusivity in the broader food supply and that request stands.

19. ***Drafting – Variation to Standard*** – NZFGC agrees with the FSANZ draft variation to the Food Standards Code to permit 2'-FL Inbiose in infant formula products. We consider the variation appropriate.