Application to amend the Australia New Zealand Food Standards Code to permit a new genetically modified source organism – *Escherichia coli* K-12 MG1655 INB-2FL_03 for the production of 2′-Fucosyllactose

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Executive Summary

This application is submitted by Inbiose N.V., based in Zwijnaarde, Belgium. The application seeks amendment to Schedule 26 of the Australia New Zealand Food Standards Code (the Code) to permit an alternative genetically modified source organism - *Escherichia coli* K-12 MG1655 INB-2FL_03 for the production of 2′-Fucosyllactose (2′-O-fucosyllactose, 2′-FL) by fermentation. Section S29—5 of the Code permits the addition of 2′-FL, as a nutritive substance, to infant formula products. Section S26—3 of the Code lists permitted food produced using gene technology, including permitted microbial sources of 2′-FL previously assessed by FSANZ (applications A1155[1], A1190[2], A1233[3] and A1251[4]). Inbiose's source organism is not listed in section S29—5.

There are no costs to consumers, industry or governments from this application. Consumers may benefit from the availability of foods containing 2′-FL, a beneficial human milk oligosaccharide, and food manufacturers may benefit from the opportunity to offer such products. This application will align Australia and New Zealand with the USA and the European Union and has the potential to enhance international trade in respect of both the import and export of infant formula products.

The application describes how the production strain is derived from the non-pathogenic bacterium *E. coli* K-12. The host organism has a defective cell envelope that renders it incapable of colonizing or surviving in the human gut. There is no known pathogenicity, toxicity or allergenicity of relevance to the food. *E. coli* are bacteria that normally inhabit the intestinal tract of humans and other animals. *E. coli* K-12 contains no known pathogenic genes (either colonization factors or toxin genes) and is universally recognized as a safe, commercial manufacturing host. *E. coli* K-12 is also used globally in the commercial manufacturing of products ranging from amino acids and vitamins for foodstuff applications,

[1] https://www.foodstandards.gov.au/code/applications/Pages/A1155.aspx
[2] https://www.foodstandards.gov.au/code/applications/Pages/A1190.aspx
[3] https://www.foodstandards.gov.au/code/applications/Pages/A1233%20-2%E2%80%B2-FL-from-new-GM-source-for-infant-formula.aspx
[4] https://www.foodstandards.gov.au/code/applications/Pages/A1251----2%CA%B9-FL-combined-with-galacto-oligosaccharides-and-inulin-type-fructans-in-infant-formula-products.aspx

to recombinant human proteins used in pharmaceutical applications, including protein products used as injectable human drugs.

Extensive purification steps remove viable cells, cell debris, and protein and peptide particles. Extensive PCR testing demonstrated that no residual DNA from the genetically modified *E. coli* production strain was present in the final 2′-FL product.

The 2′-FL of Inbiose produced using *E. coli* K-12, has received EU novel food approval and achieved GRAS status from the Food and Drug Administration in the U.S. (GRN No. 749[5] and 897[6]). The GRAS approval of 2′-FL produced by genetically modified *E. coli* K-12 K-12 MG1655 INB-2FL_03 is pending (GRN 1091[7]).

This application is limited to the approval a new source organism for the production of 2′-FL. Consequently, the General Procedure, level 1 or 2, is the appropriate procedure to be adopted in assessing this application.

Inbiose is requesting exclusive permission for its brand of 2′-FL, using the brand name 2′-FL-Inbiose, to be added to infant formula products.

5 https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=749&sort=GRN_No&order=DESC&startrow=1&type=basic&sea rch=749

6 https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=897&sort=GRN_No&order=DESC&startrow=1&type=basic&sea rch=897

7 https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=1091&sort=GRN_No&order=DESC&startrow=1&type=basic&search=1091