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Food Standards Australia New Zealand (FSANZ)
PO Box 10559
The Terrace Wellington 6143
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Date
January 31, 2022

Subject
Submission on Application A1233 - 2'-FL from new GM source for infant formula

[redacted]

Dear Sir, Madam,

DSM Nutritional Products Asia Pacific, an affiliate of DSM Nutritional Products Ltd (hereinafter "DSM") that acquired Glycom A/S (hereinafter "Glycom") in 2020, is appreciative for the opportunity to comment on Application A1233 regarding the use of 2'-fucosyllactose (2'-FL) derived from a new genetically modified *Escherichia coli* (*E. coli*) strain as a nutritive substance in infant formula products in Australia and New Zealand.

DSM remark that there is inconsistency in the approach for establishing a specification for the ingredient under evaluation:

- The proposed variation to Schedule 3 of the Australia New Zealand Food Standards Code ("the Code") is to add a specification that is specific to Friesland Campina Ingredient's (hereinafter "Friesland Campina") 2'-FL sourced from *E. coli* K-12 containing the gene for α-1,2-fucosyltransferase from *Bacteroides vulgatus*[1]. The specification is the same as that enforced in the European Union (EU) for 2'-FL sourced from a genetically modified strain of *E. coli* K-12. However, there is a fundamental difference in the approach between the EU and FSANZ in terms of defining specifications.

[1] https://www.foodstandards.gov.au/code/applications/Documents/01_A1233_CfS.pdf

In the EU, specifications for 2'-FL are not restricted by the donor gene of the fucosylating enzyme in the EU Union list of novels foods[2]. Indeed, FSANZ previously indicated in Application A1190 that the specification currently prescribed in the EU for 2'-FL has been modified to be generic based on several equivalence notifications to the EU Commission from manufacturers[3], sharing the same host organism (*E. coli* K-12). Contrary, the proposed variation to Schedule 3 of the Code by FSANZ will define specifications for 2'-FL at the level of both the host organism and the donor organism of the fucosylating enzyme.

There is currently authorisation for Glycom's 2'-FL produced by the same host organism (*E. coli* K-12) in Schedule 26[4], for which the specification in Schedule 3 is unique to Glycom's proprietary manufacturing process. The variation to Schedule 3 in the Code will substitute the previous provision for Glycom's 2'-FL defined at the level of the organism to include the donor organism of the fucosylating enzyme (*Helicobacter pylori*), which is different from the donor organism used by Friesland Campina (*Bacteroides vulgatus*)[1]. As such, the EU specification that is generic to 2'-FL at the host organism level is not representative of Friesland Campina's 2'-FL at the level of the donor organism (*i.e.*, *E. coli* K-12 containing the gene for α-1,2-fucosyltransferase from *Bacteroides vulgatus*).

- Although data submitted by Friesland Campina demonstrate that their 2'-FL is within the specification published by the EU (≥ 83%), multi-batch analytical results indicated that Friesland Campina's 2'-FL derived from *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* yields a product having higher 2'-FL content (≥ 90%)[5]. Moreover, Friesland Campina's own specifications for their 2'-FL product specify a 2'-FL content of not less than 90%[5].

  In response to comments on Application A1190 (2'-FL in infant formula and other products) relating to Schedule 3 (Identity and purity), FSANZ note that specifications in the Code are usually provided by the applicant and are based on the applicant's unique and proprietary manufacturing process. However, analytical data submitted by Friesland Campina, representative of their unique and proprietary manufacturing process of 2'-FL, do not support a lower purity specification for the 2'-FL content as indicate above.

  In the EU, the Union List specification for 2'-FL sourced from genetically modified strain of *E. coli* K-12 was lowered from a minimum 2'-FL content of 90% to 83% following a request to the Commission from Glycom, due to modifications in Glycom's downstream processing that led to slightly decreased levels of 2'-FL compensated by slightly increased levels of other milk saccharides in the final novel food[6]. There is, however, no indication in Application A1233 that Friesland Campina's unique and proprietary manufacturing process has been modified to produce a final product with a lower 2'-FL content.

DSM encourages the revisiting of the specification for 2'-FL sourced from *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*, reflecting Friesland Campina's 2'-FL at the donor organism level (as proposed for other 2'-FL substances in Schedule

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R2470
[3] https://www.foodstandards.gov.au/code/applications/Documents/A1190%20Approval%20Report.pdf
[4] https://www.legislation.gov.au/Series/F2015L00450
[5] https://www.foodstandards.gov.au/code/applications/Documents/01_A1233_SD1.pdf
[6] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R0388

3), and align specifications according to batch data yielded from their unique and proprietary manufacturing process.

DSM would like to thank FSANZ in advance for their consideration of the above comments on Application A1233.

With kind regards,

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